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# Oversight needed in human embryonic stem cell research

## by Valerie L. Witmer, J.D., Contributing Editor

Aside from the ethical and political issues that pervade public discourse on the subject, human embryonic stem cell (hESC) research presents human subject protections concerns that have wide-ranging compliance implications, according to Paul Papagni, J.D., CIP, Executive Director, Office of the Vice President for Clinical Research at The University of Texas MD Anderson Cancer Center. Speaking at the Health Care Compliance Association's 2007 Compliance Institute in Chicago, Illinois, on April 24, Papagni discussed issues surrounding hESC research from an Institutional Review Board (IRB) and regulatory perspective.

**Human subject protections concerns.** According to Papagni, HHS' Office of Human Research Protections (OHRP) does not consider research involving only coded private information or biologic samples to involve human subjects if: (1) the information or samples were not collected specifically for the proposed research project through interaction with living individuals; and (2) the investigator cannot readily ascertain the identity of the individual(s) to whom the information or samples pertain. Satisfaction of these two conditions takes the research out of the realm of human subjects research and exempts the research from full IRB review. Nonetheless, Papagni cautioned, "most institutions and state laws regarding human embryonic stem cell research have asked for IRB oversight of the donation process."

In addition to OHRP requirements, hESC research implicates principles of informed consent and protection of donor confidentiality. "IRBs will be challenged to develop consents that adequately address the potential uses [of biologic samples] in a manner that is understandable at a sixth to eighth grade level," Papagni said. With respect to donor confidentiality, he noted that donor suitability rules may require collection of medical information about donors whose biological materials were used to derive new embryonic stem cell lines, which means the Health Insurance Portability and Accountability Act of 1996 (HIPAA) privacy rule may apply to research uses of this information.

**Recommendations for oversight.** Papagni recommended two levels of oversight with respect to hESC research. First, he advised that each institution establish an Embryonic Stem Cell Research Oversight (ESCRO) committee to review and monitor all hESC research proposals. The committee should include representatives of the public and persons with expertise in developmental biology, stem cell research, molecular biology, assisted reproduction, and ethical and legal issues implicated by hESC research. The ESCRO committee would not substitute for an IRB, but rather would provide an additional level of oversight and scrutiny warranted for hESC

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research. Specifically, Papagni explained, the committee would serve several functions, including:

- providing local oversight over all issues related to derivation and research use of hESC lines;
- ensuring adherence to informed consent requirements and protection of donor confidentiality;
- reviewing compliance of all hESC research with all relevant regulations and guidelines;
- maintaining registries of hESC research conducted at the institution and of all hESC lines;
- facilitating education of investigators involved in hESC research;
- reviewing proposals not requiring IRB review; and
- reviewing and approving the scientific merit of research proposals, setting limits on research, and determining the requisite level of oversight.

Second, in light of limited federal regulation and disparate state regulations covering hESC research, Papagni recommended establishment of a national panel to assess periodically the adequacy of the National Academy of Sciences guidelines for hESC research. According to Papagni, the panel should be politically independent and without conflicts of interest, respected in the lay and scientific communities, and able to call on suitable expertise to support its oversight activities. ■

*CCH Chicago Bureau, May 21, 2007.*

## Medicare

### Hospital quality data reporting still complex

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

Hospital case studies conducted by the Government Accountability Office (GAO) showed that while existing information technology (IT) systems can help hospitals gather some quality data, the process of abstracting remains complicated. The GAO was asked to conduct the study based on HHS' ongoing promotion of electronic health records and the increasing amount of quality data reported to CMS that is stored on hospital IT systems.

**Collecting and submitting quality data.** The eight case study hospitals used six steps to collect and submit quality data: (1) identify the patients, (2) locate information in their medical records, (3) determine appropriate values for the data elements, (4) transmit the quality data to CMS, (5) ensure that the quality data have been accepted by CMS, and (6) supply copies of selected medical records to CMS to validate the data. Several factors accounted for the complexity of abstracting all relevant information in a patient's medical record, including the content and organization of the medical record, the scope of information and the clinical judgment required for the data elements, and frequent changes by CMS in its data specifications.

