

BB REVIEW

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FRAUD AND ABUSE

DHHS OIG Approves Hospital Proposal to Provide Free Dialysis

The Department of Health and Human Services Office of Inspector General (OIG) said in an advisory opinion posted January 25 that it would not impose administrative sanctions in connection with a hospital's proposal to provide free acute dialysis treatment services to chronic dialysis patients, including Medicare and Medicaid beneficiaries, who would otherwise be unable to obtain that care.

The hospital's dialysis unit provides care only to inpatients and those in need of emergency services.

According to the hospital, many chronic dialysis patients are unable to obtain dialysis care, either because of payment issues or inadequate capacity, and they end up in the hospital's emergency room or its outpatient renal clinic, which does not provide dialysis. These patients are then admitted for dialysis, occupying inpatient beds that would otherwise be available to acute care patients.

In response, the OIG noted that the hospital does not provide outpatient dialysis services and that it plans to help place patients with local outpatient dialysis facilities. In addition, the hospital would not advertise the proposed arrangement.

The OIG acknowledged that the free dialysis could generate a general feeling of "goodwill" toward the hospital that may encourage patients to use the hospital's non-dialysis services in the future, but it discounted this potential influence as "speculative and attenuated by circumstances beyond the Hospital's control."

The OIG also noted a number of factors mitigating any anti-kickback concerns, including: the hospital would absorb the cost of providing the dialysis services; the proposal was designed to help patients to find permanent dialysis care in local outpatient dialysis chairs;

the hospital had a legitimate business purpose for advancing the proposal (i.e. to free-up inpatient beds); and the free treatments were consistent with the hospital's statutory duty to provide healthcare to the community's residents.

Advisory Opinion No. 07-01 (Department of Health and Human Services. Office of Inspector January 18, 2007.)

CMS Guidance on DRA

The DRA mandate for state plans was effective January 1, 2007. CMS sent a letter to state plans on December 13, 2006 offering general guidance on their efforts to comply with the DRA.

While this letter raised some additional questions, it answered a few basic issues that providers must address to comply with DRA. First, it reiterated that it is the responsibility of each entity to establish and disseminate written policies which must also be adopted by its contractors or agents. Second, it clarified that a "contractor" or "agent" includes any contractor, subcontractor, agent or other person which or who, on behalf of the entity, furnishes, or otherwise authorizes the furnishing of Medicaid health care items or services, performs billing or coding functions, or is involved in monitoring of health care provided by the entity. Finally, it stated that although section 1902(a)(68)(C) refers to "any employee handbook," there is no requirement that an entity create an employee handbook if none already exists.

Some of the questions raised in the letter were addressed in a teleconference sponsored by CMS on January 11, 2007. Among several clarifications made, CMS said the DRA's "education" provision requires the dissemination of information to employees and vendors, but it does not require training. In addition, it maintains that "contractor" or "agent" does not include a physician on a hospital's medical staff based solely on that physician having privileges or treating patients in the hospital. We note the

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following highlights out of approximately thirty (30) questions which were addressed:

1. CMS hopes to issue regulations regarding the DRA requirements around March 31, 2007, and the DRA does not require states to amend their plans until that date. To enforce DRA requirements, however, CMS takes the position that the effective date for covered healthcare providers was January 1, 2006.

2. Since the law mandates that states adopt policies to enforce the requirements against entities receiving \$5 million or more in Medicaid funds, there was a question about CMS providing guidance to the states. CMS will not provide guidance to the states in terms of a model policy or model language regarding DRA requirements. However, CMS is working with the Department of Justice on model language to describe the Federal False Claims Act and its requirements.

3. "Adoption" of policies by a contractor or agent does not require the amendment of existing contracts. CMS will not provide guidance regarding how a covered entity enforces DRA obligations against its contractors and vendors or that, if existing contractors and vendors are bound by a clause stating they will comply with "all legal requirements," that the covered entity can simply advise its contractors and vendors of the new requirements to comply with the law.

4. With respect to related healthcare entities, even if they are separate LLCs, have separate tax ID numbers and/or separate provider numbers, CMS takes the position that the \$5 million is aggregated to determine coverage; if the state has remitted \$5 million to related entities, all are covered.

5. An exception to DRA is that, if a covered entity is part of a government agency or other entity which has divisions not providing healthcare, those other divisions are not covered. Example: A state teaching hospital/university campus is covered, but other parts of state government are not.

