CCH Health Care Compliance LETTER

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OPO final rule establishes new outcome measures

by Jay Nawrocki, M.A., Contributing Editor

New quality measures and data reporting requirements that qualified organ procurement organizations (OPOs) must meet to have their services covered by Medicare and Medicaid are set forth in a final rule issued by CMS on May 31, 2006. CMS stated that its goal is to improve OPO performance and increase organ donation. Based on the comments CMS received, the final rule was changed substantially from the proposed rule, which was published on February 4, 2005.

Certification and recertification of OPOs. OPOs will have to be re-certified every four years as opposed to every two years as originally proposed. In addition, OPOs will be able to compete to be a designated service provider only in donation service areas where the previous OPO has been de-certified.

Under the final rule, CMS will base its selection of an OPO for an open donation service area on the following criteria: (1) performance on the outcome measures; (2) relative success in meeting the process performance measures; (3) success in identifying and overcoming barriers to donation within its own service area and the relevance of those barriers to barriers in the open area; and (4) contiguity to the open donation service area.

In addition, an OPO must: (1) have a written agreement with 95 percent of hospitals in its service area that have both a ventilator, and an operating room, and have not been granted a waiver to work with another OPO; (2) offer at least once a year training to hospital employees on how to solicit patients to become organ donors; and (3) must have arrangements to cooperate with tissue banks that have arrangements with hospitals.

The final rule recertifies all 58 OPOs through July 31, 2010, and provides an opportunity the OPOs to sign agreements with the Secretary that will begin on August 1, 2006, and end on January 31, 2011. The new agreements are needed to ensure that OPOs are able to continue their organ procurement services without interruption and the Medicare and Medicaid programs can continue to pay them for their organ procurement activities after July 31, 2006.

Outcome and performance measures. The final rule establishes new conditions for coverage that include three new outcome measures: (1) donation rate; (2) observed donation rate compared to the expected donation rate, as calculated by the Scientific Registry of Transplant Recipients (SRTR); and (3) a yield measure for both organs transplanted per donor and organs used for research per donor. Based on comments to the proposed rule, the five outcome measures originally suggested were not adopted in the final rule because they were too dependant on each other. If an OPO failed to meet one, it would most likely fail to meet others.

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Wolters Kluwer Law & Business

The first outcome measure allows CMS to assess an OPO's conversion rate of potential donors to actual donors so that it can determine how an OPO has performed in regard to the donor potential (that is, the number of eligible deaths) in its own donation service area, as well as how it has performed when compared to other OPOs. The second outcome measure uses the statistical methodology developed by the SRTR for determining an expected donation rate for each OPO, which allows CMS to assess with a reliable degree of accuracy how an OPO has performed in view of its expected performance. The third outcome measure is comprised of three individual measures for organs transplanted per donor and organs used for research per donor, which allows CMS to assess how well an OPO fulfills its ultimate mission, recovering viable organs and placing them with transplant centers for transplantation, as well as its commitment to placing organs for research.

CMS will only use data from the prior 36 months in determining if an OPO has meet the three outcome measures. It will not use data from previous recertification periods.

Appeals process. Based on a Congressional mandate, CMS established a new appeals process that includes an OPO's right to request reconsideration after decertification.

The notice of decertification must contain the reasons for the decertification. The OPO must request reconsideration before the OPO may seek a hearing before the hearing officer. If a request for reconsideration is made, CMS is required to provide the administrative record that includes the evidence used in making the decertification decision.

In addition, CMS has expanded the circumstances under which an OPO can appeal a decertification due to involuntary termination or nonrenewal of its agreement and may appeal on both substantive and procedural grounds. The appeals process includes procedures for OPOs to request reconsideration and to request a hearing. The process also includes additional rights and procedures that provide an opportunity for an OPO to obtain a fair and expeditious hearing and a decision on its appeal before the competition process begins and new agreements must be signed.

"This rule establishes a competitive framework for OPO certification based on rigorous performance-based quality measures for OPOs," stated CMS Administrator Mark B. McClellan, M.D., PhD. It "will support and enhance the Department's unprecedented success in saving lives by increasing organ donation and transplantation," McClellan added. The final rule becomes effective July 31, 2006. ■

Final rule, 71 FR 30982, May 31, 2006, Health Care Compliance Reporter, ¶700,011; CMS News Release, May 30. 2006.

