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Healthcare organizations advised to focus on quality of care

by Catherine Hubbard, M.A., Contributing Editor

Healthcare organizations should focus on the goal of improving quality and creating efficiencies in their systems, John Marren, co-managing partner of Hogan Marren, Ltd., Chicago, said during a January 19 Healthcare Financial Management Association audio conference. "The first thing you do for any compliance activity is to define a mission and a goal that is focused on quality and use of evidence-based medical technology. The overarching goal should be improving care for the patient", he added.

Rewarding quality care. The government has recognized the benefits of rewarding quality care. In March, MedPAC advised Congress to do everything necessary for Medicare to begin to reward providers' participation in the use of technology to support disease management, Elizabeth Simpkin, president of The Lowell Group, Inc., Chicago said. She emphasized that consumers need information on providers' clinical performance through the use of benchmarks and scorecards. Under CMS' Hospital Quality Initiative, all five clinical areas have improved according to early indicators. Median quality scores for hospitals rose for bypass operations, acute myocardial infarction, treatment for heart failure, hip and knee replacement and treatment of pneumonia, Simpkin explained, noting that there has been improvement even in the absence of mandated participation.

Pay-for-performance. With pay-for-performance products, there's a trend toward increased transparency, expansion into preferred provider organizations and self-funded products, tiered reimbursement rather than a single annual bonus, and rewarding both specialists and primary care physicians, Simpkin said. Marren suggested organizations define what performance is and how to measure performance. "Having the structures and process in place and getting the data that's necessary will allow you to engage in a discussion with CMS on what the information means," he said, adding that people need to create their own data sets to engage in a dialogue rather than be dependent on CMS data alone. Although Stark issues may arise when moving toward pay-for-performance, it will be easier to find support for the plan if the overarching goal is to improve quality and reduce under use, overuse and misuse of services Marren said. "Those are precisely the goals that underscore Stark," he said.

Working with physicians. Simpkin stressed the importance of working with physicians to determine core measures, patient safety initiatives and standards of care. Physicians should be partners in the technology, quality and efficiency equation. "Physicians are the key to success of hospital quality initiatives. Getting them involved is the way to make it work," she added. ■

CCH Washington Bureau, Jan. 27, 2006.

Standards for charity care and debt collection practices proposed

by Stacey Fahrner, J.D., M.P.H, Contributing Editor

Illinois became the latest state to address the issue of hospital charity care and debt collection activities when the State Attorney General, Lisa Madigan, announced on January 23, 2006, two pieces of legislation that would require tax-exempt hospitals in Illinois to deliver an aggregate amount of charity care as well as prevent aggressive or harassing tactics when seeking payment from patients. Although the federal government and most states do not currently legislate charity care minimums, hospital charity care policies have been hotly debated at both the federal and state level in recent years.

Both Illinois and federal laws require tax-exempt hospitals to provide charity care, yet no clear standards have been set. Madigan argues "hospitals that benefit from huge tax breaks have an obligation to give back to the community." In 2003, the average, non-government, tax-exempt hospital in Illinois spent less than 1 percent of hospital charges on charity care. The need for charity care is further compounded by rising health care costs and increasing numbers of uninsured and working poor.

Elements of the proposed legislation. The "Tax Exempt Hospital Responsibility Act" would require that each hospital implement a charity care policy guaranteeing poor uninsured individuals free or deeply discounted care. The Act also would require tax exempt hospitals to deliver a minimum total annual amount of charity care, calculated as 8 percent of hospital operating costs. Hospitals could comply with the requirement by providing charity care to eligible individuals at the hospital, through an affiliated medical clinic, or through mobile units or other similar programs. Hospitals that receive payment through the Illinois Public Aid Code also may claim the portion of the costs not covered by the payments.

The companion bill, the "Hospital Fair Billing and Collection Practices Act," would require all tax-exempt and for profit hospitals to avoid unfairly aggressive and harassing tactics when seeking payment from patients. Patients would be given explicit rights to inquire abut or dispute a bill. Hospital governing boards would be required to adopt fair billing and collection policies and approve any post-judgment collection action such as wage garnishment or liens on property.