Because the process is complex, most of the case study hospitals relied on clinical staff to abstract the quality data, resulting in increased demands on clinical staff resources. Offsetting the demands placed on clinical staff were the benefits that case study hospitals reported finding in the quality data, such as providing feedback to clinicians and reports to hospital administrators.

**IT limitations.** The limitations reported by officials in the case study hospitals included: having a mix of paper and electronic records, which required staff to check multiple places to get the needed information; the prevalence of data recorded as unstructured narrative or text, which made locating the information time-consuming because it was not in a prescribed place in the record; and the inability of some IT systems to access related data stored in another IT system in the same hospital, which required staff to access each IT system separately to obtain related pieces of information. Hospital officials expected the scope and functionality of their IT systems to increase over time, but this process will occur over a period of years.

**Recommendations.** CMS has sponsored studies and joined HHS initiatives to examine and promote the current and potential use of hospital IT systems to facilitate the collection and submission of quality data, but HHS lacks detailed plans, including milestones and a time frame against which to track its progress. GAO recommended that the Secretary of HHS identify the specific steps the department plans to take to promote the use of health IT for the collection and submission of data for CMS' hospital quality measures and inform interested parties about those steps, the expected time frame, and associated milestones. ■

*GAO Report, GAO-07-320, April 1, 2007.*

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## $4 million settlement paid by wheelchair supplier

**by Geraldine Szuberla, J.D., LL.M., Contributing Editor**

The SCOOTER Store Inc. (the supplier) will pay the United States $4 million and give up many millions more in pending claims for reimbursement to Medicare to settle allegations that the company violated the civil False Claims Act and defrauded the United States, the Department of Justice (DOJ) announced on May 11, 2007.

The company's pending Medicare claims would have generated approximately $13 million in payment. The cash component of the settlement package includes a $500,000 contribution by founder Douglas Trent Harrison, who also agreed to forego dividends from his shares in the company for the next year in exchange for a release of his personal liability.

**Equipment billing abuses.** The settlement resolves a lawsuit brought by the United States in 2005, in which the government alleged that the supplier engaged in a multi-media advertising campaign to entice beneficiaries to obtain power scooters paid for by Medicare, Medicaid, and other insurers. Instead of the "zippy" power scooters that were advertised, the supplier sold the beneficiaries expensive power wheelchairs that they did not want or need, or could not use.

By representing to physicians that their patients wanted and needed power wheelchairs, the supplier obtained thousands of "Certificates of Medical Necessity" from physicians who did not know about the company's fraudulent practices. The supplier then billed government and private health care insurers for power wheelchairs, which were far more costly than power scooters, and collected millions of Medicare and Medicaid dollars.

The supplier received $5,000 to $7,000 in reimbursement for each power wheelchair it sold, more than twice the amount for a scooter, which sold for around $1,500 to $2,000. Many beneficiaries had no idea what kind of equipment they were getting, until it was delivered by the supplier.

The government's lawsuit also alleged that the supplier knowingly sold used power mobility equipment to beneficiaries and billed Medicare as if the equipment were new, in violation of Medicare regulations.

In addition, the government alleged that the supplier charged Medicare millions of dollars for unnecessary power mobility accessories.

"This settlement is part of our ongoing commitment to fighting abuse of Medicare's durable medical equipment benefit," said Assistant Attorney General Peter D. Keisler. "Equipment suppliers whose practices violate the law need to know that we are dedicated to protecting Medicare funds and beneficiaries from their fraudulent schemes."

New rules for power mobility implemented last year by HHS are designed in part to prevent the abuses that resulted in the government's lawsuit against the supplier. The government has also stated that durable medical equipment companies and their relationships with physicians are of increasing interest because of the optential for kick-backs.

**Results of settlement.** The supplier will operate for the next five years under a Corporate Integrity Agreement with the HHS Office of the Inspector General (OIG) to help ensure future compliance by the company with Medicare regulations. The civil settlement resolves several lawsuits filed by The SCOOTER Store against the United States seeking payment for its claims to Medicare. As part of the settlement, the supplier gave up those claims and agreed to dismiss the lawsuits.

The civil settlement also resolves claims in a suit brought by a whistleblower who was a former employee of the supplier. The whistleblower will receive $3,228,251 as the statutory award, and the whistleblower's suit will be dismissed.