6. CMS provided conflicting answers to questions regarding attending physicians and others who are not employees of the hospital. The term contractor covers "persons who authorize Medicaid covered services." The definition may be limited to those persons acting on behalf of the entity, but CMS' answers on this point were somewhat inconsistent.

7. CMS does not require employees or others to sign acknowledgment they are aware of the requirements. CMS will not issue guidance approving particular forms of proving compliance.

MS Legislation on DRA

The Mississippi Medicaid Fraud Control Act contains criminal penalties for making a false, fictitious or fraudulent claim for Medicaid benefits (which includes any money paid under the Medicaid program). Mississippi Medicaid has worked on legislation to comply with the Deficit Reduction Act of 2005 ("DRA"). Senate Bill 2279 proposes to amend the existing law, and we will keep you updated on the bill's progress.

MEDICARE

New IDTF Rules

The Centers for Medicare and Medicaid Services (CMS) recently issued sweeping new enrollment requirements for independent diagnostic testing facilities ("IDTF"s) that could have a severe impact on the IDTF segment of the diagnostic imaging market. In Transmittal 187 to the Medicare Program Integrity manual, CMS announced detailed new requirements for IDTF providers intended to implement a Final Rule issued by the Department of Health and Human Services (HHS) on December 1, 2006. The Transmittal was published on January 26, 2007 and is scheduled to become effective on February 26, 2007.

Among the most notable new requirements announced in the Transmittal, IDTFs will be prohibited from sharing space or equipment with any other active Medicare IDTF or "supplier." CMS has provided one exception to the space and equipment sharing prohibition which applies solely to physicians who own an IDTF and share space with the IDTF. The Transmittal also requires that no supervising IDTF physician can serve as a supervising physician at more than three IDTF sites in the United States. In addition, any technical staff performing tests at the IDTF must be full time employees of the IDTF and hold appropriate credentials. A number of other important requirements are contained in the Transmittal, the full text of which can be accessed at <http://www.cms.hhs.gov/transmittals/downloads/R187PI.pdf>.

Assuming the effective date is not delayed, IDTFs will have less than one month to evaluate and make necessary changes to their structures for compliance with the Transmittal requirements. Because IDTF enrollment requirements are a Medicare condition of coverage, submitting Medicare payment claims in violation of these requirements would trigger the False Claims Act, as well as put an IDTF at risk of losing its Medicare provider number.

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HEALTH INSURANCE

President Proposes Health Insurance Plan

In his State of the Union address on January 23rd, the President outlined a two-part proposal for expanding healthcare coverage: 1) changing the tax code to provide a standard deduction for health insurance; and 2) shifting existing federal funds to state programs that help the uninsured obtain private coverage.

Under the President's plan, those with health insurance, regardless of whether the policy was purchased individually or through an employer, would have a standard tax deduction of \$15,000 for families or \$7,500 for individuals. At the same time, health insurance would be considered taxable income. The plan is aimed at "leveling the playing field" between those who purchase coverage on their own rather than through an employer.

The second part of the plan, called the "Affordable Choices Initiatives," includes federal grants to states pursuing innovative programs to help their uninsured get basic private health insurance coverage. Prior to the State of the Union, California and Massachusetts announced proposals along this line.

Not surprisingly, the proposal has since been met with heavy criticism from many fronts, and consensus by the now-Democratic majority in Congress on both parts of the plan will be required for implementation.

Georgia Legislation Proposes Comprehensive Reform

The first major health care reform bill introduced in the 2007 session of the General Assembly would enact ambitious measures to price insurance premiums more competitively and set up a mechanism for consumers to shop online for medical services. The ultimate goal is to reduce the ranks of Georgia's 1.7 million uninsured, its sponsor, state Sen. Judson Hill (R-Marietta), said Monday. "This is the beginning of a dialogue, not the end result," he said in an interview.

The 60-page Senate Bill 28, the "Insuring Georgia's Families Act," also would offer tax exemptions on some health care plans. Under the measure, people who earn \$60,000 and more would have several options of ways to pay their bills, he said, but "not paying your bills is an option we are taking off the table." The bill urges people to take more responsibility for their own health and "not go to the emergency room at taxpayer expense," Hill said. "We're at a crossroads with health care, and standing still is not an option."

