CCH Healthcare Compliance LETTER

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CMS announces adoption of National Provider Identifier

by Sharon Sofinski

The Centers for Medicare & Medicaid Services (CMS) has announced that healthcare providers will be required to use the National Provider Identifier (NPI) as the standard unique identifier in filing and processing healthcare claims and other transactions.

According to CMS, "The use of the NPI will reduce costs and improve efficiency in the nation's health care system by eliminating the need for health care providers to maintain, keep track of, and use multiple identification numbers assigned by the various health plans they bill." The final rule adopting the NPI was published in the Federal Register on January 23, 2004 (69 FR 3434).

Compliance date. All health care providers that are covered entities must obtain NPIs and use them in standard transactions no later than the compliance date of May 23, 2007. (The compliance date for small health plans is May 23, 2008.) Providers that are not covered entities may obtain NPIs but are not required to do so.

Each health care provider will be assigned one numeric NPI, and that NPI will be permanent. Adoption of the standard health care provider identifier means that a provider is to use only one identifier, its NPI, to identify itself in all standard transactions. The NPI replaces all legacy numbers.

Applying for a NPI. NPIs will be issued by the National Provider System, which CMS is now developing. Health care providers may begin applying for NPIs through the National Provider System after May 23, 2005, the final rule's effective date. CMS will release more information on the NPI, including details on the application process and the availability of NPI application forms, as the effective date nears.

Administrative simplification. The adoption of the NPI is the latest step in implementing the administrative simplification provisions of HIPAA. The Secretary of Health and Human Services (HHS) has already adopted standards for electronic transactions and code sets, for the privacy and security of certain individually identifiable health information, and for the unique health identifiers for employers. In the future, HHS will adopt standards for unique identifiers for health plans and for claims attachment transactions. ■

CCH Chicago Bureau, January 23, 2004

Health plans warn expansion of tort suits to ERISA plans would reduce quality of care

by Catherine Hubbard, MA, Contributing Editor

Allowing state tort suits based on plan coverage decisions would lead to reduced health care quality, according to Stephanie Kanwit, special counsel to the American Association of Health Plans-Health Insurance Association of America (AAHP-HIAA). "The current tort system is broken. Let's not extend the current tort system to health plan coverage decisions," she said during a recent conference call. Kanwit warned that allowing state tort suits based on plan coverage decisions would lead to increased health care costs at a time when employers are already coping with double-digit inflation. She spoke during a January 15 conference call sponsored by the AAHP-HIAA and the American Health Lawyers Association.

The Supreme Court has accepted two key Texas cases—*Aetna Health, Inc. v. Davila* and *CIGNA Healthcare of Texas, Inc. v. Calad*. At issue is whether patients can pursue state tort claims against ERISA plans. In *Davila*, a physician prescribed a medicine thought to cause fewer gastrointestinal problems than other pain medicines on the formulary Aetna administered for Davila's employer. But the formulary required that Davila enter a "step program," meaning the drug prescribed is a covered plan benefit only if the member has already tried other less expensive drugs on the formulary, said Kanwit. The less expensive medicine led to an adverse reaction. Yet Davila failed to avail himself of other options, like representing to Aetna that he could not take the less expensive drug, invoking his right to an independent appeal or even paying for the medicine himself, she noted.

In *Calad*, a woman underwent a hysterectomy and was discharged from the hospital after one day. She suffered complications and had to return a few days later. Like Davila, she did not invoke her right to an independent appeal as to whether an additional stay was "medically necessary."

Instead of invoking their rights, both plaintiffs sued under the Texas Health Care Liability Act (THCLA), alleging that their respective HMOs had failed to use ordinary care when making medical necessity determinations, that the HMOs' systems made substandard care more likely, and that the HMOs acted negligently. The U.S. Court of Appeals for the Fifth Circuit concluded that ERISA does not preempt Calad's and Davila's claims relating to the THCLA because the act authorizes a tort cause of action, while ERISA creates causes of action for breach of contract.

"The THCLA imposes a duty on HMOs in making 'health care treatment decisions' and provides a cause of action for patients harmed by a breach of that duty."

