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Wolters Kluwer Law & Business

CMS evaluates financial incentives to improve quality, reduce costs

CMS has announced a three-year demonstration program, known as the Physician-Hospital Collaboration Demonstration (PHCD), to examine whether allowing hospitals to provide financial incentives for physicians for quality and efficiency improvement can increase patient quality of care while reducing hospitals' and Medicare costs. PHCD is authorized under §646 of the Medicare Modernization Act of 2003.

The demonstration program. The demonstration requires tracking patients for an entire episode of care, which generally extends well beyond a hospitalization, to determine the impact of hospital-physician collaborations on preventing short and longer-term complications, duplication of services, coordination of care across settings, and other quality improvements that hold great promise for eliminating preventable complications and unnecessary costs.

The demonstration will examine the effects of the incentive payments system-wide as hospitals and physicians within a geographic area collaborate on similar quality improvement initiatives and work together to assure that appropriate longer-term outcomes and other quality measures can be tracked appropriately. The program will focus on the entire scope of health care for a surgical episode or other episode of illness involving hospital care. For example, incentive payments to surgeons for achieving lower infection rates and fewer readmissions with complications could both improve patient outcomes and lower overall hospital and Medicare costs.

Selection of participants. CMS will support projects submitted by consortia, comprised of physician groups and their affiliated hospitals in improving quality and reducing overall costs for the episode of care. A consortium may consist of health care groups and up to 12 of their affiliated hospitals in a single geographic area comprising no more than one state. The demonstration will encompass physician groups and up to 72 hospitals in a limited number of geographic areas across the country. MS will give preference to proposals submitted by a health care group consortium, composed of health care groups and affiliated hospitals, because it needs a sufficiently large demonstration size to reliably measure impacts on longer-term patient results and overall Medicare costs, CMS Administrator Dr. Mark McClellan said, adding that "[t]his is very different from traditional 'gainsharing' with its short-term focus."

Payment. The hospital would be paid its usual inpatient rate for the patient's care, but would pay to the physician a portion of the savings resulting from quality improvement and efficiency initiatives taken by the physician. Such incentive payments would be allowed only for documented, significant improvements in quality of care and savings in the overall costs of care. ■

CMS News Release, Sept. 6, 2006.

OIG approves Part D assistance program

by Katherine G. Geraghty, J.D., Contributing Editor

A nonprofit, tax-exempt, charitable organization's proposal to subsidize Medicare Part D premium and cost-sharing obligations on behalf of financially needy individuals with end-stage renal disease and chronic kidney disease would not constitute grounds for the imposition of sanctions under the anti-kickback regulations, according to an Office of Inspector General advisory opinion.

Beneficiary grants. Under the proposed arrangement, the organization established objective criteria for determining eligibility for assistance based on the applicant's medical condition and financial needs and not with regard to the applicant's choice of physician, provider, or insurance company. The arrangement would require that qualified patients submit a grant application, usually with assistance from a social worker, and, if approved, would receive financial assistance from the organization for up to one year, after which the recipient could reapply.

Typically, Part D premium payments would be made directly by the organization to the beneficiary's insurance company and cost-sharing grants would be paid directly to physicians, providers, or suppliers of items and services, including drugs. The arrangement also would require that an applicant be under the care of a physician with a treatment regimen in place at the time of application.

Donor funding. The proposed arrangement would be funded by private donors, including dialysis providers and suppliers, pharmaceutical manufacturers, insurance companies, and other individuals and entities. Donations would be made in cash or cash equivalents and donors would be permitted to change or discontinue their contributions at any time.

Donors also would have the ability to support condition-specific programs. In addition, donors would receive a monthly statement from the organization with the aggregate number applicants, upon request, but would not be privy to individual patient information.

OIG evaluation. The organization's grants to Medicare beneficiaries would not constitute grounds for the imposition of civil money penalties because assisting eligible, financially need applicants on a first-come, first-serve basis, is not likely to influence a beneficiary's selection of a particular provider, practitioner, supplier, or product, OIG concluded. Additionally, donor contributions to the organization would not be grounds for sanctions because the program is properly structured such that industry stakeholders could effectively contribute to charitable assistance programs to help needy Medicare beneficiaries.

The OIG's findings are only applicable to the aforementioned program. ■

OIG Advisory Opinion, No. 06-09, Aug. 18, 2006, Health Care Compliance Reporter, ¶500,144.