Impact on hospitals. The Illinois Hospital Association (IHA) argues that these additional financial burdens could threaten the wellbeing of many hospitals facing serious financial challenges. One out of every three hospitals in Illinois is losing money on overall operations and, since 1994, 22 hospitals have closed. The IHA argues further that a hospital's benefit to the community cannot be measured simply in terms of the charity care it provides. For example, hospitals provide certain needed services at a financial loss, such as emergency care, trauma care, burn care, and neo-natal units. The financial burden on hospitals is exacerbated because Medicare and Medicaid account for over half of the average hospital's revenues, yet pay substantially less than the cost of providing care. Medicare pays 92 percent of the cost of care and Medicaid pays only 73 percent of the cost of care.

According to the IHA, hospital charity care and debt collection policies have been addressed through guidelines adopted in 2003 by the IHA and the Metropolitan Chicago Healthcare Council, which include free care to patients at or below the federal poverty level and discounted care to patients between 100 and 200 percent of the federal poverty level. The guidelines also call for reasonable, fair, and consumer friendly billing and collection practices. The IHA states that nearly all Illinois hospitals meet or exceed the guidelines.

In addition, under Illinois law, hospitals are accountable for publicly reporting the community benefits they provide including charity care, government sponsored indigent health care, subsidized health services and bad debt. The IHA cautions that the Attorney General's office should thoroughly study these reports before any new requirements are imposed on hospitals.

For further discussion on charity care see the *CCH Health Care Compliance Letter* articles entitled "Overview of charity care requirements imposed upon nonprofit hospitals," by David M. Flynn (April 4, 2005) and"Valuing charitable care "(June 15, 2005). ■

Illinois Attorney General Press Release, Jan. 23, 2006. Statement of Ken Robbins, President, Illinois Hospital Association, Jan. 23, 2006.

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Unless otherwise noted, all paragraph references are to the CCH Health Care Compliance Reporter.

Grassley plans to address executive compensation of non-profits

by Jeff Carlson, Contributing Editor

Executive compensation in the non-profit industry is a priority, Senate Finance Committee Chairman Charles E. Grassley's (R-Iowa) told a Iowa reporters during a teleconference on January 12. Grassley hopes to change compensation to a more market-based system where salaries are based on geographical location as opposed to arbitrary decisions.

A comprehensive bill on charitable reform, one of Grassley's top priorities from 2005, fell by the wayside in late fall as Congress turned its attention to the devastation wreaked by severe hurricanes, but Grassley plans to continue work in that area. Although several non-controversial provisions from his original charitable giving reform bill found their way into the tax reconciliation package (S. 2020), there is still more to do, according to Grassley. He admits, however, that it will be done in a "piecemeal" fashion and not through major legislation.

"I think that we're going to make the board of directors justify their compensation without getting an outside person saying a person running this organization ought to get paid such and such," Grassley said, adding that he thinks that such "witnesses" are used as a justification for "paying almost any amount of money, even ridiculous amounts of money" to executives in the charitable giving sector. ■

CCH Washington Bureau, Jan. 13, 2006.

Fraud and Abuse

Mentally ill targeted in respiratory therapy billing scheme

by Gené Stephens, J.D., Contributing Editor

A doctor and his biller were convicted of fraudulently billing Medicare for more than $7.6 million for performing respiratory treatments on mentally ill patients that were not necessary, were not performed in accordance with Medicare rules, or not performed at all. Approximately 2,200 claims totaling almost $500,000 were submitted for dates that the doctor was out of the country. Medicare paid an estimated $1.9 million of the claims and Medi-Cal paid more than $600,000 of the claims.

Medicare's investigation. The investigation of the doctor and the biller began when a parent of a mentally ill Medicare beneficiary reviewed her son's statement and noticed an unusually high amount of respiratory treatments billed to Medicare although her son did not have a respiratory condition. The parent subsequently contacted Medicare's hotline number and complained. Medicare's investigation revealed an almost-daily billing for respiratory treatments for residents at many of the other board and care facilities throughout Southern California.