Texas law. In Texas, the THCLA provides a cause of action in tort for patients injured as a result of an HMO's violation of a standard of care in making decisions that affect the quality of medical treatment, explained David Mattax, chief of the financial litigation division in the Texas Attorney General's Office. "The THCLA imposes a duty on HMOs in making 'health care treatment decisions' and provides a cause of action for patients harmed by a breach of that duty," he said during the conference call. He noted, however, that the duty imposed by the act is distinct from the duty imposed by ERISA. THCLA claims are not claims for benefits or for the enforcement of ERISA rights that would be preempted under the court's precedent, Mattax noted.

Furthermore, Mattax said, Congress never intended to transform tort suits into ERISA suits. "Congress did not clearly and manifestly intend to displace state-law tort actions for consequential damages resulting from negligent medical decisions by HMOs so as to transform them into federal claims for ERISA benefits," he said. Also, the Court has never held that Congress intended to displace state malpractice laws providing remedies for negligent medical judgments by HMOs, he said. Terri Keville, a partner with Manatt, Phelps & Phillips, Los Angeles, California, added that health plans do not agree that the utilization review decisions at issue constitute "health care treatment" decisions covered by THCLA.

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Implications. In its decision, the Fifth Circuit was not stating the law as it is currently, said Keville during a January 20 interview. "This would be a change in the law and a significant expansion of potential liability for plans," she said. Depending on the nature of the claim, she said, "This would open the door to what is essentially malpractice liability for medical directors and other utilization review personnel who are making decisions about what benefits health plan enrollees are eligible to receive."

Since utilization review personnel often are not in a physician-patient relationship with enrollees, Keville said, they usually are not exposed to tort suits. In most states, a doctor can't be liable for medical malpractice with respect to a patient unless the doctor was actually treating that patient, she noted. "Arguably, if the Fifth Circuit decision is upheld, then a utilization review physician who works for a health plan and did not have a physician-patient relationship could be sued for malpractice over decisions he or she made with respect to eligibility for a particular benefit under the plan," she said.

Up to this point, the Supreme Court has held that a patient in an employer-sponsored plan must file any suit under ERISA to challenge an adverse benefits decision. "If it's an employer-sponsored plan, then it's covered by ERISA and you have to sue under ERISA," Keville said. But she noted that patients can still sue their doctors for malpractice, regardless of ERISA. "ERISA has never eliminated that option," she said. "The question is whether tort laws apply to these other people that the patient probably never meets."

Letters to the Editor

The CCH Healthcare Compliance team welcomes comments or questions regarding articles published in the CCH Healthcare Compliance Letter. Send comments to Sharon Sofinski, Coordinating Editor, at sofinsks@cch.com. For more information about the CCH Healthcare Compliance Portfolio visit our online store at http://health.cch.com.

HMO reaction. Kanwit said allowing state tort suits based on plan coverage decisions would:

- Reduce health care quality caused by "defensive medicine," which could lead to over-utilization of services.
- Reduce flexibility for plans and insurers to conduct activities promoting health care quality and evidence-based medicine.

"Congress did not clearly and manifestly intend to displace state-law tort actions for consequential damages resulting from negligent medical decisions by HMOs so as to transform them into federal claims for ERISA benefits."

- Extend a "culture of blame," rather than a "culture of performance."
- Complicate employer health plan design, funding and administration.
- Subject plan sponsors and employers to unpredictable and significant potential tort liabilities.
- Lead plan sponsors and employers to contract—not expand—coverage categories, especially where cost-effectiveness of treatment is debatable.

ERISA already provides many legal remedies to patients, Kanwit said, such as the ability to sue to recover "benefits due" and appropriate equitable relief to redress violations; procedural protections, such as independent review of HMO medical necessity decisions and a mandate for "full and fair review of the claim," including consultation with a "health care professional" in the field. AAHP-HIAA has filed an Amicus brief, backing the two health plans.

The 1974 ERISA provides employers with an incentive to establish and fund plans and eliminates the costly effects if plan sponsors had to comply with multiple regulatory regimens, Kanwit said. She noted that managed care organizations deny only a small percent of coverage claims—less than two percent of plan enrollees were denied coverage and of that amount, she noted, only six percent resulted in failure to meet pre-authorization criteria. "ERISA is the foundation of the voluntary, employer-sponsored health care system," said Kanwit. ■

CCH Washington Bureau, January 26, 2004

On The Front Lines

Updates: Enforcement of OSHA TB rules; enforcement of discrimination laws against physician groups

by Richard R. Fritz

In this On The Front Lines article, Richard Fritz of Polsinelli Shalton & Welte discusses two recent developments: OSHA's delay in enforcement of the respiratory protection standard that governs workers exposed to tuberculosis, and the clarification of the enforceability of discrimination laws against physician groups.