Congress questions JCAHO's accreditation processes

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

Senator Grassley (R-Iowa), along with Sen. Max Baucus (D-Mont.), and Rep. Pete Stark (D-Calif.), released the text of their letter to the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) regarding their ongoing investigation of the Commission's process for determining the eligibility of hospitals to participate in the Medicare program and its relationship with a subsidiary corporation.

GAO investigation. A 2004 Government Accountability Office (GAO) investigation requested by Grassley, Baucus, and Stark found serious deficiencies in JCAHO's accreditation process. The report found that JCAHO's pre-2004 hospital accreditation process did not identify three-quarters of the hospitals determined by state agencies to have serious deficiencies in Medicare requirements, which could limit a hospital's ability to provide adequate care and patient safety. Based on these findings, the GAO is in the process of conducting a second investigation related to whether certain conflicts of interest impair JCAHO's ability to independently accredit hospitals. Of particular concern is the Commission's consulting subsidiary, Joint Commission Resources (JCR), which profits from the sale of products and services that aid hospitals in meeting JCAHO's accreditation standards.

Request for information. In the letter, Grassley, Baucus and Stark requested that JCAHO's president, Dennis S. O'Leary, provide information regarding the Commission's new accreditation process, "Shared Visions - New Pathways," which was introduced in January of 2004. Specifically, the letter asked for information showing

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Quality of Care (cont.)

that the new program had improved patient safety, including a detailed account of deficiencies in accredited hospitals and a summary of results of any unannounced surveys.

The congressmen also asked that O'Leary provide an explanation of services or duties performed in connection with payments identified on the JCR's 990 tax form for tax years 2003 through 2005, including management fees, royalty fees, funding agreements, and payments due or transferred to a parent company. The letter requested that the Commission provide a point of contact by May 23, 2006, and any documents or written responses to the letter no later than June 8, 2006.

A proposed accreditation legislation. Rep. Stark has been advocating for stronger accreditation procedures for over a decade. He first raised the issue of hospital accreditation problems at a hearing in 1990, and again in 2000 and 2002. Stark also introduced legislation in 1999 to increase public representation on the governing boards of national accrediting entities and to require those entities to have open meetings. The Congressman sponsored legislation in 2004 that would have brought JCAHO's accreditation process, which currently is statutory, under the authority of CMS; however, Congress did not act on the legislation. The group intends to introduce revised legislation to include any new findings by the GAO. ■

Senator Grassley News Release, May 19, 2006.

HIPAA

CMS urges providers to apply for NPI before May 2007 deadline

Covered health care providers have one year to obtain National Provider Identifiers (NPI). The NPI must be used in standard health care transactions, specified by the Health Insurance Portability and Accountability Act of 1996 (HIPAA) no later than May 23, 2007, by covered health care providers, health plans and health clearinghouses, however, small health plans have until May 23, 2008, to comply. Legacy identifiers will not be accepted after that date. CMS is urging health care providers to apply for the NPI well before May 22, 2007.

NPI defined. The NPI, which is administered by CMS, is a 10-digit, numeric identifier that does not expire or change. The identifier helps to ensure that medical claims are processed on time and payments are made correctly. The Medicare fee-for-service program began accepting the NPI, along with the Medicare legacy identifiers, from health care providers in HIPAA standard claims transactions in January 2006.

Once a covered health care provider has an NPI, it must share the NPI with any entity that needs it to identify the covered health care provider in a standard transaction. Health plans and health care clearinghouses should make every effort to ensure that the NPI is incorporated into their systems and processes so that they can be used successfully by the May 23, 2007, deadline.

Obtaining an NPI. Health care providers may obtain their NPI in one of three ways:

(1) apply on-line by using the web at https://NPPES.cms.hhs.gov;
(2) call the NPI Enumerator (1-800-465-3203) and request a paper NPI application form, complete it, and mail it back to the address on the form; or
(3) apply for a bulk enumeration, which allows an Electronic File Interchange Organization (EFIO) approved by CMS to obtain a number of providers' NPI.