The scheme. Evidence revealed that the doctor and biller targeted mentally ill residents of board and care facilities throughout Southern California and paid kickbacks to marketers, owners, and administrators of the facilities to gain access to the patients. The doctor also provided the residents with gifts, including sodas, candy, donuts, and cigarettes to entice them into taking the respiratory treatments.

The doctor paid respiratory therapists to perform daily or almost daily respiratory therapy on the mentally ill residents regardless of whether the residents had respiratory conditions. The treatments and testing of the patients took place in the facility without the presence of a doctor in violation of Medicare rules. The treatments were then billed as performed at the doctor's office or in a mobile medical van to avoid Medicare violations. Under Medicare law, such treatments are prohibited at board and care facilities. The doctor and the biller also submitted bills for dates that the residents were not present at the board and care facilities and were either considered in- or out-patients at other hospitals.

The doctor and biller are scheduled for sentencing on March 13, 2006, and may face the maximum statutory sentence of 10 years in prison. ■

DoJ Press Release, Dec. 23, 2005.

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On The Front Lines

Beware off-label use of devices

by Fay Rozovsky, J.D., M.P.H., Contributing Editor

Healthcare facilities are the laboratories of innovation. New uses are identified frequently for devices approved for other purposes. Often with the best of intentions care providers think that it is acceptable to "try" such devices for other purposes. Other care providers may be more cautious and seek approval from an institutional review board for an "off-label" use of a device. As seen in the following example, the result may be surprising.

The facts

The orthopedist had done a lot of reading about a surgical device. He had used the device in a number of knee procedures with great success. He also believed that if adapted in a certain way, it could be very helpful with certain shoulder procedures. He decided to try it. The doctor's partner told him to think it over carefully. "What you are talking about is clinical research. No one is going to let you march into the operating room and use that device for an off-label purpose. You need to get this approved by the Institutional Review Board (IRB). Here is the telephone number of the Research Office." The doctor called the Research Office and made an appointment to see the Clinical Research Coordinator. After explaining what he intended to do with the device, the orthopedist was rather surprised by the reaction of the Clinical Research Coordinator. "Doctor, there is no need to bring this forward to the IRB. You are not collecting data, you are not using the device for research, and therefore, it does not meet the criteria for review by the Institutional Review Board. What you are talking about is individual professional judgment." The orthopedist told his partner about the discussion. His colleague shook his head and said, "Professional judgment? No way. This is a risky idea. You need to explore this further."

"A healthcare facility has an independent duty of care towards patients. Once it is on notice that a credentialed care provider intends to use equipment in an unapproved manner, the facility is obliged to intervene to safeguard the patient."

Off-label risk

The orthopedist's partner was correct. Off-label use of a surgical device is not a matter of unilateral professional judgment. Such a decision can trigger a number of risk considerations:

- **Consent to treatment**. This may be a material risk for the patient. As such there is a need to explain to the patient that the equipment will be used in an off-label manner and what the potential benefits and risks may be along with information about treatment alternatives. The consent process also should address the possibility that the patient's health plan will not cover off-label use of a device.
- **Patient safety.** A fundamental aspect of patient safety is to make certain that all the tools, processes, and procedures are well-known to the team involved in a procedure. Off-label use of a device does not fit this model, especially if the team is unfamiliar with using the device in this manner. It goes further, especially with post-operative care in which the recovery unit or medical-surgical floor team is uncertain how to manage a patient in this situation.
- **Device warranty.** Using a device for a purpose different from the stated terms found in a warranty will void the manufacturer's responsibility for a failure.

Healthcare facility accountability

If the hospital or surgi-center knew or should have known that a care provider was using a device in an unacceptable manner, could the facility be held accountable? The answer may be yes. A healthcare facility has an independent duty of care towards patients. Once it is on notice that a credentialed care provider intends to use equipment in an unapproved manner, the facility is obliged to intervene to safeguard the patient. In this content "notice" may mean a challenge relayed

by the operating room supervisor, or a concern expressed by a medical colleague. The failure to stop unapproved use of a device resulting in foreseeable injury to the patient would set the stage for healthcare facility liability.