OSHA Delays Enforcement of Rules Regarding Potential Exposures to Tuberculosis

On January 14, 2004, the Occupational Safety and Health Administration (OSHA) announced that it will delay several provisions of the general industry respiratory protection standard that now governs workers potentially exposed to tuberculosis (TB). OSHA Administrator John Henshaw stated that the requirements will be delayed until July 1, 2004 so that smaller, non-health care employers may become familiar with the provisions, and have "every opportunity to be able to successfully come into compliance."

During the delay in enforcement, OSHA will not cite these new requirements for employers with workers exposed only to TB. All elements of the rules will continue to be enforced under the corresponding elements of the current respiratory protection standard. To meet the requirements when they go into effect, establishments will need to revise their respiratory protection program, conduct annual respiratory fit testing, and perform a medical evaluation and annual training for employees using respirators.

Revocation of 1971 Respiratory Protection Rule

OSHA's January 14 announcement comes on the heels of its revocation of its respiratory protection rule at 29 C.F.R. 1910.139, which was in effect specifically for employers of workers potentially exposed to TB. The agency decided to revoke the TB rule on December 31, 2003 "because it does not believe a standard would substantially reduce the occupational risk of TB infection." In so doing, OSHA abandoned its TB proposal setting forth health care specific requirements that it began working on in 1993.

OSHA stated that "the number of tuberculosis cases in the United States has declined by more than 40 percent." Henshaw said in a December 30, 2003 statement that the declines were especially noted in high-risk workplaces such as hospitals where TB is diagnosed, treated, and isolated. Accordingly, Henshaw noted that control of TB hazards is being addressed through other methods, and a TB standard is not necessary. Instead, Henshaw stated that OSHA intends to:

- Provide guidance to workplaces with less medical expertise and fewer resources than hospitals, and to use cooperative relationships with employers, public health experts, and other government agencies to promote TB control; and
- Continue to enforce the general duty clause of the Occupational Safety and Health Act and relevant existing standards in situations where employers fail to implement available precautions and expose workers to the hazards of TB infection.

General Industry Rule Will Be Followed

As a result of OSHA's December 31 revocation, the health care industry will utilize the general industry respiratory protection standard to protect against TB now set to begin on July 1. The requirements of the general industry standard are not as detailed as the revoked rule. The revoked rule was to specifically apply to: (1) hospitals, (2) long-term care facilities for the elderly, (3) correctional facilities and other facilities that house inmates or detainees, (4) hospice facilities, (5) shelters for the homeless, (6) facilities that offer treatment for drug abuse, (7) facilities where high-hazard procedures are performed, (8) laboratories that handle specimens that may contain "M. tuberculosis," and (9) certain social work facilities. Now, hospitals and other high-risk facilities will follow the general industry standard requirements. To meet the requirements of the general industry standard, all employees will be required to:

- Update the facility's respirator program;
- Comply with amended medical evaluation requirements;
- Conduct annual fit testing of respirators;
- Meet certain training requirements; and
- Meet certain recordkeeping requirements.

Criticisms from Unions

Since OSHA began working on the TB proposal in 1993, health care unions, including the American Federation of State, County and Municipal Employees (AFSCME) and the Service Employees International Union (SEIU), have been calling on OSHA to issue an effective TB standard for health care workers. AFSCME and SEIU repeated their appeals to OSHA and the United States Department of Labor last year, citing a "renewed

urgency because workers are also facing the threat of SARS" and terrorist attacks. The unions see the actions as a step backwards, especially since many the respiratory protection standards will not kick in until a case of TB is diagnosed.

Implications for Hospitals

Most likely, larger hospitals have been familiar with, if not following, the hospital specific requirements that were revoked in December. The general industry standard, while less burdensome on employers, may require adjustments in hospitals' current TB prevention practices. Compliance officers should review the general standard requirements, comparing them to their hospitals' current practices in order to maintain compliance with OSHA standards.