Under the law, all HIPAA covered healthcare providers, whether they are individuals or organizations, must obtain an NPI for use to identify themselves in HIPAA standard transactions. For more details about NPI and EFI, visit www.cms.hhs.gov/NationalProvIdentStand/. ■

CMS News Release, May 25, 2006.

On The Front Lines

Creating a Collaborative Clinical/Compliance Culture

by Gynelle Baccus, R.N., PhD., Contributing Editor

After two decades in nursing education, I moved into a Compliance Analyst position. Quickly, I realized many nurses do not understand the basics of compliance, nor are they taught about compliance during their education. Yet, nurses strategically can provide the essential link between the compliance/financial/business side and the clinical side of healthcare.

When nurses hear the word "compliance," many think of patient education and a patient's compliance with the medical and nursing care plans; however, with recent corporate scandals and legislation mandating compliance education, nurses, especially those in nursing management, need to expand their definition of compliance to include their hospital's corporate compliance program. This new expanded view of "compliance" includes learning a new vocabulary, collaborating with others involved in the hospital's revenue cycle, understanding the purpose and elements of a compliance program, and being able to identify and report potential compliance violations and unethical behavior.

What Does Compliance Have To Do With Nursing?

In our highly regulated healthcare system, a compliance department provides a self-governing program that promotes ethical and legal business practices. Every new nurse manager has to learn about compliance and understand the relationship between compliance and patient care. Linking regulations to patient education and advocacy is important when teaching nurses about compliance. Additionally, Compliance Officers can reinforce that teaching by attending regularly scheduled manager meetings or nursing staff meetings.

Many hospital compliance programs have an emphasis on fraud and abuse in the Medicare and Medicaid programs; however, compliance with all laws and regulations that impact healthcare are within their scope. How does this impact nursing? Simply put, nurses need to be aware of all regulations, policies, and laws impacting their clinical areas. Relating specific examples of the need to understand regulations can be accomplished by linking patient education and patient advocacy with that knowledge of regulations.

For example, the more nurses know about Medicare regulations, the more they can advocate for the patient. If the nurse does not understand CMS rules about self-administered drugs, then how can the nurse act as an advocate for the patient? Many beneficiaries may not understand that Medicare does not cover self-administered drugs while the beneficiary is in the emergency room or in an observation unit. Consequently, if the hospital provides the beneficiaries self-administered drugs during an emergency room or observation stay, the hospital will charge the patient for the cost of the drugs and the patient will be responsible for the charges. Hospitals, however, allow patients to take their own self-administered drugs if they bring them in the original containers and the pharmacist verifies they are the correct drugs. The nurse, therefore, should instruct the patient or patient's family to bring in self-administered drugs from home so the patient won't be billed for self administered drugs taken during an emergency visit or stay in an observation unit.

Dealing with capturing charges is another example of how nurses can be affected by compliance issues. Nursing managers understand that these "lost charges" may amount to the addition or reduction of a staff nurse on their unit. Staffing is of great concern to most nurse managers, so tying captured charges into the staffing issue grabs their attention. Helping nurse managers see how an issue relates to them, makes it easier for them to appreciate the need to understand Medicare and Medicaid regulations.

Talk the Talk!

Unfortunately, many basic nursing curricula do not include any business courses! Additionally, most nursing curricula do not discuss corporate compliance programs. New nurses may be learning about compliance for the first time during orientation. When those nurses are promoted into management positions, they should have further training in compliance matters. Creating a rapport and collaborative culture is the goal and the need to "speak the same language" is essential.

Compliance Officer's role. To address this goal, the Compliance Officer should spend one-on-one time with all new managers and new physicians. Meeting the Compliance Officer in person is critical for future collaborative efforts. At that meeting, the Compliance officer should review the

hospital's program and essential elements of the program. He or she also should discuss the most recent audits.