Risk management perspective

The Clinical Research Office Director gave the orthopedist an incorrect answer. Off-label use of a device is not a unilateral determination by a credentialed care provider. It requires a comprehensive evaluation by an interdisciplinary team to make certain that the intended use is appropriate, feasible, and safe. Further, the potential for "off label use" of devices slipping through the system augers to the need for staff education and an additional element in the "time out" process in the operating room.

Risk management strategies

Consider the following strategies for managing the risks associated with off-label use of devices:

(1) **Address off-label use in the medical staff bylaws.** Discuss with the medical staff the addition of a bylaw requirement that any nonresearch based off-label use of devices must be approved by an interdisciplinary committee composed of representatives of the medical staff, nursing, pharmacy, other clinical departments, and management.

(2) **Evaluation criteria.** Develop and utilize objective, evidenc-ebased criteria for assessing the proposed off-label use of a device. Determine if the proposed use requires IRB approval. Take into consideration staff competencies, back up for failed devices, post-surgical care management, and transfer plans for those patients who require tertiary care. A good evaluation tool for this purpose is a prospective failure mode effect analysis. Potential failure modes or risks that are identified should be examined carefully. If the potential failures cannot be addressed, the result may preclude off-label use of the device.

(3) **Demonstrated competencies.** Determine if the care provider and the surgical team have the necessary skill and training to use the device in the proposed off-label manner. Team training is important in this regard. Consideration might be given to use of simulation to "stress test" the team in the proposed off-label use of the device.

(4) **Legal and insurance review.** In addition to the clinical evaluation, consider a legal and insurance analysis. What are the legal concerns? Will current insurance coverages respond to claims involving the off-label use of the device? The answers to these questions may result in a recommendation against the off-label use of the device outside the context of a formal clinical trial process.

"Determine if the care provider and the surgical team have the necessary skill and training to use the device in the proposed off-label manner. Consideration might be given to use of simulation to 'stress test' the team in the proposed off-label use..."

Conclusion

No one wants to thwart advancement in therapeutic interventions with medical devices. New uses for accepted devices may enhance quality outcomes. However, adaptation should be done in a reasoned manner, focused on patient safety and reasonable risktaking. This decision involves clinical, business, and operational factors. Looking at the risks in a comprehensive manner can help identify concerns and in many instances lead to development of successful strategies for the benefit of all. ■

Fay Rozovsky is the President of The Rozovsky Group, Inc. and a faculty member in the Department of Legal Medicine at Virginia Commonwealth University Medical College and the Barton Certificate Program in Healthcare Risk Management. She has more than two decades of experience in healthcare risk management. She has published more than 500 articles on subjects in health law, risk management, patient safety, and medical ethics.

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Medicare Part D presents new opportunities for fraud and abuse

by Catherine Hubbard, M.A., Contributing Editor.

"Medicare Part D plans will have a great deal of complicated issues and a great deal of money flowing through them, so there's tremendous opportunity for fraud and abuse," David Bloch of Reed Smith LLP, Washington, D.C. remarked during a January 23 Health Care Compliance Association audio conference. Because the new prescription drug program will likely open the door to increased fraud and abuse in the health care system, it's important to identify the most common types of prescription drug fraud and find ways to combat the problem.

Fraud and abuse in pharmacies. Pharmacies can commit fraud in a number of ways, Bloch said. For instance, they can:

(1) substitute a generic for a brand name drug without passing the savings on to beneficiaries,

(2) fill part of a prescription and bill for the full amount, or

(3) fail to process a credit for returned drugs.

Other types of fraud a pharmacy may commit involve reselling drugs recovered after a patient has passed away, selling samples, and selling expired drugs.