■ ■ ■

Federal Appeals Court Clarifies Discrimination Laws' Enforceability Against Physician Groups

On January 14, 2004, the United States Court of Appeals for the Third Circuit reinforced the Supreme Court's recent decision regarding whether physician shareholders are counted as "employees" for determining whether they are subject to the federal discrimination laws. Under Title VII of the Civil Rights Act and the Americans With Disabilities Act, employers must have fifteen or more employees as a prerequisite to any action under the statutes. The Age Discrimination in Employment Act requires at least twenty employees for enforcement. The Third Circuit in *Ziegler v. Anesthesia Associates of Lancaster, Ltd.* elaborated on the specific factors for establishing that physician shareholders are considered as "employers" rather than "employees." Under the discrimination laws, an individual in a single occupational setting cannot be considered as both an employee and employer, and thus, the determination often results in a drastically increased or lessened exposure to the federal discrimination laws.

Anesthesia Associates is a professional association with nineteen shareholder anesthesiologists and thirteen non-shareholder anesthesiologists. The plaintiffs sued for sex discrimination under Title VII, but the trial court granted summary judgment to Anesthesia Associates, holding that the nineteen shareholders were employers, not employees, and thus the thirteen remaining employees could not establish jurisdiction under Title VII.

In affirming the trial court's decision, the Third Circuit closely followed last year's Supreme Court decision in *Clackamas v. Gastroenterology Assocs., P.C.*, which outlined the analysis for determining whether physician shareholders should be considered as employees for purposes of jurisdiction under the Americans with Disabilities Act. The Supreme Court in *Clackamas* held that each of the following six factors, drawn from the Equal Employment Opportunity Commission Compliance Manual, is relevant in deciding whether a given individual may be classified as an employer or employee:

- Whether the organization can hire or fire the individual or set the rules and regulations of the individual's work;
- Whether, and if so, to what extent the organization supervises the individual's work;
- Whether the individual reports to someone higher in the organization;
- Whether, and if so, to what extent the individual is able to influence the organization;
- Whether the parties intended that the individual be an employee, as expressed in the written agreements or contracts; and
- Whether the individual shares in the profits, losses, and liabilities of the organization.

The Third Circuit in *Ziegler* expanded on the Supreme Court's factors in deciding that the physician shareholders are deemed to be employers, rather than employees. Small professional associations should closely review the factors set forth in *Ziegler* in order to avoid potential liability under the federal discrimination statutes: The factors identified by the Third Circuit include:

- The physician shareholders share ownership and are accorded equal voting rights in virtually all matters, including hiring, termination, offers of partnership, and contracting with outside parties.
- Each shareholder is required to make a capital contribution.
- The shareholders' compensation is not tied to their performance, and none of the shareholders are supervised or evaluated by anyone. Eighteen of the nineteen shareholders receive compensation based on the group's profits.
- Only licensed anesthesiologists may become shareholders.
- The shareholders are liable for their acts of professional negligence and for those of persons acting under their supervision.
- The shareholders were referred to as "partners" amongst themselves, within the healthcare community, and by office personnel, including the plaintiffs in the lawsuit.
- The shareholders executed shareholder agreements.
- The shareholders executed "employment agreements" that provided "substantially full time" engagement in the practice of anesthesiology and provide for compensation as determined by a board comprised of shareholders. In contrast, the other employees, including the plaintiffs, executed agreements that specified a forty-five-hour work week and provide for a fixed annual salary.

The Third Circuit's decision is somewhat in contrast to recent decisions in the Second and Ninth Circuits, which have held that a shareholder-employee of a professional corporation is an "employee" for purposes of the anti-discrimination statutes because he or she is not a "partner" of the organization. Phy-

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Obtaining informed consent when conducting clinical research

by Catherine Hubbard, MA, Contributing Editor

Companies that conduct clinical research need to take several precautions in order to avoid legal problems. Not all research will benefit the subjects, so it is crucial to explain to potential subjects the difference between therapeutic care and clinical research. You might also have to provide materials in different languages and hold a Q&A session with potential subjects and their families to make sure they understand the goals of the researchers. Also, it's best to work closely with the National Institutes of Health and the Food and Drug Administration (FDA), which oversee clinical research.