The case was investigated by the FBI's San Antonio Health Care Fraud Unit, the Texas Attorney General's Medicaid Fraud Control Unit, and the OIG; it was handled by the U.S. Attorney's Office for the Western District of Texas and the Civil Division of the DOJ. ■

*DOJ Press Release, May 11, 2007.*

On The Front Lines

# Risk managing the CMS rule on restraints & seclusion, Part II

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

*This is Part II of a two-part article that highlights risk management concerns implicated by the new CMS rule on the use of restraints and seclusion. Part I discussed the rationale for the regulatory change, the meaning of restraint and seclusion within the regulatory scheme, and proper use of restraints and seclusion. Part II discusses requirements for training in the use of restraints and seclusion, reporting deaths associated with the use of restraints and seclusion, and training and clinical documentation. It also provides strategies for shaping hospital policy and procedure to promote patient safety and avoid prohibited practices.*

## Trainer requirements

To be certain that staff receive appropriate instruction on the use of restraints and seclusion, the final rule sets forth requirements for those providing staff training. Specifically, the regulation states that trainers must possess the right qualifications "as evidenced by education, training, and experience in techniques used to address patients' behaviors."[16]

CMS did not provide any definitions pertinent to trainer qualifications, and the subject received little discussion in the preamble. This suggests that hospitals have considerable latitude in selecting those qualified to provide training. To some extent, the qualifications will be shaped by the anticipated content of the training programs.

## Training requirements

The final rule places considerable emphasis on staff training for those qualified to apply restraints, implement seclusion, or carry out monitoring and assessment of patients undergoing such interventions.

### Key factors for qualified staff

Those qualified to apply restraints, implement seclusion, or conduct monitoring and assessment must receive education and training. They must have demonstrated knowledge of what is required for the service population. Further, they must demonstrate competency at orientation and on a periodic basis thereafter.[17]

### Physicians and LIPs

At a minimum, physicians and licensed independent practitioners (LIPs) must have a working knowledge of hospital policy on restraints and seclusion. Hospitals may require additional training that takes into consideration the specific needs of the patient service population and the competency of the physicians and LIPs in the use of restraints and seclusion. CMS stated in the preamble that if house staff, hospitalists, and covering psychiatrists "are directly involved in the care of a patient in restraint[s] or seclusion, a hospital may determine that training is necessary to ensure competency of these individuals in this area."[18]

### Core training requirements

CMS was very explicit with respect to what topics should be included in training. Although other topics may be added to the training requirements, the following are required:

- Techniques to identify staff and patient behaviors, events, and environmental factors that may trigger circumstances that require the use of a restraint or seclusion.
- The use of nonphysical intervention skills.
- Choosing the least restrictive intervention based on an individualized assessment of the patient's medical, or behavioral status or condition.
- The safe application and use of all types of restraint or seclusion used in the hospital, including training in how to recognize and respond to signs of physical and psychological distress (for example, positional asphyxia).
- Clinical identification of specific behavioral changes that indicate that restraint or seclusion is no longer necessary.
- Monitoring the physical and psychological well-being of the patient who is restrained or secluded, including but not limited to, respiratory and circulatory status, skin integrity, vital signs, and any special requirements specified by hospital policy associated with the 1-hour face-to-face evaluation.
- The use of first aid techniques and certification in the use of cardiopulmonary resuscitation, including required periodic recertification.[19]

### Training intervals

The final rule specifies three categories in which staff must be trained and able to demonstrate competencies with respect

to the use of restraints and seclusion, as well as monitoring, assessing, and caring for patients in an intervention. This training must occur prior to any intervention, during orientation, and on a periodic basis in accordance with hospital policy.[20]

### Contract personnel

If contract personnel are going to be involved in the application of restraints or implementation of seclusion, the expectation is that they will meet the training requirements. CMS stated in the preamble that the use of such interventions by untrained regular and contract staff would constitute a violation of the final rule.[21]

## Reporting deaths associated with the use of restraints or seclusion

The final rule specifies three situations in which hospitals must report deaths associated with the use of restraints or seclusion:

- When the death occurs while the patient is in a restraint or seclusion;
- When a patient dies within 24 hours after removal from a restraint or seclusion; and
- When it is "reasonable to assume that the use of restraint or placement in seclusion contributed directly or indirectly to a patient's death" that occurs within one week after such an intervention.[22]

### How and when deaths are to be reported to CMS

The report is to be made by telephone.[23] The telephone call must be made "no later than the close of business the next business day following knowledge of the patient's death."[24]

### What is meant by "reasonable to assume"

CMS takes the position that "reasonable to assume" includes those "deaths related to restrictions of movement for prolonged periods of time, or deaths related to chest compression, restriction of breathing or asphyxiation."[25]

## Documentation requirements

The final rule contains three distinct documentation requirements. One deals with training, the second addresses clinical documentation, and the third focuses on deaths associated with the use of restraints or seclusion.

### Training documentation

The hospital is obliged to document in staff personnel records that training and documentation were completed successfully.[26]

### Clinical documentation

When restraints or seclusion are used to manage a patient's violent or self-destructive behavior, the one-hour face-to-face evaluation must be documented in the patient's medical record. The documentation should include:

- A description of the patient's behavior and the intervention used;
- Alternatives or other less restrictive interventions attempted (as applicable);
- The patient's condition or symptom(s) that warranted the use of the restraint or seclusion; and
- The patient's response to the intervention used, including the rationale for continued use of the intervention.[27]

### Documenting the death report

The time and date of a patient's death associated with the use of restraints or seclusion, as reported to CMS, must be documented in the patient's medical record.[28]

## Risk management strategies for working with the restraint and seclusion rule

Although many aspects of the final rule are similar to the requirements delineated in the interim regulation, the changes merit careful risk management analysis and new strategies to achieve a successful implementation. These strategies include the following:

1. *Do a risk management review of existing policies and procedures.* Compare existing hospital policies, procedures, and practice routines with what is found in the *Final Rule*. Ask legal counsel for advice on state law requirements to determine if legislation or regulations set more stringent standards that should be followed. When state law surpasses the CMS *Final Rule*, consider adding to the overall policy statement language that recognizes that the hospital is obliged to follow this more stringent standard. Taking such an approach may be important should a state agency surveyor on behalf of CMS question the hospital practice.
2. *Make certain policy and procedure avoid prohibited practices.* Work with clinical personnel to remove any reference to PRN (*i.e.*, "when necessary") or standing orders for the use of restraints and seclusion, practices that are not permitted under the *Final Rule*. Reinforce with clinical leadership and staff that restraints may not be used to exact punishment or to address staffing shortages. Be certain that they understand that restraints *should not* be used to exert discipline or retaliation or to coerce patients into following a form of behavior.
3. *Practical training is essential.* Work with those responsible for training to offer comprehensive, practical sessions for all front line personnel who may have to apply restraints or manage implementation of seclusion, or who may be responsible for monitoring, assessing, or caring for patients in such inter-

ventions. Consider inclusion of verbal training skills to help deflect the need for restraint or seclusion. Work with staff on cultural and linguistic skills, verbal judo, and other nonphysical interventions. Make certain staff can demonstrate competencies using role-playing, case studies, and skills-based testing.