Pharmacies should be careful, when explaining different plans to customers, not to steer them toward any particular plan. "A pharmacy can provide objective information about particular plans, including identifying to patients which plans the pharmacy participates in, but they should not be receiving any compensation for directing enrollees to a particular plan, nor should they be trying to prefer or place one plan over another," Bloch advised.

Other areas of potential fraud. Bloch identified formularies, marketing, the donut hole, and rebate issues as other areas of potential fraud. The "donut hole" is the gap in prescription drug coverage, between $2250 and $3600, in which prescription drug plans are not required to provide coverage and beneficiaries must cover 100 percent of the costs of drugs.

- *Formulary issues.* CMS is concerned about formularies that appear to try to carve out beneficiaries who are expensive to cover, Bloch noted. "Formulary design is going to be important," he said. Medicare does not require plans to have formularies, but many plans will choose to have formularies as a cost-cutting measure.
- *Marketing.* While prescription drug plans are allowed to market themselves, the concern is that plans should be set up to be available to the broadest possible range of Medicare eligible beneficiaries. "Marketing plans that seem skewed toward lower-cost beneficiaries would be problematic," he explained.

"A pharmacy can provide objective information about particular plans, including identifying to patients which plans the pharmacy participates in, but they should not be receiving any compensation for directing enrollees to a particular plan. . ."

- *The donut hole.* Another area of potential fraud will be the temptation to keep enrollees in the donut hole as long as possible, according to Bloch. Even plans that are trying to comply will find it difficult to compute true out-of-pocket costs. "That's going to make it very difficult for plans six months from now to figure out, 'When exactly did the donut hole kick in?'" he said.
- *Rebate issues.* Another difficulty will be finding the right exception for rebates. Although the Medicare Modernization Act of 2003 (PubLNo 108-173) anticipates plans will negotiate rebates, it is difficult to figure out what exception the rebates fit into, Bloch noted. "The Anti-Kickback Statute wasn't drafted with Medicare Part D in mind and doesn't fully fit Part D plans," he said, adding that "the important thing will be to show intent to comply with the statute."

False Claims Act. Initially, the Department of Justice will focus primarily on False Claims Act violations, according to James Sheehan, Associate United States Attorney, Philadelphia, Pennsylvania. "Any pharmaceutical fraud involving any major managed care plan or prescription drug plan (PDP) in the United States will now be a fraud or a false claim in the United States," he said.

Most of the false claims under Part D will probably involve prescription claims to PDPs, when the pharmacist sends in a bill for a drug or a patient sends in a claim for a payment, Sheehan predicted. False claims also can occur in Medicare Advantage Plans, he noted.

In addition, prescription claims for people over age 65 submitted to employer prescription plans receiving the 28 percent subsidy from CMS give rise to false claims, Sheehan said. "A false claim for a prescription submitted to a purely private pharmacy benefit plan that receives the subsidy from the federal government, is a False Claims Act violation." he explained.

Likewise, kickbacks and sample sales, research and marketing frauds on any of the drugs sold to a Medicare beneficiary of Medicare Part D can be a false claim under Part D, Sheehan said. "There's going to be a significant expansion of claims against drug manufacturers and drug providers," he predicted.

Sheehan suggested working with pharmacy benefit managers to help combat fraud. "They can be of huge benefit to this program in fraud control," he said. He noted that their computer systems are sophisticated. For instance, they can identify copays, covered drugs, preferred drugs and eligibility. There is potential

for fraud by these organizations, but their role in identifying fraud by others is significant, he said.

"We can make this program work by identifying fraud early, working closely with physicians and pharmaceutical manufacturers to identify third-party fraud," Sheehan concluded. ■

CCH Washington Bureau, Jan. 25, 2006.

CEO faces FCA claim related to unallowable cost report expenses

by Susan L. Smith, J.D., M.A., Contributing Editor

The government's complaint against a president and chief executive officer (CEO) of a health care company related to cost reports filed in 1998 and 1999 and the failure to file cost reports in 2000 and 2001, alleging False Claims Act (FCA) violations for the 1998 and 1999 reports, payment by mistake, and unjust enrichment was sufficient, according to the U.S. District Court of Northern Illinois.