"From a compliance perspective, looking at human subject research is thorny," said F. Lisa Murtha, chief privacy officer for The Children's Hospital of Philadelphia. Compliance officers should sit down with study coordinators as they talk with potential subjects and their families. "It's amazing the information that can be gleaned from sitting in on one of those conferences," Murtha said. She spoke during a recent conference call sponsored by the Health Care Compliance Association.

Compliance officers should also review the written materials used at these meetings and see how investigators or coordinators answer questions about the research. Officers should ask: "Is this something they rush through, or is it done thoughtfully and completely?" Murtha said. They also should find out whether participants "really understand what they're getting into," she said. Institutions might need a translator to relay questions the potential subject or the family might have, she added.

Consent must be informed, understood and voluntary, said Kendra Dimind, a partner in the Washington, D.C. office of Epstein, Becker & Green. "In no way, shape or form should a research participant be forced or coerced into participating in research," she said.

Dimind stressed that institutions should make sure potential subjects understand the difference between medical therapy and research. While medical therapy is taking care of the patient's needs, research is collecting generalizable knowledge to advance the care of patients in general. Many people get that confused. To avoid this so-called "therapeutic misconception," investigators should make sure the research subject understands what the researcher is doing. "Tell it like it is," Dimind said.

Preventing litigation. Murtha outlined how to prevent litigation through increased internal oversight. "You cannot overestimate the power of a strong investigation and monitoring program," she said.

Investigators and coordinators should:

- Examine the relationship between the research program and the research subject, including the marketing materials provided to potential subjects. "Is it thoughtful, is it thorough, is it accurate and complete?" she asked.
- Question whether the consent process is comprehensive and whether there is continuing communication throughout the study. "Make sure that as things change, subjects are updated accordingly," she said.
- Examine the relationship with the Institutional Review Boards (IRBs). Many organizations have been considering accreditation of their institution's human subject protection programs, said Murtha. Also, many academic medical research and large research organizations have their own IRBs that work on institutionally based protocols, she said. "External IRBs can also be quite effective, particularly as it relates to multi-site clinical trials and research at smaller organizations."
- Be aware of financial relationships. "Don't underestimate the relationship with the subject in looking at sponsored research agreements, the financial relationships among investigators and any companies involved," she said.
- Make sure appropriate policies and procedures are in place and are updated continuously and thoroughly. Even though the rules are in the CFR, having an institutional policy can be a valuable tool in ensuring compliance, she said.

Murtha recommended research organizations improve lines of communication, train staff regularly, perform ongoing monitoring of research activities and coordinate a research compliance oversight committee. "Getting the buy-in of investigators is absolutely critical. Having them take part in a committee like this can go a long way toward bringing them on board," she said.

Murtha also suggested institutions use standardized forms, templates, and Informed Consent documents to the extent possible. "Starting from a basic format can save people—particularly new investigators—a lot of time," she said.

Work closely with government agencies. An important relationship to consider is that between the investigator and government agencies. "Let's face it, the government will not allow you to continue to participate in research unless you meet regulatory requirements," Murtha said. Interaction with the government agencies, including site visits, are a critical component of establishing credibility, she said. She advised researchers to remain open to having the government come in, and even suggested asking the NIH Office for Human Research Protections (OHRP) to provide educational sessions to research institutions. "These can be incredibly valuable," she said. She said that when her hospital asked to meet with OHRP, the representatives were very forthcoming. "They provided incredibly valuable insights into what's going on at the federal level," she said.

The FDA also plays a big part. "You can't conduct clinical research without consideration of FDA rules," Murtha said. The FDA Human Subject Protection Regulations govern research on drugs, biologics, and devices regardless of study sponsorship, Murtha noted. Unlike NIH rules, which relate to NIH-funded studies, the FDA regulations cover any type of research that relates to drugs, biologics and devices, regardless of sponsors or unfunded research. "Even the unfunded research needs to follow all the rules," Murtha said.

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Senators seek funds for Medicare anti-fraud and education initiatives

by Catherine Hubbard, MA, Contributing Editor

Senate Finance Committee Chairman Charles E. Grassley, R-Iowa, and ranking member Max Baucus, of Montana, want the Department of Health and Human Services (HHS) to provide funds to ensure the new Medicare program receives full scrutiny to prevent waste, fraud and abuse.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (DIMA) (PubLNo 108-173) provides the Centers for Medicare and Medicaid Services $1 billion for fiscal years 2004 and 2005 to implement the law. In a January 27 letter, Grassley and Baucus asked HHS Secretary Tommy Thompson to direct part of the funds to the HHS Office of Inspector General (OIG), which fights fraud and abuse. They also want HHS to direct some of the money to State Health Insurance Assistance Programs (SHIPs), which provide education, counseling and outreach services.