CMS' McClellan resigns; Administration, Congress react

by Catherine Hubbard, M.A., Contributing Editor

CMS Administrator Dr. Mark McClellan announced that he is leaving the agency as of early October after heading the agency for two and one half years. McClellan said he will spend the next weeks "ensuring a smooth transition as the agency continues efforts to promote a skilled and motivated workforce, accurate and predictable payments, high-value health care, confident and informed consumers, and collaborative partnerships to accomplish all this."

Transitioning. McClellan, who also served as Food and Drug Commissioner before joining CMS, said it is a good time for the transition. He said he is leaving Medicare and Medicaid in a "fundamentally good position," noting that the new Medicare prescription drug benefit is up and running and saving seniors money and the agency is focusing on offering preventative services and identifying and paying for quality care. In addition, CMS is working with states on innovative approaches to expand Medicaid coverage.

An advocate of pay-for-performance, McClellan said the administration is making real progress toward performance-based payments and that its work in the area will continue.

The future. McClellan said he wants to spend more time with the

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family and is not sure what his next job will be. A physician and economist, McClellan is on leave from his professorship at Stanford University and may consider one of the many Washington area think tanks. He does not know exactly what he will do, but he expects to continue working in the health care arena. He did not predict who will fill the CMS slot.

Administration reaction. White House spokesman Tony Snow said McClellan "led the successful modernization of the Medicare prescription drug benefit and worked to modernize Medicare and Medicaid in ways that will help seniors and other beneficiaries get better health care at a better price."

"Mark McClellan oversees the ongoing implementation of the biggest change to Medicare in its history. Starting up the drug benefit was the federal program equivalent of a Mars landing. There were bound to be some start-up problems, and glitches continue. Dr. McClellan ... should get credit for a lot of behind-the-scenes work to make sure millions of Medicare beneficiaries get their prescriptions filled smoothly," according to Sen. Chuck Grassley (R-Iowa), chairman of the Senate Committee on Finance, said.

Sen. Max Baucus (D-Mont.), ranking Democrat on the Senate Finance Committee, said, "Mark's knowledge of medicine, economics, and health policy made him suited to lead CMS during the initial implementation of the new Medicare prescription drug benefit. Transitioning to the drug benefit has been rocky at times, but he has shown a willingness to go back and fix mistakes so as to make the benefit work for seniors. Mark has also worked with me to advance quality and pay-for-performance systems that can help rescue America's ailing health care system. His successor will have big shoes to fill, and will need the same level of expertise, commitment, and focus on quality to prepare Medicare for the retirement of the baby-boom generation." ■

CCH Washington Bureau, Sept. 6, 2006.

CMS reforms QIO oversight

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

CMS Administrator Mark McClellan outlined the actions the agency will take to enhance its oversight and evaluation of the Medicare Quality Improvement Organization (QIO) program in a report to Congress. The report was developed as a result of internal CMS review and a recent Institute of Medicine (IOM) report, which made recommendations to CMS to improve its oversight of QIOs.

CMS program improvement activities. QIOs are organizations that work under contract with CMS to improve quality of care and address beneficiary complaints. The IOM's recommendations for improvements focused on five areas, including: (1) quality improvement and performance management; (2) data processing; (3) program management; (4) program evaluation; and (5) program funding. According to McClellan, those recommendations generally are consistent with the improvements that CMS has undertaken. CMS improvement activities include:

- strengthening evaluation and design to better assess the impact of the program;
- strengthening financial oversight;
- increasing competition for QIO contracts;
- enabling QIOs to release information to beneficiaries about QIO findings related to complaints;
- directing QIOs to focus on the achievement of quality and efficiency goals; and
- directing QIOs to support local initiatives to develop and use information on quality and cost to help beneficiaries.

In addition, as part of the Bush administration's transparency initiative, QIOs have been directed to provide better information on quality and costs to both consumers and providers. According to McClellan, "by updating the QIO program to reflect the most promising new approaches to develop and use information on quality, we are taking another step in our efforts to empower consumers to find better care and better value."

QIOs also will participate in performance-based pilot programs in which they will provide increased technical support for payment reforms to pay providers based on higher quality and lower overall costs of care.