Revenue cycle meetings. In addition to meeting with the Compliance Officer, nursing staff as well as representatives from Coding, Patient Financial Services, Compliance, Denial Management, ChargeMaster Manager, and other clinical areas (Surgery, Rehabilitation, Lab, Emergency, Dialysis, Respiratory, Cardiac Catheterization, Radiation Oncology, Pharmacy, Diet Therapy, Imaging, and Sleep Disorders) should be included in revenue cycle meetings. There may be many revenue cycle groups within the hospital. Every profession has its own vocabulary; yet, these meetings need a "common" vocabulary to stimulate discussion and problem-solving. Creating a glossary of revenue cycle terms is one way to help new nursing managers become more active participants on the revenue cycle team.

Speaking the same language. In addition to revenue cycle terms, the glossary should include the acronyms for the terms as the Compliance Officer and revenue cycle team may refer to the terms by the acronym. The following is just a partial list of terms that could be included in a glossary for nurses:

- **ABN** (Advanced Beneficiary Notice). A form that should be given to the Medicare patient to notify the patient that Medicare may deny payment for the item or service that is to be furnished. The ABN should be signed by the patient.
- **CMS** (Centers for Medicare and Medicaid Services), formerly HCFA. The federal agency that runs the Medicare program.
- **CPT**® (Current Procedural Terminology). A system that consists of codes that are used to identify medical services and procedures, which was created and is maintained by the American Medical Association.
- **Clean claim**. A claim is a request for reimbursement for services rendered to a patient that the hospital submits to a Medicare contractor or other health insurer. A clean claim is one that is processed without requiring further investigation, documentation, or correction.
- **DRG** (diagnostic related group). A system that classifies inpatients by specific diagnoses for Medicare payment purposes.
- **Fraud**. To knowingly and purposely bill for services that were never provided to a patient or bill for a service that has a higher reimbursement than the service provided.
- **FI** (fiscal intermediary). A private company that has a contract with Medicare to pay Part A and some Part B bills. Also called "Intermediary."
- **HIPAA** (Health Insurance Portability and Accountability Act of 1996). A law enacted to protect the privacy of personal information.
- **IPPS** (inpatient prospective payment system). The Medicare reimbursement method for inpatient services.
- **LCD** (local coverage determination). A decision by the fiscal intermediary whether to cover a particular service on an intermediary-wide basis. Medicare contractors, however, are required to follow national coverage determinations (NCDs) (see below). An LCD can not supersede an NCD. If an NCD does not specifically exclude/limit an indication or circumstance, or if the item or service is not mentioned at all in an NCD or in a Medicare manual, it is up to the Medicare contractor to make the coverage decision. The LCD, which can be several pages long, gives providers guidance for documentation and coding.
- **Medically necessary**. Refers to services or supplies that are proper and needed for the treatment of the patient's medical condition and meet the standards of good medical practice.
- **NCD** (National Coverage Determination). A decision by Medicare that set the extent to which specific services, procedures, or technologies will be covered on a national basis.
- **OPPS** (Outpatient Prospective Payment System). Refers to the Medicare payment system for services rendered in outpatient settings (like same day surgery, etc.).

This glossary may be included in the hospital's Revenue Cycle Manual and distributed to all new members of the revenue cycle team. The important thing is that everyone speaks the same language. If acronyms are used in the meetings, their meaning should be clarified for new members of the team. This gesture will increase participation and problem solving at revenue cycle meetings.

Collaborate, Collaborate, Collaborate.....

Nurses, especially nurse managers, need to collaborate with a variety of other healthcare team members on the revenue cycle team on an individual basis. Specifically, nurse managers should meet with the Compliance Officer, the Denials Manager, and the Manager of the ChargeMaster. Meeting with these team members on a one-to-one basis is the best way to familiarize a new nurse manager to the duties of the position. In addition, new nurse managers are likely to ask more questions during this one-on-one orientation with key team members than during a regular revenue cycle meeting.

This personal interaction allows time for nurse managers to gain an overview of compliance, major rules, regulations, and statutes that impact the hospital system, and an explanation of the elements of a corporate compliance program. Additionally, the nurse manager can find out how to appeal denials and understand monthly denial reports for a specific patient unit. Lastly, the nurse manager can be shown the chargemaster and begin to understand the charges that are made on a specific clinical unit.