"The SHIPs and the HHS OIG must receive substantially increased funding in the next two fiscal years and have a robust role in implementing the act if we are to ensure that Medicare beneficiaries receive all of the benefits and protections that Congress intended this legislation provide," the Senators said in the letter.

Specifically, the senators want the OIG to receive at least $15 million in increased funding in fiscal year 2004 and $25 million in 2005. They also want at least $41 million in 2004 and in 2005 to enhance SHIPs' capacity to provide counseling and education to Medicare beneficiaries.

Grassley and Baucus asked Thompson to provide by February 10 detailed information setting forth how HHS plans to allocate and spend the funds provided through section 1015 of DIMA. "The need for a proactive, well-run and well-funded OIG has never been more critical," the lawmakers said.

(Press release from Sen. Charles E. Grassley, R-Iowa, dated January 28, 2004, and text of letter from Grassley and Sen. Max Baucus, D-Montana, January 27, 2004.) ■

CCH Washington Bureau, January 30, 2004

Successful completion of rehabilitation program still equates to a "conviction"

by Richard C. Sarhaddi, Esq., Contributing Editor

The Departmental Appeals Board (DAB) affirmed the decision of the Inspector General (IG) to exclude Victoria L. Winterhalter, a registered nurse and certified nurse anesthetist (RN/CNA), from participating in Medicare and other federally-funded programs for a period of five years. The exclusion stemmed from the Winterhalter's conviction of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

The crux of Winterhalter's argument was that she was not "convicted" of criminal offenses.

Rehabilitation program in lieu of conviction. The RN/CNA was charged with and plead guilty to four felony counts of theft of drugs and four counts of tampering with drugs. The court notified her that she was eligible for intervention in lieu of conviction under Ohio State law, and directed that she be placed in a supervised rehabilitation program. Twenty-one months later, on May 30, 2003, the IG notified Winterhalter that she was excluded from participating in Medicare and other federally funded programs for period of five years. The IG stated that it based its decision to exclude the RN/CNA based on her alleged felony conviction pursuant to §1128(a)(4) of the Social Security Act (the Act). Then, on June 13, 2003, the court granted Winterhalter's motion to dismiss her criminal case, expunged her record and terminated her probation. In addition, the court ruled that she successfully completed her court-ordered rehabilitation. Nonetheless, the IG did not terminate her exclusion, and she appealed the IG's decision to the DAB.

RN/CNA's arguments. The crux of Winterhalter's argument was that she was not "convicted" of criminal offenses. The DAB, however, found that she indeed was convicted of criminal offenses because she (1) plead guilty of the offenses and (2) entered into intervention in lieu of conviction. Both actions taken by Winterhalter are consistent with the types of programs that Congress sought to include in its definition of a conviction. Supporting this conclusion is that fact that the court would have enforced a judgement of conviction against Winterhalter if she failed to complete the rehabilitation program.

She also argued that since the court dismissed her indictment and expunged her criminal record, she was not effectively convicted, and therefore her exclusion is not warranted. The DAB disagreed, stating that programs which require rehabilitation in lieu of a final adjudication fit within the meaning of "conviction" in §1128(i)(4), and that "the significant factor for purposes of deciding whether a petitioner was convicted within the meaning of §1128(i)(4) is her entry into an intervention program and not her successful completion of that program."

Therefore, it is irrelevant that she successfully completed this program—the fact that she entered into the program is enough evidence to find she was convicted within the meaning of the Act. Also having no bearing on the decision is the fact that her case was dismissed and her criminal record was expunged. Regardless of these subsequent court actions, Winterhalter plead guilty of violations that rendered her, in the eyes of the IG, to be untrustworthy to provide care to beneficiaries and recipients of federally funded programs, and she was properly excluded. ■

CCH Chicago Bureau, February 2, 2004

False Claims

Hospital, clinic pay to settle false claims charges

by Sharon Sofinski

The U.S. Attorney for the Central District of Illinois recently announced that **Shelby Memorial Hospital** in Shelbyville, Illinois, has paid $1.75 million to the United States under the terms of a False Claims Act civil settlement.