The report also stated that as part of CMS' ongoing internal review of the program, CMS will continue to consider IOM recommendations and make changes as appropriate in the future. ■

CMS Report to Congress, Sept. 1, 2006, Health Care Compliance Reporter, ¶350,012.

On The Front Lines

Part 2: Protecting Tax-Exempt Health Care Organizations from IRS Attack: Fifth Circuit Rules Against Imposition of "Intermediate Sanctions"

by Albert Y. Lin, Esq., Contributing Editor

This is the second of a two part article offering an in depth analysis of the recent decision in the closely watched tax case, Caracci v. Commissioner,[1] in which the United States Court of Appeals for the Fifth Circuit set forth a detailed summary of key facts that helped a tax-exempt home health agency fend off Internal Revenue Service (IRS) penalties assessed following its conversion to a for-profit health agency. Part 1 provided an overview of the remedies available to the IRS in policing tax-exempt organizations and discusses the events that lead to the Fifth Circuit's decision. Part 2 analyzes the Fifth Circuit's reversal and highlights the compliance lessons to be learned from the case.

In a resounding victory for Sta-Home, the Fifth Circuit completely reversed the Tax Court decision and rendered judgment in favor of Sta-Home. The judges drafted a decision peppered with scathing critiques of IRS methods and procedural abuses, and found that the liabilities of the Sta-Home entities exceeded its assets with no excess benefit to the Sta-Home insiders resulting.

Perhaps the Fifth Circuit's decision would not have reflected such vehemence if the IRS had been more deliberate in its audit and assessment of penalties. Instead, the Fifth Circuit found the Tax Court record showed a "cascade of errors" on the part of the IRS, beginning with the delivery of deficiency notices that assessed intermediate sanction penalties based only on preliminary numbers and without a final economic study. Discovery records showed the IRS arguably jumped the gun in an effort to prevent Sta-Home from correcting any excess benefit and avoid the severe 200 percent intermediate sanction penalty. The IRS also rushed to issue the notices out of concern for an expiring statute of limitations. Unfortunately, even though the premature notices were based on admittedly sparse valuation information, the IRS persisted in defending the notices for several years into the litigation and did not adjust the values under actual trial. These exacerbating facts meant the IRS assessment was arbitrary and erroneous, and the burden of proof shifted to the IRS to prove its case.

Proving the Sta-Home Case

The *Caracci* case outlined the processes that Sta-Home did correctly in the process of conversion to a for-profit entity and in shifting the burden of proof to the IRS.

Using the right appraiser and documenting prior and contemporaneous valuations and business judgment. Most importantly, Sta-Home won in part because it demonstrated a "careful and conscientious approach" to the original conversion, and contemporaneously with the original conversion, obtained not only a health care attorney but a separate tax attorney who obtained two appraisals of Sta-Home's assets and liabilities. It also investigated other alternatives to meet cash flow and access to capital when facing upcoming changes from the PIP to PPS Medicare reimbursement systems (as evidenced by written correspondence with attorneys). The record also showed that Sta-Home realized it would be unable to find a buyer; as the only prospective purchaser had acquired a home health care agency in a prior year.

The Fifth Circuit clearly favored the appraiser used by Sta-Home in the Tax Court trial. Of primary importance was that the Sta-Home appraiser demonstrated expertise in not simply the health care industry, but the home health care industry specifically. His analysis of Sta-Home took eight weeks, during which he spent time at the Sta-Home facilities throughout Mississippi. In contrast, the Fifth Circuit noted, somewhat cheekily, that the IRS expert spent only two days in Mississippi, not all business related. The Tax Court opinion was nowhere near as disparaging as the Fifth Circuit. It may have been that the IRS expert did have experience in general health care industries, if not in specific home health care businesses. The lesson remains that deliberate and careful valuations, with very specific analysis of the business of the entity in question, is essential in leading to a positive outcome.

Using the right comparables. Setting aside the level of detail going into valuations, the Fifth Circuit found that the Tax Court erred in its valuation method and its application of the facts used in applying its valuation method. First, the Fifth Circuit determined the Tax Court's adoption of the IRS expert's MVIC valuation method failed to take into

account specific assets of Sta-Home, instead adopting a more general and indirect valuation. Second, and perhaps more seriously, the multiple used in arriving at the value after the invested capital was calculated was wrong because it used solvent, public companies as comparables. The comparables used by the IRS were less reliant on Medicare, generated profits, and at least one had substantial equity.