4. *Effective training is not one time only.* Be certain that leadership and the qualified trainer understand that training is required at the time of orientation and on a regular basis thereafter. Use "lessons learned" from specific events and information from the field to enhance skills-based training.
5. *Determine what is appropriate training for physicians and other LIPs.* Work with the medical staff to decide what level of training is needed for physicians with respect to ordering and assessing the use of restraints and seclusion. Determine what needs to be accomplished with respect to delineating privileges for this purpose under medical staff bylaws. Be certain that contracted personnel - including emergency room physicians, nurse practitioners, physician assistants, and hospitalists - have the requisite education, training, and demonstrated competencies in terms of ordering restraints and seclusion and evaluating patients in such interventions.
6. *Develop appropriate documentation tools.* Collaborate with qualified training personnel, physician leadership, and other clinical leaders in designing and implementing practical methods for meeting documentation practices for substantiating completion of training, in-service updates, clinical determinations for the need to resort to restraints or seclusion, and death reporting. Consider implementing a hospital-wide assessment tool for initial use and monitoring of patients receiving restraint or seclusion interventions. Think about including key factors such as alertness, mental status, hydration, nutrition, physical integrity, ability to communicate, mobility, and opportunity to use bathroom facilities. Remember to develop specific documentation practices for discontinuing the use of restraints and seclusion and the clinical basis for such a decision.
7. *Beware of audio and visual monitoring practices.* Develop practical guidelines for the use of audio and visual monitoring for patients receiving a combined restraint and seclusion intervention. Make certain that the monitoring practice is done by qualified personnel who are assigned this specific task. Be certain that patients in this category are under continuous audio and visual observation, meaning that staff who need relief receive it so that there is ongoing monitoring. Include in the guidelines what is the expected location of the monitoring in relation to the patient such that prompt intervention can be accomplished should the need arise to assist the individual.
8. *Develop effective staff communication strategies.* Have in place clear, unambiguous methods for obtaining prompt assistance with patients who need or who are in a restraint or seclusion intervention. Be certain that hospital-based paging systems use a consistent code when requesting assistance.
9. *Beware certification and the need for specialty training.* Recognize that with pediatric patients specific training and certification may be required, including pediatric advanced life support. Assess current practices for "high risk" populations for whom staff should receive specialized training, including those patients undergoing barbiturate detoxification and patients with a history of osteoporosis, asthma, severe heart disease, or obesity. Be certain that personnel files include documentation of demonstrated competencies in these specialty areas.
10. *Obtain legal advice for documenting patient deaths.* Obtain from legal counsel practical guidance on how to manage documentation of the death of a patient who received intervention with restraints or seclusion. Take into consideration state laws for mandatory reporting, federal patient grievance laws, and how to document the conversation with a CMS representative. Consider using a witness to listen in on the telephone report and then documenting the time, date, name of the person contacted, and his or her title. Be certain to inform the CMS representative that a witness is on the telephone call. The name and position of the witness should be included in the documentation of the call. Discuss with legal counsel whether it is prudent to document the call and other information subject to mandatory reporting in a log to demonstrate federal, state, and hospital policy.

## Conclusion

CMS is expected to issue an interpretive guideline to accompany the *Final Rule*. This additional tool will be instructive in shaping hospital policy and procedure on the use of restraints and seclusion. Federal or state regulatory requirements do not relieve a hospital of its duty to create a culture of patient safety and effective communication with patients and their loves ones as well as among staff. Communication skills may be a potent tool in reducing the need for restraints and seclusion. Respect for patients' rights and, at the same time, the safety and well-being of staff, other patients, and visitors can help set a framework for achieving the right balance in the use of restraints and seclusion. Along with proper use of quality data, risk management trending, and environmental scans, practical steps can be taken to achieve good training for staff and effective interventions for the good of all involved in the use of restraints and seclusion.



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[16] *Final rule*, 71 FR 71378, 71428.
[17] *Id.*
[18] *Id.* at 71402.
[19] *Id.* at 71428.
[20] *Id.*
[21] *Id.* at 71403.
[22] *Id.* at 71428.
[23] *Id.*
[24] *Id.*
[25] *Id.*
[26] *Id.*
[27] *Id.*
[28] *Id.*

## Nonprofit hospitals under increased scrutiny

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

The tax-exempt status of nonprofits in health care is under increased scrutiny as politicians, unions, consumers, and courts examine whether hospitals that claim the exemption are providing adequate charity care and benefit to the community, according to health law attorney Neville M. Bilimoria of Duane Morris, Chicago. "We have heightened scrutiny from all sides against nonprofit hospitals," he said during a recent American Bar Association audio conference and in comments to CCH on May 17, 2007.

Minimum charity care standards in hospitals has been a hot issue for Congress in the last few years, said Richard Frazier with Saul Ewing, Philadelphia. It is not clear, however, how aggressive the new Congress will be, he said.