The government's FCA claims as to the 2000 and 2001 reports, however, were dismissed based on the government's failure to allege with particularity the costs that were fraudulently filed in those reports. In addition, the three-year federal statute of limitations for tort actions applied to bar the government's common law fraud claim, the court concluded,

The allegations. For the 1998 and 1999 cost reports, the government alleged that the CEO sought and received reimbursement for fraudulent expenses on the cost reports in question including excessive owner, administrator and staff compensation; improper related party expenses; legal expenses; charitable contributions; car leasing expenses; interest on unnecessary borrowing for other business ventures; the costs of purchasing stock and patient lists from another health care company; and late fees and penalties for submitting the company's bills late.

For the 2000 and 2001 cost reports, the government alleged that the company received interim payments from Medicare at the outset of 2000 and 2001 but failed to file cost reports in 2000 and 2001 reconciling its interim payments for these years with the actual Medicare-related costs it had incurred.

False claims. The CEO contended that the FCA claims for the 1998 and 1999 cost reports should have been dismissed based on the failure to adequately plead that a false claim had been presented to the government. The court found that the government sufficiently alleged that the CEO caused a false claim to be presented to an officer or employee of the United States for payment or approval by alleging that the CEO and his company submitted false claims to the intermediary, the intermediary paid those claims out of its commercial bank account and then requested and received reimbursement from the Federal Reserve Bank.

The government's FCA claims based on the company's failure to file its 2000 and 2001 cost reports, however, did not meet the requirements for an FCA claim. In contrast to its allegations of fraudulent claims in the 1998 and 1999 cost reports, the government did not identify specific claims that the company fraudulently filed in 2000 or 2001. Therefore, the government's FCA claim based on the company's failure to file its 2000 and 2001 cost reports was dismissed.

Other claims. The statute of limitations for the government's FCA, payment by mistake, and unjust enrichment claims is six years and, therefore, none of these claims was likely time-barred. The court, however, required the government to amend its complaint to properly allege that the facts underlying these claims arose on or before June 28, 1999. The statute of limitations on the common law fraud claim expired approximately a year before the complaint was filed.

The court determined that the government sufficiently alleged that the CEO was paid by mistake and unjustly enriched as a result of the fraudulent reports allegedly filed by his company. The government's allegations included that the CEO had signed and certified the fraudulent cost reports submitted in the company's name and that he received unearned payments, including salary payments, as a result of those actions. ■

United States v. Squire, N.D. Ill., Dec. 12, 2005.

Billing for services provided by nonexistent companies leads to fraud conviction

by Susan Smith, J.D., M.A., Contributing Editor

A former senior manager of a health care service company (employer) was sentenced to fifteen months imprisonment for defrauding his company and Medicaid and Medicare by submitting more than $900,000 in fraudulent billing invoices between the period of October 2000 through September 2004, according to the opinion of the U.S. District Court of New Jersey.

Nonexistent companies. The former manager devised a scheme involving health care service companies, the "Caruso Companies," that did not exist. He contracted with two outside vendors to bill for health care services provided by these nonexistent companies and regularly provided the vendors with false and fraudulent invoices from the Caruso Companies for health care services that had not actually been provided. The vendors, in turn, submitted these invoices to the employer for the purported services.

Upon receiving the fraudulent invoices from the vendors, the employer mailed checks for payment to the vendors and billed Medicaid and Medicare. The vendors kept a percentage of the payment for administrative fees. The remaining fees were paid to the former manager.

Losses and restitution. Of the $900,000 in sustained losses, $450,000 was paid by Medicaid and more than $40,000 was paid by Medicare. In addition to his term of imprisonment, the former manager was ordered to pay restitution to the health care service company in the amount of $303,993.77. ■

United States v. Caruso, D. N.J., Jan. 4, 2006, Health Care Compliance Letter, ¶800,074.