CERTIFICATE OF NEED

Georgia CON Senate Bill 53

Senate Bill 53 has been introduced in the Georgia Senate to allow specialty cancer hospitals to do business in Georgia without obtaining a certificate of need. The bill specifically says that any facility with fewer than 50 beds that plans to treat cancer can open without obtaining a CON as long as 65% of patients come from outside the state of Georgia. This means that these facilities would not have to demonstrate need, would not have to treat the indigent, and would not have to accept Medicaid or Medicare. In addition, there is no provision in the law that would give the state the ability to enforce the 65% requirement. The bill will most likely be assigned to the Senate Health and Human Services Committee.

PRIVACY

HIPAA – It Is Not Just For Federal Courts Anymore

For the first time, a federal circuit court of appeals has confirmed that Congress did not create a private right of action under the Health Insurance Portability and Accountability Act ("HIPAA"), 42 U.S.C.A. § 1320d-1, et seq. In *Acara v. Banks*, 470 F.3d 569, 571 (5th Cir. 2006), the Fifth Circuit held:

HIPAA does not contain any express language conferring private rights upon a specific class of individuals. Instead, it focuses on regulating persons that have access to individually identifiable medical information and who conduct certain electronic health transactions. 42 U.S.C. §1320d-1. . . . Because HIPAA specifically delegates enforcement, there is a strong indication that Congress intended to preclude private enforcement.

Premising federal subject-matter jurisdiction on the HIPAA statute, Plaintiff Margaret Acara filed a claim in Louisiana federal court against her physician for allegedly disclosing Ms. Acara's private medical information without consent during a deposition. However, the trial court dismissed Ms. Acara's claims on the grounds that it did not have jurisdiction over the dispute since there was no private right of action under HIPAA. The Fifth Circuit agreed and affirmed the trial court's ruling.

The Fifth Circuit's holding that HIPAA precludes private lawsuits is consistent with the positions uniformly taken by other federal courts that have addressed the subject in previously published opinions. As the federal courts close their doors to claims for HIPAA violations,

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plaintiff's lawyers will increasingly turn to state courts to remedy a HIPAA violation.

The *Acara* ruling is limited only to the existence of a private claim under HIPAA for a HIPAA violation. It does not preclude a private claim under state law based on a HIPAA violation. Persons responsible for protecting Protected Health Information should bear in mind that HIPAA guidelines still can play an important role in providing the legal standard in lawsuits asserted under state law for what essentially amount to HIPAA violations. Federal and state courts in Alabama, Mississippi, and Georgia routinely have used federal securities law standards to establish the applicable legal standard in state securities fraud lawsuits. The short mental leap to apply HIPAA standards to state law civil actions already has been taken by some courts in other states, for example, *Acosta v. Byrum*, No. COA06-106, (North Carolina state court action, 2006) and *Bigelow v. Shockley*, No. Civ. A. 04-2785 (federal court in Louisiana, 2005).

In the *Acosta* case, a former patient filed state law privacy and negligence claims against a clinic staff member, who allegedly gained access to the patient's medical file and shared her private medical information with third parties, and against a physician for allegedly granting the access. In reviewing the trial court's dismissal of the case for the plaintiff's failure to plead her claims sufficiently, the *Acosta* court noted that, because North Carolina (like Alabama) is a notice pleading state, the plaintiff need only provide "notice of how she plans to establish the duty that was negligently breached." The court then held that "defendant has been placed on [sufficient] notice that plaintiff will use the rules and regulations of the [hospital and health system] and HIPAA to establish the [state law] standard of care."

In *Bigelow*, a husband and wife brought privacy and negligence claims against hospital employees alleging that, while the husband was under anesthesia, the employees had demeaned him and had posted pictures of him in that condition. Because the complaint also alleged a violation of HIPAA regulations, the defendants removed the case to federal court. However, in remanding the action back to state court, the *Bigelow* court observed that "it is clear that the *Bigelow*'s reference to violations of HIPAA was made purely within the context of their asserted state law privacy and negligence claims. . . . The alleged violation of HIPAA was referenced only as an element of the petition's state law negligence and privacy causes of action."

Courts currently agree that HIPAA does not provide a private right of action for patients whose identifiable medical information has been disclosed improperly. That provides limited comfort, however, because the very absence of

such a federal remedy makes it more likely that courts will permit HIPAA to be used to establish the applicable standard in state law actions seeking to redress a HIPAA violation. HIPAA's impact will continue to grow and be felt beyond the four corners of the statute.