Demonstrated proper documentation and analysis of compensation and intangibles. The Fifth Circuit also focused on the unique aspects of the Medicare reimbursement system that needed to be reflected in the valuation process. The Tax Court's original finding of excess benefit resulted from its argument that Sta-Home could have realized a profit had it not paid a staff year end bonus of some $1.78 million. The Fifth Circuit noted these bonuses were not really "bonuses" in the traditional sense, but deferred, unpaid employee pay (in part from deferral of first-month pay of all Sta-Home employees necessitated by the PIP system). Moreover, failure to pay the bonuses would have lowered the Medicare reimbursement by an equivalent amount. The Sta-Home executives withheld their own "bonuses" along with other employees. Moreover, none of the aggregate compensation of executives or employees were ruled unreasonable — the chief executive officer and highest paid board member, Michael Caracci, received approximately $230,000 annually and Joyce, as chief operating officer and administrator, received approximately $140,500 annually for running a system with $44 million in revenues.

The Tax Court had disagreed with the Sta-Home expert's assertion that the various intangible assets, including certificates of needs, the Medicare-dependent client base, the aging and largely uncollectible accounts receivables, and licenses, had no value. The Fifth Circuit, however, brought up the IRS's own authority, Rev. Rul. 59-60,[2] which requires unprofitable intangible assets to be assigned a zero value.

With this summary of problems in the Tax Court opinion, the Fifth Circuit reversed the lower court's decision stating that the *Caracci* case "begins and ends with the Commissioner's refusal to recognize the legal effect of its own errors."

Compliance Lessons and Conclusions

Compliance officers and advisors to tax-exempt health care organizations should expect, post-*Caracci*, that the IRS will be far more meticulous and careful in pursuing intermediate sanction cases in major transactions in which insiders have potential to profit. While a victory for Sta-Home, the *Caracci* case admittedly was a hastily litigated case by relatively junior IRS members. Even with Sta-Home having very favorable facts, the IRS managed to drag the litigation through more than six costly years.

In reviewing potential transactions, tax-exempt health care organizations should consider whether it has *adequately valued assets* and considered *valid business options* before undergoing a transaction that may benefit insiders. Such transactions may include more than the outright for-profit conversions of the type described in *Caracci.* The case's principles have relevance to include transfers of assets to for-profit subsidiaries, joint ventures with private physicians, and dissolution and liquidation of exempt organizations.

The Sta-Home case had a happy result primarily because the Sta-Home executives, counsel and accountants were able to document *prior and contemporaneous* valuation and analysis of their transaction. These facts help *shift the burden of proof* to the IRS if the transaction comes under attack. A convincing expert at trial would not be enough.

In valuation situations, the organization should be careful to consider what the appraisers use as *comparables*. Being in the same industry and geographical area will not be enough; the patient base and revenue sources are of equal weight. The appraiser should have not only general health care experience, but experience with the specific issues surrounding its actual business, such as Medicaid reimbursement and cash flow. The *Caracci* case illustrates that there was a distinction between general health care experience and home health care experience.

One thing is certain - future IRS auditors will be more experienced, and far more careful, after the *Caracci* case. With the heightened investigation into the tax-exempt health care industry, as evidenced by recent executive compensation questionnaires and community benefit compliance surveys issued by the IRS, the compliance officer's understanding of *Caracci* and the intermediate sanction regime cannot be overstated. ■

Albert Y. Lin, Esq., an associate at Brown McCarroll LLP in Austin, Texas, practices in the firm's health care and tax groups representing tax-exempt and governmental hospital systems, ambulatory surgery centers, physician groups, and other health care providers. Albert has extensive experience with formation, structuring, and reorganization of tax-exempt entities. He is a certified public accountant and represents clients directly before the IRS and Department of Labor in tax and benefits matters. Along with Frank Sheeder, Esq. of Jones Day, Dallas, Texas, he co-authored several chapters in the CCH Health Care Corporate Governance Guide, which provides explanations and practical advice related to corporate compliance issues for tax-exempt health care organizations.

1 *Caracci v. Commissioner*, 2006 U.S.App. LEXIS 17370 (July 11, 2006), *rev'g* 118 T.C. 25 (2002). See *Health Care Compliance Reporter* ¶*800,187*. See *also* ¶*880,052*.