Orientation for new nurse managers also should include a basic understanding of the elements of a compliance program

and a discussion of risk assessment, recent audits, and the Office of Inspector General's WorkPlan.

This initial orientation period will provide the new nurse manager with the background to feel more comfortable about clarifying reports, reporting potential compliance issues, and creating new charges for a clinical unit.

At the core of collaboration is the mutual respect staff should have for each other and the shared goal of quality patient care. This mutual respect will develop more easily once the nurse manager has been empowered to understand the facility's denial reports, compliance audits, and how to report compliance concerns.

Nurse auditors. If the hospital's Compliance Department has nurse auditors, then be sure that the new nurse manager gets acquainted with them. Nurse auditors, usually, registered nurses, can help the nurse manager understand documentation issues and charging issues specific to a clinical unit. The Compliance Officer can encourage new nurse managers to utilize these nurse auditors as another resource in identifying trends related to charging and documentation issues.

Continuing education. Annual continuing education about the revenue cycle is needed to update nursing and other hospital managers. Using web-based instruction or celebrating Compliance Week annually can be used for these updates. Additionally, forwarding clinical-specific rules/regulations to the clinical nurse manager helps them stay abreast of current changes.

Nurses' Role in Reporting Potential Compliance Issues

Open lines of communication are essential to any effective compliance program; but helping nurse managers understand the purpose of a compliance helpline and what to report also is essential. Nurses are "on the front lines" in terms of patient care, quality of care, and patient safety. Consequently, nurses should know what compliance issues to report and when. During the orientation period, new nursing managers should be given examples of compliance issues, such as:

(1) patient issues, including problems with consent or patient rights;
(2) employee issues, such as problems with health, safety, behavior in the clinical areas as well as credentialing issues;
(3) confidentiality issues, such as privacy issues or possible HIPAA violations;
(4) drug/narcotic issues;
(5) sexual harassment;
(6) disposal of medical waste;
(7) policy/procedures issues, such as concerns about not following current policies;
(8) charging issues, including proper collection practices;
(9) clinical trials, including questions/concerns about patient issues related to clinical trials;
(10) suspected fraud or abuse of any kind; and
(11) questions/concerns about interpretation of LCDs for clinical area.

Conclusion

Nurses, especially those in management positions, can provide strategic links between the financial and clinical sides of healthcare; but they must have thorough orientation to the following areas:

- a glossary of revenue cycle terms and acronyms,
- a one-on-one orientation with the Compliance Officer, Denials Manager, and ChargeMaster Manager,
- explanation of the elements of a compliance program,
- examples of ways regulations relate to patient advocacy, and
- examples of compliance issues to report/helpline information.

A shared vocabulary, shared understanding of the purposes of compliance, and shared views on reporting compliance issues can result in a collaborative clinical/compliance culture. This shared culture will result in more compliant behavior and more willingness to share compliance issues.

Gynelle Baccus, R.N., PhD. is Compliance Analyst for Southern Illinois HealthCare, Carbondale, Illinois. In this role, she attends Revenue cycle meetings, works with staff on developing policies and procedures, helps staff with interpreting regulations, and serves on the facility's Institutional Review Board. Prior to her work as a Compliance Analyst, Gynelle taught nursing for 27 years at Southern Illinois University Edwardsville School of Nursing. She can be contacted at gynelle.baccus@sih.net.

Fraud and Abuse

Specialty hospital moratorium ends, but concerns continue

by Catherine Hubbard, M.A.
Contributing Editor

The moratorium on specialty hospitals will not be extended, but CMS will pursue ways to increase health care safety, and improve the Medicare payment system, according to CMS Administrator Mark McClellan's statements at a May 17, 2006, Senate Finance Committee hearing. McClellan explained that physician-owned specialty hospitals are legal under the existing whole hospital exception to the physician self-referral law and elimination of the exception "cannot be done administratively."

Congressional response. Senate Finance Committee Chairman Charles Grassley (R-Iowa) said he wants the administration to review patient safety and quality of care at specialty hospitals and he wants CMS to make a "serious commitment" to their oversight.