Medicare Reform

CMS announces first MAC contract awards

by Jenny Burke, J.D., Contributing Editor

Four specialty contractors will now be responsible for handling the administration of Medicare claims from suppliers of durable medical equipment, prosthetics and orthotics. The new contracts awarded represent a first step in CMS' initiatives designed to improve service to beneficiaries and providers, support the delivery of coordinated and quality care, and provide greater administrative efficiency and effectiveness for fee-for-service Medicare.

Selection process. The four newly announced Durable Medical Equipment Medicare Administrative Contractors (DME MACs) were the first of 23 contracts to be awarded prior to 2011 to fulfill requirements of the contracting reform provisions of the Medicare Modernization Act of 2003 (MMA) (PubLNo 108-173). The new DME MACs replace the current Durable Medical Equipment Regional Carriers (DMERCs).

Contracts were awarded through an open bidding process to companies who offered the best overall value to the government, in light of costs, technical qualifications, and other considerations such as past performance, corporate responsibility, and their understanding of the special requirements involved in processing claims for medical equipment and prosthetics provided to beneficiaries. The geographic jurisdictions are slightly realigned from those serviced by the DMERCs.

Each DME MAC contract awarded will include a base period and four one-year options. DME MACs will have the opportunity to earn award fees based on their ability to meet or exceed the performance requirements set by CMS. MAC contracts must be put up for competitive bidding no less than every five years.

"For the first time in Medicare's 40-year history, we have been able to select our administrative contractors through a full and open competition to provide the best service at the lowest cost," CMS Administrator Mark B. McClellan said. ■

CMS News Release, Jan. 6, 2006.

In the News

CEO, COO indicted in medical device scheme

The chief executive officer and chief operations officer of a medical supply company have pled not guilty to a 37-count indictment alleging that they engaged in a scheme to bilk Medicare by billing for more expensive orthopedic supplies than what patients received. In addition, the executives allegedly defrauded the Federal Employee Health Benefits Program by upcoding their products. The maximum sentence upon conviction is 10 years in federal prison and $250,000 fine per count. ■

DoJ Press Release, Jan. 10, 2006.

MD convicted of health care fraud resulting in death

A physician, who operated several pain management clinics in Ohio, was convicted of 57 counts of fraud, including two counts of health care fraud resulting in death. The physician billed insurance companies thousands of dollars for visits that lasted only a few minutes. In addition, by indiscriminately prescribing the same regime of injections and narcotic drugs to his patients, the physician rendered patients physically dependent and in some cases addicted to pain medication. Two patients died as a result of overdoses of pain medication, which the physician continued to prescribe even after he had reason to know that the patients were abusing the drugs. ■

DoJ Press release, Jan. 13, 2006.

Antitrust thresholds revised

The Federal Trade Commission (FTC) announced revised thresholds for the Hart-Scott-Rodino Antitrust Improvements Act of 1976 (Hart-Scott-Rodino) as required by the amendments of Section 7A of the Clayton Act. The adjusted threshold amounts relate to the jurisdictional merger and acquisition thresholds provided under Hart-Scott-Rodino. Adjusted threshold amounts for assessments and the collection of filing fees also have been included. Persons and entities contemplating certain mergers or acquisitions must file notification with both the FTC and the Assistant Attorney General as well as wait for a designated period of time before beginning the transaction. The new thresholds take effect 30 days after January 18, 2006. ■

Notice, 71 FR 2943, Jan. 18, 2006, CCH Health Care Compliance Reporter,¶760,019; FTC Press Release, Jan. 13, 2006 .

JCAHO issues alert to improve medication safety

The Joint Commission on Accreditation of Healthcare Organizations issued an alert urging intensified attention to the accuracy of medications given to patients as they transition from one care setting to another or one practitioner to another. Medication reconciliation provides an opportunity to assure that the patient is receiving all medications necessary to his or her care and eliminates any medications no longer needed by the patient. The United States Pharmacopoeia stated that last year it received more than 2000 voluntary reports of medication reconciliation errors. In 1999, the Institute of Medicine estimated that more than 7000 deaths occur each year in hospitals due to medication errors. ■

JCAHO Press Release, Jan. 25, 2006.