2 Rev. Rul. 59-60, 1959-1 C.B. 237.

Schering-Plough settles improper marketing, Medicaid fraud charges

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

To resolve criminal charges and civil liabilities in connection with illegal sales and marketing programs for certain drugs, Schering-Plough Corporation and its subsidiary, Schering Sales Corporation (Schering Sales) have agreed to pay a total of $435,000,000, according to the U.S. Department of Justice.

In addition, the federal Medicaid program and each of the state Medicaid agencies that paid for prescriptions of Claritin RediTabs, a nonsedating antihistamine, and K-Dur, used in treating stomach conditions, will obtain the benefit of the best price offered by Schering to commercial purchasers of those drugs and Schering will pay appropriate damages for improperly promoting its drugs for uses not approved by the Food and Drug Administration (FDA) and for offering or paying kickbacks to physicians to prescribe those drugs.

Criminal charges. Schering Sales has agreed to plead guilty to a one count criminal conspiracy to making false statements to the FDA regarding its improper drug promotional activity and to CMS regarding its best price for certain drugs and will pay a $180,000,000 criminal fine. As a result of its criminal conviction, Schering Sales will be excluded permanently from participation in all federal health care programs.

Schering Sales will plead guilty to charges that it conspired with others to give free Claritin RediTabs to a major health maintenance organization (HMO) to disguise a new lower price being offered to the HMO to obtain its business. Drug manufacturers are required to report to CMS their best price on drugs provided to certain commercial customers, including HMOs, and to pay quarterly rebates to the Medicaid program to be sure the program obtains the benefit of that low price. From April 1998 through 1999, Schering Sales reported a false best price to CMS, which failed to include the new low price of Claritin RediTabs provided to the HMO, to avoid paying millions of dollars in additional rebates to the Medicaid program.

Schering Sales also will plead guilty to charges that it conspired with others to make false statements to the FDA in response to the FDA's inquiry regarding certain illegal promotional activities by the company's sales representatives at a national medical conference for oncologists. Those false statements were designed to reassure the FDA that the promotional activities were isolated and not directed by the home office, when the activities were widespread and part of the national marketing plan. In addition, the company advised the FDA that it had taken appropriate steps to reinforce the message that such promotional activities were prohibited, when the company knew and expected that those activities would continue.

Civil claims. The civil settlement resolves allegations that Schering-Plough Corporation and Schering Sales knowingly caused the submission of false or fraudulent claims for drugs that were not eligible for reimbursement. The government's claims against Schering included that the corporation had:

(1) misreported its best price to CMS on Claritin ReidTabs to evade Medicaid rebate liability;
(2) misreported its best price on private-labeled K-Dur to CMS to evade Medicaid rebate liability;
(3) overcharged the Public Health Service (PHS) entities because of its misreporting of best price to CMS;
(4) induced physicians to start patients on Intron A for Hepatitis C by paying them remuneration through three marketing programs;
(5) induced physicians to use Temodar for certain patients with brain tumors and brain metastases and use Intron A for certain patients with superficial bladder cancer through improper preceptorships, sham advisory boards, lavish entertainment, and improper placement of clinical trials; and
(6) knowingly promoted off label uses of Temodar and Intron A despite not having FDA approval.

The corporation agreed to settle its civil False Claims Act liabilities and liabilities under the Food Drug and Cosmetic Act for a total of $255,025,000. Specifically, Schering will pay $159,502,000, plus interest, to the United States in civil damages for losses suffered by the Medicare program, the federal portion of the Medicaid program, the Veteran's Administration, the Department of Defense and the Federal Employees Health Benefits program as a result of its improper drug promotion and marketing misconduct, and Medicaid rebate fraud.

Schering also will pay a total of $91,602,000, plus interest, to settle its civil liabilities to the 50 states and the District of Columbia for losses the state Medicaid programs suffered. In addition, Schering will refund $3,921,090 to the PHS programs that also were entitled to a lower price on certain drugs.

CIA amendment. Schering-Plough Corporation will be subject to an amendment to its existing Corporate Integrity Agreement (see *Health Care Compliance Reporter* ¶420,340), which requires Schering to continue extensive work that it has undertaken in the last two years to monitor and correct the shortcomings in its drug sales, marketing and pricing activities. After the government uncovered the activities, Schering-Plough cooperated with the investigation and actively worded oncompliance issues thorugh a significantly expanded compliance department. ■

U.S. Department of Justice News Release, Massachusetts, Aug. 29, 2006.