Frazier noted that then-House Ways and Means Committee Chairman William Thomas (R-Calif.) introduced legislation in late 2006 that would have required hospitals to provide a minimum level of charity care. In addition, Senate Finance Committee ranking member Charles Grassley (R-Iowa) has written a letter to the Government Accountability Office requesting information on uncompensated care and other benefits provided by nonprofit hospitals. The Internal Revenue Service also has said it plans to release guidance and a report on hospital compliance.

**Scrutiny in Illinois.** Activity in Illinois indicates a trend toward scrutiny. If hospitals continue to lose in court and legislation designed to increase the demands of the exemption prevails, Illinois communities could lose many of the benefits nonprofit hospitals add, Bilimoria noted. Such benefits include medical research; medical education; free medical screenings; health and wellness programs, seminars, and fairs; community outreach programs; and vaccinations and inoculations. "If nonprofit hospitals somehow are treated as for-profit entities, these hospital community services no longer will be provided, leaving perhaps county health departments to pick up the slack," he predicted.

In September 2006, the Illinois Department of Revenue affirmed recommendations of the Champaign County Board of Review to revoke Provena Covenant Medical Center's property tax exemption, requiring the hospital to pay $1 million in property taxes (*see* "Hospital tax-exemption revoked for insufficient charity care," Health Care Compliance Letter, Oct. 16, 2006). The Board alleged that Provena had not demonstrated it was a charitable institution, even though Provena annually provides $1 million in charity care, subsidizes the Medicare and Medicaid programs by more than $10 million, and provides $250,000 in outreach services to the community, Bilimoria told CCH. Provena is appealing the Department's decision, he noted.

In January 2005, Carle Foundation Hospital in Urbana, Illinois, was sued in state courtby a class of uninsured patients over its allegedly unfair billing practices. On April 22, 2005, the Champaign County Board of Review recommended that the Illinois Department of Revenue deny a $2 million property tax exemption for Carle, saying the hospital did not meet the state's criteria for exemption because it overcharged the uninsured and allowed for-profit physician groups to run many of its services (*see* "Second Illinois hospital denied tax exemption," Health Care Compliance Letter, March 20, 2007). In February 2007, the Department of Revenue upheld the recommendation and denied Carle its property tax exemption. Carle is appealing, Bilimoria said.

He added that more recently, in February 2007, the Illinois Department of Revenue surprisingly and summarily denied Richland Memorial Hospital's property tax exemption even though it is a community nonprofit hospital located in a rural area and the Richland County Board of Review had granted the hospital the tax exemption. The Richland hospital case is likely to be appealed, he noted.

Finally, last year, Illinois Attorney General Lisa Madigan proposed the Tax Exempt Hospital Responsibility Act (Illinois House Bill 5000), which would require hospitals to provide charity care equal to at least eight percent of their operating costs (*see* "Standards for charity care and debt collection practices proposed," Health Care Compliance Letter, Feb. 6, 2006). Bilimoria stated the proposal does not take into account that some hospitals may find it hard to meet the eight percent requirement for charity care. To meet the requirement, hospitals might have to consider busing in patients from other communities and attract low-income patients. "The one-size-fits-all nature of the eight percent of operating costs requirement does not work well in some communities," depending on the demographics surrounding the community hospital, he added.

**Perception, the real problem.** The scrutiny on nonprofits in health care is largely a problem of perception, possibly resulting from the public's misconception of nonprofit hospitals, according to Bilimoria. While the picture being painted of the nonprofit hospital industry in the litigation and media reports is one of hospitals that allegedly take advantage of their status to reap large surpluses, which they spend on such things as executive compensation and capital expansion projects, the real underlying public grievance is that hospitals do not provide the same discounts to the uninsured that the large payors, such as Medicare, Medicaid, and commercial managed care organizations, can negotiate. This should not be a nonprofit hospital's burden to bear, Bilimoria said. "Rather, it is the reality of today's managed care health care system."

The lack of access to health care does not warrant this attack on hospitals' exempt status, Bilimoria opined. Instead of blaming nonprofits in health care, he concluded, society needs to consider how much it is willing to spend on health care, who should have access, and at what point quality of health care should be sacrificed to increase access to health care for the uninsured and underinsured. ■

*CCH Washington Bureau, May 17, 2007.*

## Tax-Exempt (cont.)

### IRS releases directive on electronic health records

**by Larry Perlman, J.D., M.B.A., C.P.A., Contributing Editor**

Hospitals that provide financial assistance to physicians in acquiring and implementing electronic health records (EHR) software will not be in violation of IRS prohibitions against private inurement or private benefit under Code Sec. 501(c)(3), according to a memo issued by Lois Lerner, Director of the IRS Exempt Organizations Division.