In a lawsuit filed against Shelby Memorial Hospital on February 28, 2002, the government alleged that the hospital had submitted false claims to Medicare since January 1994, using specific diagnosis codes for gram negative pneumonia that were not supported by patients' medical records. The government alleged that the hospital "knew or recklessly disregarded" the falsification of the diagnosis codes in order to get higher reimbursement from Medicare.

While Shelby Memorial denied the allegations, it agreed in September 2003 to settle the lawsuit for $1.75 million to avoid the time and expense of litigation. It also agreed to cooperate with the government's ongoing investigation of Medicare fraud, and entered into a three-year corporate integrity agreement with the Department of Health and Human Services (HHS), under which Shelby Memorial agrees to improve its billing procedures and demonstrate those improvements to HHS.

Calling Medicare fraud "one of the primary threats to the continuing viability of the Medicare system," U.S. Attorney Jan Paul Miller stressed the need to scrutinize hospitals who bill for services to Medicare patients to ensure that they are following medical coding guidelines at all times.

Along with the U.S. Attorney's Office for the Central District of Illinois, the Office of Inspector General of HHS and the Illinois State Police participated in the Shelby Memorial investigation. The U.S. Attorney's press release is at http://www.usdoj.gov/usao/ilc/press/2004/january/011504shelby.htm.

In another false claims suit, **Kerlan-Jobe Orthopaedic Clinic** paid the government $2.65 million to settle allegations that it defrauded Medicare and other federal health insurance programs over an eight-year period beginning in 1993. Kerlan-Jobe is the team physician clinic for the Los Angeles Lakers, Dodgers, and Kings.

Trevor R. Baylor, former director of Kerlan-Jobe's health information systems department, brought a whistleblower suit against the clinic and its physicians, alleging that they knowingly overbilled Medicare, Medi-Cal, the Department of Labor's Office of Workers' Compensation Programs, and the Department of Defense's TRICARE program for office visits and outpatient procedures. According to the lawsuit, internal audits at Kerlan-Jobe discovered the problem, yet the clinic made no effort to refund the overpayments. Kerlan-Jones did not admit to any wrongdoing.

Under the qui tam provisions of the False Claims Act, Baylor will receive 21 percent of the settlement amount, or $556,500, plus attorney's fees. Agents from the U.S. Department of Labor and the Office of Inspector General of the U.S. Postal Service participated in the investigation.

The U.S. Attorney's press release on the Kerlan-Jobe settlement is at http://www.usdoj.gov/usao/cac/pr2004/004.html. ■

CCH Chicago Bureau, January 22, 2004

Clinical Research (cont.)

FDA works with individuals, companies, and institutions to help promote compliance with rules that govern clinical research, Murtha said, noting that it has a wide variety of discretionary capabilities related to human subject research. The FDA can extend a review of the research if it has any questions, can send warning letters and can disqualify or debar individuals or institutions from conducting the research. The agency also can disqualify IRBs if it finds they are not doing their job. "One of the chief abilities the FDA has in regulating and monitoring human subject protection is their ability to conduct ongoing audits," said Murtha.

Under FDA regulations, an IRB is an appropriately constituted group that has been formally designated to review and monitor biomedical research involving human subjects. In accordance with FDA regulations, an IRB has the authority to approve, require modifications in, or disapprove research.

The FDA monitors research through the review of required reports from investigators, sponsors, institutions, and IRBs as well as through a program of on-site inspections and audits. "It's not uncommon to have them visit from time to time," Murtha said. ■

CCH Washington Bureau, February 2, 2004

On the Front Lines (cont.)

sician groups should review the factors identified in *Ziegler* to determine whether the group can potentially avoid application of the federal discrimination laws. Compliance officers should beware, however, that most state discrimination laws apply to groups with much fewer "employees" (sometimes as few as one employee), which means that applicability of various discrimination laws cannot be altogether avoided. Nonetheless, the *Ziegler* case can provide important instruction to physician associations in forming and maintaining the structure of the groups.

Rich Fritz is an attorney in the Kansas City, Missouri office of Polsinetti Shalton & Welte. He concentrates his practice in the areas of labor, employment and employee benefits litigation.