Ranking member Max Baucus (D-Mont.) contended that specialty hos-

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pitals contribute to rising health costs. "We need to get more for our health-care spending and it appears that specialty hospitals aren't helping," he said. McClellan explained that the agency is working to increase price transparency and revise the diagnosis related group payment method to make payments more in line with the actual costs of care.

Both Senators have been involved in an effort to understand the impact of physician-owned specialty hospitals on patients, community hospitals, and the Medicare and Medicaid programs. On March 6, 2006, they asked the HHS Inspector General and the Government Accountability Office to review patient safety and quality as well as financial arrangements at physician-owned specialty hospitals. They also have asked the Medicare Payment and Advisory Committee (MedPAC) to further examine the impact of specialty hospitals on community hospitals. The two primary areas of concern are patient safety and the use of taxpayer dollars through Medicare and Medicaid.

Legislative background. The 18-month moratorium for new specialty hospitals, which ended on June 8, 2005, was mandated by the Medicare Modernization Act of 2003 (PubLNo 108-173). Under the moratorium, new physician-owned specialty hospitals were unable to take advantage of the "whole hospital exception" of the physician self-referral statute.

After the moratorium expired, CMS suspended the enrollment of new specialty hospitals, while reviewing the agency's enrollment procedures. The Deficit Reduction Act of 2005 (PubL-No 109-171) extended the suspension until CMS developed a strategic and implementation plan regarding physician investment in specialty hospitals. According to a CMS spokesperson, CMS does not need more time for the review. ■

CCH Washington Bureau, May 17, 2006.

Antitrust

FTC panel hears arguments in hospital merger dispute

by Dave Hansen, Contributing Editor

Evanston Northwestern Healthcare Corporation (ENH) and the Federal Trade Commission (FTC) debated during oral arguments on May 17, 2006, whether a federal judge's 2005 ruling that ENH violated antitrust laws by acquiring Highland Park Hospital merited a divestment of the corporation. ENH was formed in 2000 when two Cook County hospitals, Evanston and Glenbrook, purchased Highland Park Hospital, located in a north suburb of Chicago. The FTC brought suit against ENH, alleging that prices rose by nearly 50 percent after the merger, compared to a 4 to 6 percent yearly price increase at Highland Park Hospital prior to the merger. Chief Administrative Law Judge Steven J. McGuire ordered ENH to divest Highland Park Hospital after ruling that the merger substantially lessened competition in violation of the Clayton Act.

Competitive effect of merger. Duane M. Kelley, arguing on behalf of ENH, claimed that the FTC did not prove the merger stifled competition, noting that the hospitals reside in different geographical areas and, therefore, do not directly compete with one another. Kelley also reasoned that the hospitals provided very different services. For example, unlike Highland Park Hospital, Evanston is a teaching hospital and has a tertiary care center.

ENH also argued that the benefit to consumers as a result of the merger outweighed the risk of harming competition. Kelley indicated that splitting the hospitals six years after the merger could cause patients to lose access to doctors and improvements in cardiac and cancer care made possible by access to a teaching hospital.

The FTC countered that the merger gave ENH pricing power with no commensurate increase in patient outcomes because there were no important hospitals between Evanston and Highland Park. The FTC also stated that there was no evidence to support the argument that patients themselves benefited significantly from the merger.

Determining an appropriate remedy. Panel members expressed concern that splitting the hospitals could reduce the medical care patients now receive at Highland Park Hospital. FTC Commissioner Pamela Jones stated that she felt a divestiture was a drastic remedy and questioned whether there may be a more appropriate remedy. FTC Chairperson Deborah Platt Majoras along with other Commission members asked if allowing the hospitals to bill separately would be a more reasonable alternative.

Counsel for the FTC, Chul Pak, responded that allowing the hospitals to bill separately would not resolve the antitrust issue as the hospitals would still be owned by the same company. Pak told the panel that divestiture would be the only way to achieve competition in this case. He added that divestiture would in no way harm the quality of health care to consumers, claiming that there existed ample legal precedent for divestiture after six years.

Following oral arguments, attorneys for both sides agreed that this case presents challenging issues for the FTC and neither expect a decision in the immediate future, indicating that it could take the commission as long as six months to hand down a ruling. ■

CCH Washington Bureau, May 17, 2006.