Corporate Governance

Experts provide tips to ensure hospital board effectiveness

by Catherine Hubbard, M.A., Contributing Editor

In this post-Enron and Sarbanes-Oxley (SOX) era, even nonprofit health care facilities will face increasing scrutiny for ineffective governance, according to experts who spoke at an American Bar Association conference on strategies for effective board governance. The panel warned that health care compliance officers and counsel need to understand board of director fiduciary duties, the business judgment rule, and good faith standards.

"The standard is going to be higher," said Paul DeMuro, a partner with Latham & Watkins, Los Angeles. Although SOX does not apply to nonprofits, directors have a fiduciary duty to stakeholders, said DeMuro. With rising public debt, skyrocketing health care costs and a more active investor community, there will be more scrutiny from rating agencies, bond insurers and the public, DeMuro added.

DeMuro advised that counsel look at the relationships the board of directors has to members of the community, both financial and business, noting that courts will look at relationships outside the company and how those relationships affect the board's independence. For instance, a director's independence might be questionable if he or she is selling consulting or legal services to the health care entity, has business or personal relationships with people in a management making role, works as a local insurance agent or at a local bank, or even has a spouse with close ties to the hospital, DeMuro said.

"All of these are potential conflicts of interest, which need to be addressed," he said. He also suggested that board members consult applicable state laws and conflict of interest policies of the company and disclose any perceived conflicts of interest.

Board meetings. DeMuro said counsel should look at whether the board meets in executive session without the chief executive officers, asks probing questions, controls the agenda, encourages operational or legal audits and reviews, and documents its discussions. Failure to follow these basic steps should call into question the effectiveness of the board, DeMuro stated.

Business judgment rule. Cary Miller, a partner with Hooper, Lundy & Bookman, Inc., San Diego, discussed a recent case in which the hospital was sued for breach of fiduciary duty and negligence related to its decision to hire and rely on reports from a management company. A trial judge ruled that the directors' decisions were protected under the business judgment rule. "The rule protects well meaning directors even though they may be misinformed, misguided and honestly mistaken," added Miller, who successfully defended the board.

Under the business judgment rule, directors are not liable for errors and mistakes in judgment as long as they (1) are disinterested and independent, (2) acted in good faith, and (3) are reasonably diligent in informing themselves of the facts, Miller stated.

"This ruling has great importance for nonprofit directors. It represents the willingness of a federal district court judge to exonerate directors by applying the business judgment rule," according to Miller. "This should provide some comfort to nonprofit directors and all who represent them," he added. ■

ABA Conference, July 26, 2006.

Health Information Technology

National HIT system plans proceeding slowly

by Katherine G. Geraghty, J.D., Contributing Editor

Although HHS has made progress in the implementation of a national health information technology (IT) system, there is still much work to be done, David Powner, Director of Information Technology Management Issues of the Government Accountability Office (GAO) told the Subcommittee on Federal Workforce and Agency Organization and the Committee on Government Reform on September 1, 2006.

HHS said it intended to release a strategic plan later this year, although no such action has been taken. Powers stated that without a detailed plan it is uncertain whether HHS will meet President Bush's goal for the development of a national IT strategy and the adoption of interoperable electronic health records by 2014.

Areas of progress. Powner testified that HHS has made progress in five key areas. First, HHS has advanced the use of electronic records by defining initial certification criteria for electronic health records and certifying 22 vendors' products and has established interoperability standards for a health information exchange. As part of the effort, HHS coordinated with the National Institute for Standards and Technology to align federal and private sector standards for interoperable health IT. Additionally, HHS awarded contracts for developing prototypes for a national network to four contractors, proposed more than 1,000 functional requirements and held the first nationwide health information forum.

HHS also has addressed privacy and security issues associated with the nationwide exchange of health information by selecting standards to help ensure privacy and confidentiality, working with 34 states and territories to perform assessments of the impact of policies and laws on security and privacy practices and formed a new workgroup specifically to address privacy and security policy issues. Lastly, HHS has integrated public health systems into a national network. HHS made recommendations to help support sharing of clinical care data with local, state, and federal biosurveillance programs, including the development of materials for public education.