According to the memo, some hospitals believe that their medical staff need a financial incentive to acquire and implement EHR systems that would allow them to connect to a hospital's EHR system. The benefits provided by the hospital, however, must fall within the range of health items and services allowed under the EHR anti-kickback safe harbors (42 U.S.C. § 1320a-7b) and Stark exceptions (42 U.S.C. § 1395nn).

In addition, the subsidy agreement must provide that the tax-exempt hospital (1) complies with HHS EHR regulations on a continuing basis; (2) may access all of the electronic medical records created by the physician; (3) ensures that the health items and services are available to all of its medical staff physicians; and (4) provides the same level of subsidy to all of its medical staff or varies the level of subsidy by applying criteria related to meeting the health care needs of the community.

"The taxable hospitals are already doing this," said Lerner on May 11 at the American Bar Association's Section of Taxation 2007 May Meeting in Washington, D.C. "The tax-exempt hospitals were concerned that there may be a concern from our end with regard to [these benefits and] exemption."

Catherine Livingston, IRS Assistant Chief Counsel, who also spoke at the ABA meeting, clarified that the memo only addresses exemption implications, and not any income tax issues that may arise. ■

*CCH Chicago Bureau, May 15, 2007.*

# In the News

## House panel passes bill to protect SSNs

A House committee passed a bill designed to limit the circulation of Social Security numbers. The bill, entitled the Social Security Number Protection Act (H.R. 948), would give the Federal Trade Commission rulemaking authority to restrict the sale of Social Security numbers and determine appropriate exemptions, including for purposes of law enforcement, national security, public health and safety, and credit verification. The legislation would preempt similar state laws. The House Energy and Commerce Committee approved the bill on May 11. The Ways and Means Committee shares jurisdiction over the legislation.

*CCH Washington Bureau, May 11, 2007.*

## Fraud in MA plan marketing targeted

The Senate Special Committee on Aging on May 16, 2007, addressed unethical and illegal practices that some sales agents reportedly have used to enroll Medicare beneficiaries in private Medicare Advantage plans. Committee Chairman Herb Kohl (D-Wisc.) said he is working with the National Association of Insurance Commissioners and other stakeholders to develop legislation to expand states' authority to oversee plans and agents. Abby Block, director of CMS' Center for Beneficiary Choices, said CMS is taking actions that range from warning letters to civil monetary penalties and removal from the program for violators. Agents may not solicit Medicare beneficiaries door-to-door, and they must ask for a beneficiary's permission before providing assistance in the beneficiary's residence, she noted. Karen Ignagni, president of America's Health Insurance Plans, said the association is working with member organizations to require (1) core competency training, (2) background checks, (3) beneficiary attestation on the enrollment application, and (4) outbound post-enrollment calls to verify the beneficiary's intent to enroll and understanding of key plan benefits and structure.

*CCH Washington Bureau, May 16, 2007.*

## Drug company resolves FCA allegations

Medicis Pharmaceutical Corporation of Scottsdale, Ariz., will pay the United States $9.8 million to settle allegations that the company violated the False Claims Act with respect to claims submitted to Medicaid. The settlement resolves allegations that Medicis promoted the use of a topical skin preparation, Loprox, for use on children under the age of 10, without approval by the Food & Drug Administration (FDA). The government alleged that from approximately November 2001 through April 2004, Medicis sales personnel targeted pediatricians, urging the doctors to use Loprox as a treatment for diaper rash. The use of Loprox, which is approved by the FDA as a fungicide for use on patients over 10 years of age, is not a "medically accepted indication" for the treatment of diaper dermatitis and other skin disorders in children under 10. The Food, Drug & Cosmetic Act prohibits pharmaceutical companies from marketing or promoting a drug for uses that the FDA has not approved, a practice known as "off-label marketing."

*DoJ Press Release, May 8, 2007.*