COMMENTARY

Teleradiology

Teleradiology, the electronic transmission of radiological images from one location to another for the purposes of interpretation and consultation, has successfully entered routine health services and by many accounts, now ranks as telemedicine's largest field. This technology is predicted to play a significant role in improving service access to rural and remote areas, and carries the potential of alleviating the current world-wide shortage of radiologists. However, teleradiology services are currently characterized by a compromise between expense and quality of digital images, as well as billing and reimbursement obstacles, quality of care concerns and state licensure requirements. This article will highlight the potential benefits and practical challenges associated with teleradiology.

Advantages of Teleradiology

Teleradiology is rapidly establishing its presence as an effective solution to the problem of provision of radiological services. In many cases teleradiology has become a necessity for healthcare facilities to outsource some of their imaging interpretation needs. Small, rural hospitals and clinics with no staff radiologist can send images to teleradiology providers throughout the world, making it possible to have images read within minutes rather than days.

In instances where hospital expertise is focused on general radiological services, teleradiology permits images of complex problems to be transmitted to major medical centers for evaluation and advice. In addition via teleradiology, a clinical radiologist may seek an expert second opinion from a specialist, without transferring the patient. This minimizes discomfort and disruption for the patient, may avoid a repeat examination and improves efficiency of service delivery.

There is immense pressure on radiologists, given the huge volume of images being churned out from innumerable CT/MRI and other imaging machines worldwide combined with an ever-increasing shortage of radiologists. Teleradiology has become a financially advantageous approach to solving these issues. The technology has led to reduced workload pressure on radiologists, faster turn around time for patients, and cost savings for hospitals who

are finding that teleradiology presents an attractive alternative to having radiologists available twenty-four hours a day.

Improved continuing professional development is also possible where teleradiology is used as an educational device with case presentations or tutorials provided by educational centers for groups of clinical radiologists or individuals in their own hospitals. This is especially significant for the continuing education or training for isolated or rural health practitioners, who may not be able to leave a rural practice to take part in professional meetings or educational opportunities.

Challenges

It is increasingly difficult to get malpractice insurance policies to apply to telemedicine. The Center for Medicare & Medicaid Services (“CMS”) considers the site of service to be the location where the professional service was provided, and Medicare does not allow payment for services that are outsourced to places outside the United States. For international teleradiology services, Medicare permits payment only if the services are a preliminary interpretation.

Medicare reimbursement and other billing issues can arise with teleradiology. Hospital settings are probably the easiest setting in which to utilize teleradiology services without running into these kinds of regulatory concerns because Medicare does not require interpretations to be performed on the hospital campus, and hospitals are allowed to bill for the interpretations under the Medicare Modernization Act (“MMA”) Section 952 exception. MMA Section 952 advises that the CMS will pay a person, group or facility enrolled in Medicare for services provided by a physician under contract, regardless of where in the United States the service is furnished. However, because of the 2005 Medicare Physician Fee Schedule Rules, group practices are not as fortunate and must provide services to its patients onsite. Because of this Stark onsite requirement, separate billing of Medicare services is the best way to proceed for group practices. Additionally, for Independent Diagnostic Test Facilities (“IDTF”), since the technical and professional components of the service are not performed at the same location when utilizing teleradiology interpretations, the two components must be billed separately, specifying the two separate locations and dates of service. IDTFs also have a more rigorous supervision requirement, creating a situation where, if an IDTF contracts with an out-of-state group to interpret its images, local radiologists must take on a supervision-only role.

Problems regarding quality of care also can arise because emergency room referrers often do not know off-site image readers, and generally the

more the referrer knows and trusts the radiologist, the more they trust their medical opinion. A 2003 survey found that in up to 10% of teleradiology cases the scans were unreadable due to poor image quality, raising other quality of care concerns. Additionally, there are sometimes incompatibilities between Picture Archival and Communication Systems (“PACS”) of different vendors or a lack of integration with PACS and Radiology Information Systems. Generally, in order to combat some quality of care concerns, many companies use only U.S. board-certified radiologists to read their images, even if a radiologist is located in another country.

The American College of Radiology (“ACR”) has outlined standards for teleradiology that require the radiologist to be licensed in the state in which they read the image and the state in which the transmitting facility is located. Most medical boards view the radiologist who interprets images from outside the state as having traveled electronically into the state and thus to be subject to the patient’s state licensing laws. Additionally, radiologists are required to be credentialed at the transmitting facility, and for certain modalities the radiologist must be certified by the American Board of Radiology. The standards set by the ACR make it easier to select reliable and reputable teleradiology companies, but have also caused many hospitals to streamline the teleradiology services they offer because of logistical and legal considerations.

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