Recommendations. As in May 2005 and March 2006, the GAO recommended that HHS establish detailed plans and milestones for each phase of the project to ensure that the President's goals for the widespread adoption of a national IT system by 2014 were met. ■

OIG Testimony, No. 06-107IT, Sept. 1, 2006.

EMTALA

Medical treatment of patient does not violate EMTALA

by Anuradha Gupta, J.D., Contributing Editor

Evidence that a hospital physician treated a patient in the same manner as he would any other patient presenting with a similar condition, coupled with the decedent's parents' failure to present evidence that the patient was treated differently from any other patient under similar circumstances, was sufficient to defeat an Emergency Medical Treatment and Active Labor Act (EMTALA) violation claim, according to the U.S. District Court for the Eastern District of Missouri.

The patient died the day after she came to the hospital complaining of migraine headaches for the preceding three days. Based on the patient's history of migraine headaches, blood work, and results of a physical exam, the examining physician concluded that the patient was suffering from chronic migraine headaches, not an acute emergency. He prescribed migraine medications, ordered a CT scan for the next day, and then discharged the patient. The hospital was aware that the patient did not have medical insurance.

The parents alleged that the hospital violated EMTALA by failing to provide an appropriate medical screening, failing to provide stabilizing treatment, and by improperly discharging decedent. Under EMTALA, a hospital must "provide for an appropriate medical screening exam within the capability of the hospital's emergency department . . . to determine whether or not an emergency medical condition . . . exists." The appropriate medical screening examination provision is only violated by disparate treatment of a patient and not by negligence in the screening or diagnostic process.

Accordingly, any factual dispute regarding the physician's actions had no bearing on whether there was an EMTALA violation because the requirements of the appropriate medical screening provision were satisfied. ■

Irvin v. Pike County Memorial Hospital, D. Miss., Aug. 7, 2006, Health Care Compliance Reporter, ¶800,202.

In the News

New uniform billing form in 2007

The National Uniform Billing Committee has approved the UB-04 form as the replacement for the UB-92 form. Health plans and clearing houses must be ready to receive the new UB-04 by March 1, 2007. Healthcare providers such as hospitals, skilled nursing facilities, hospice and other institutional claim filers can use the UB-04 beginning March 1, 2007; however, there will be a transitional period between then and May 22, 2007, during which they can use either form. Beginning May 23, 2007, the UB-92 no longer will be acceptable.

CCH Chicago Bureau, Aug. 29, 2006.

California law establishes fines against hospitals for patient injury

The California Legislature has approved the Comprehensive Health Facility Quality Enforcement Act (SB 1312), which provides for the proactive enforcement of state safety laws as part of the annual licensure and certification process and, for the first time in state history, establishes fines up to $50,000 for hospitals that injure a patient. The Act requires inspections and investigations of long-term care facilities certified by the Medicare or Medicaid program to determine compliance with federal standards and California statutes and regulations, eliminates existing law that provides an exemption for specified health care facilities from periodic inspections by the Department of Health Services (DHS), and authorizes DHS to assess administrative penalties on hospitals based on deficiencies constituting immediate jeopardy to the health and safety of a patient. For nursing homes and intermediate long-term care facilities, the Act requires that state law be enforced proactively. Current practice is for the state to cite and fine a nursing home only after someone has been injured. The Act, when signed by Governor Schwartzenegger, will become effective, in part on January 1, 2007.

CCH Chicago Bureau, Sept. 6, 2006.

AHIP president comments on executive order

"President Bush's Executive Order [of August 22, 2006, which requires four federal agencies to share with beneficiaries information about prices and quality of services, and improve health information technology systems] paves the way toward a system that rewards the delivery of high-quality care, fosters an interoperable health care system, and takes steps to ensure that consumers are equipped with the best available information they need to make health care decisions," according to America's Health Insurance Plans' (AHIP) President Karen Ignagni. Health insurance plans are leading the way by collecting and disclosing quality and price data and making personal health care information more available to their members; working with hospitals, physicians, consumers, purchasers and others to develop a uniform template for performance measurement to create a more efficient and effective health care system; and advancing an interconnected and interoperable health care system in which health information can be exchanged electronically and in a secure framework. "Through all of these initiatives, health insurance plans will meet the challenges set out in today's executive order and play a leadership role in the transition to a safe, effective and quality-oriented health care system," Ignani concluded.

America's Health Insurance Plans' News Release, Aug. 22, 2006.