Anti-kickback

No kickback violation for employee solicitation of patients

by Michelle Oxman, J.D., Contributing Editor

A dentist, who paid employees "by the head" to solicit Medicaid patients and drive them to appointments, could not be prosecuted under the state anti-kickback law because the "safe harbor" provisions of the federal law preempted the state law, according to the Florida Supreme Court. The court concluded that the Florida statute criminalized conduct that Congress intended to be shielded from prosecution.

Federal versus state law. At issue was the state law's lower level of culpability required to constitute a violation. Federal law prohibits actions committed knowingly and willfully. Consequently, the government must prove that the defendant acted with knowledge that his or her conduct was unlawful. In contrast, the state law defines "knowingly" to include negligent conduct.

In addition, the federal statute protects through "safe harbors" any conduct that the Secretary has defined by regulation, which includes an exception for employer payments to employees. The state law contains no exceptions for employer payments.

The state argued that the federal employment exception did not apply to "per head" compensation. The court, however, found that Congress clearly intended to protect all employment relationships. Furthermore, the Office of Inspector General stated specifically that the safe harbor exception allowed an employer "to pay an employee in whatever manner he or she chose for having that employee assist in the solicitation of program business. . ."

According to the court, the presence of safe harbors in federal law reflects a purpose to assure that certain conduct would remain lawful and that inadvertent violations were not intended to be pubishable. Because of the difference in the level of culpability, the Florida law interfered with the accomplishment of those federal purposes and concluded that the federal anti-kickback law preempted the state law. ■

State of Florida v. Harden, Fla., May 18, 2006, Health Care Compliance Reporter, ¶800,161.

In the News

CMS issues interim report on specialty hospitals

CMS released an interim report to Congress outlining the steps taken to implement a provision in the Deficit Reduction Act of 2005 (DRA) (PubLNo. 109-171) affecting specialty hospitals. That provision requires CMS to develop a strategic plan to determine whether (1) physician investments in specialty hospitals are proportional to their investment returns; (2) the investment is a bona fide investment; and (3) the Secretary should require specialty hospitals to disclose investment information on an annual basis. The steps include enforcement of payment restrictions for new specialty hospitals; proposed payment reforms for more accurate inpatient hospital reimbursement; payments for services by ambulatory surgical centers; clarifying the Emergency Medical Treatment and Labor Act (EMTALA) obligations; better evidence on financial arrangements, and care to low income and charity patients; and support for enforcement against inappropriate investment activities. A final report to Congress will be issued later this year.

CMS Media Release, May 9, 2006.

AHIC announces EHR recommendations

The American Health Information Community (the Community) unanimously approved and delivered 28 recommendations yesterday to HHS Secretary Mike Leavitt for his consideration. The Community was formed in 2005 to help advance efforts to reach President Bush's call for most Americans to have electronic health records (EHRs) within ten years. Recommendations were made on how to make health records digital and interoperable while protecting patient privacy and the security of those records. Among the recommendations, the Community advised that (1) the Health Information Technology Standards Panel (HITSP) identify and define standards that will enable secure messaging between patients and clinicians, reporting results from laboratory testing, and availability of electronic registration information to replace the medical clipboard; (2) the Certification Commission for Health Information Technology (CCHIT) incorporate HITSP standards as criteria for product certification on an ongoing basis to ensure interoperability; and (3) a subgroup should be formed to frame privacy and security issues relevant to the work of the breakthroughs. The Community also unanimously adopted all CCHIT criteria for certification of ambulatory EHRs.

HHS News Release, May 17, 2006.

Red Cross security breach

The American Red Cross (Red Cross) recently experienced a breach of information security in the Missouri-Illinois Blood Services Region. A former employee, who used donor identifying information to obtain credit cards and other accounts, has been indicted by a federal grand jusry and is awaiting trial in connection with the breach. Red Cross announced that it is taking the steps to ensure that this type of security breach does not occur in the future, including: software changes to further restrict access to social security numbers, continuing investments in state of the art technology to increase information security, and employee training.

Red Cross Press Release, May 18, 2006.