CCH Health Care Compliance LETTER

Volume 12, Issue 9 health.cch.com May 5, 2009

Comprehensive health care reform bill promised by early June

On April 20, 2009, Senators Edward M. Kennedy (D-Mass.), chairman of the Senate Health, Education, Labor, and Pensions Committee, and Max Baucus (D-Mont.), chairman of the Senate Finance Committee, sent a letter to President Obama laying out their commitment to mark-up comprehensive health care reform legislation by early June. The senators' joint letter expressed an intention to take a shared approach to health care reform legislation, so that the measures the committees report can be quickly merged into a single bill for consideration by the full Senate. "We have a moral duty to ensure that every American can get quality health care. We must act to contain the growth of health care costs to ensure our economic stability; to help American businesses deal with the health care challenge; and to make sure we are getting our money's worth," the senators wrote.

Rockefeller's principles. On April 21, 2009, Sen. Jay Rockefeller (D-W. Va.), chairman of the Senate Finance Subcommittee on Health Care, outlined his principles for a 21st century health care delivery system as the Finance Committee unveiled a series of roundtables leading up to health care reform legislation. Sen. Rockefeller's principles for reforming the health care delivery system are: (1) create a National Director for Health Care Quality; (2) strengthen the Medicare Payment Advisory Commission (MedPAC) and provide expedited implementation of its recommendations; (3) provide the Agency for Healthcare Research and Quality with greater authority to coordinate public and private quality improvement; and (4) require health information technology as a "condition of participation" in Medicare by 2015.

OIG strategy. At the first Senate Finance Committee roundtable discussion on health care reform held on April 21, 2009, Lewis Morris, Chief Counsel of the Office of Inspector General (OIG), presented a detailed statement on how curbing fraud, waste, and abuse must be an essential component of any health care reform strategy drafted by Congress.

According to Morris, federal health care program history shows us that the way the health care system reimburses for items and services will determine how the dishonest will exploit it. For example, when Medicare pays on a fee-for-service basis, providers have an incentive to increase the number and complexity of the services. When the program pays on a capitated basis, however, the incentive is reversed and patients may not receive necessary services for which the provider has been paid. Morris stated that for the health care system to adequately serve the medical needs of current patients and remain solvent, reform efforts must embrace five principles:

- **Scrutinize individuals and entities that want to participate as providers and suppliers, prior to their enrollment.** Screening measures must require accreditation standards, proof of business integrity or surety bonds, periodic

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recertification, on site verification that conditions of participation have been met, and full disclosure of ownership and control interests.

- **Establish payment methodologies that are reasonable and responsive to changes in the marketplace.** The health care system also must anticipate that providers may alter their practices in response to program integrity efforts. Payment systems should seek to maximize positive behavior (i.e., high-quality, cost-effective care) and safeguard against negative incentives.
- **Assist health care providers and suppliers in adopting practices that promote compliance with program requirements, including quality and safety standards.** Health care providers must be partners with government in ensuring the integrity of health care programs and should adopt internal controls and other measures that promote compliance and prevent, detect, and respond to health care fraud, waste, and abuse. The government also must play a leadership role in promoting the health care industry's commitment to integrity.
- **Vigilantly monitor the programs for evidence of fraud, waste, and abuse.** The health care system compiles an enormous amount of data on patients, providers, and the delivery of health care items and services. Federal health care programs, however, often fail effectively to use claim-processing edits and other information technology to identify improper claims before they are paid.
- **Respond swiftly to detected frauds, impose sufficient punishment to deter others, and promptly remedy program vulnerabilities.** OIG investigations have shown an increase in organized crime involvement in health care. Criminals test a system's payment edits and program integrity algorithms by "pinging" the system with small batches of test claims and then submit fraudulent claims that are below those thresholds. The health care system must respond more quickly once a vulnerability is identified. Medicare also needs to be able quickly to void compromised Medicare beneficiaries or provider numbers and sanction those who traffic in this type of information.

Morris concludes that: (1) the anti-fraud measures and program safeguards that must be used depend on the way the system and its payments are structured; (2) a comprehensive health care integrity strategy should be an integral element of any systemic health care reforms; and (3) the OIG and law enforcement partners will need new tools and sufficient resources if they are to succeed in the fight against health care fraud, waste, and abuse. ■

CCH Chicago Bureau and OIG Statement, April 21, 2009

Compliance efforts should not take a holiday in a recession

by Paul R. DeMuro, CPA, MBA, JD, CHC

Given the declining financial situation that many health care companies face, reports abound of layoffs or reductions in force. Hospitals have been particularly hard-hit. With declines in insured patients, increases in co-payments and deductible amounts, increases in charity care and bad debts, and investment losses, many hospitals have had to resort to layoffs or hiring freezes.

A particularly interesting area where hospital staff has been reduced or resources cut, is in the area of compliance. Perhaps, most interesting in this regard is that the above factors increase the issues faced by compliance officers, not decrease them. That is, as finances become limited, compliance issues tend to increase. For example, is the hospital appropriately applying and adhering to its charity care and bad debt policies? What financial compliance issues might arise as a result of not meeting various debt covenants or reserve requirements?

Have investment losses caused a hospital faculty to be unable to complete certain of its building, electronics health record, or other projects? Does a health care system have an investment venture capital fund and, if so, is it able to meet the commitments/capital calls associated with same? Health care systems are finding it increasingly difficult to recruit physicians, and physician practices that are finding it difficult to maintain their financial viability in this economic climate, often turn to hospitals for assistance. As a result, hospitals are employing more physicians, developing medical foundations, and building or enhancing integrated delivery systems. These trends also tend

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CCH Health Care Compliance Letter is published 24 times a year by CCH, a Wolters Kluwer business, 4025 W. Peterson Avenue, Chicago, IL, 60646. Subscription rate is $305 per year. First-class postage paid at Chicago, Illinois, and at additional mailing offices. POSTMASTER: SEND ADDRESS CHANGES TO *CCH Health Care Compliance Letter*, 4025 W. PETERSON AVENUE, CHICAGO, IL 60646. Printed in U.S.A.

to increase the scope of compliance activities, not decrease them.

Certainly compliance departments have tried to be more efficient by using web-based training applications and by increasing use of technology to enhance their monitoring, education, and other compliance functions. As compliance budgets are stressed even further, one wonders how cuts in compliance will be affected. Reports exist of hospitals delaying filling compliance positions and postponing certain training and compliance activities. The initial reaction may be that compliance should shoulder its share of the pain, but the effects of such costs can be devastating. If the compliance issues were declining as a result of the economic crisis, that is – if there were less business activities, fewer patient encounters, less physician relationships, and less regulation – one can understand how decreasing the resources of a compliance department and compliance efforts might be justified. Except, however, in some instances such reduction in elective surgeries, discussions with a number of compliance professionals suggest that there are more compliance issues to be addressed with no expansion of compliance resources. What will be the effects of such reduction in compliance efforts? A potential consequence will be that compliance efforts will not be as effective.

It only takes one employee or physician without the proper compliance training to do something or fail to do something to result in very expensive compliance problems or one area to be monitored to be "postponed" when problematic activity is occurring. Although compliance professionals should strive to be as efficient as possible and use as much technology as possible to stretch their resources in a most cost efficient manner, they need to be careful to ensure that they can accomplish what they need to do to be effective in their positions, and management and boards of directors need to ensure this will be the case. Otherwise, they may frustrate the purpose of the cuts in the compliance areas. Paybacks to federal and state governments can well exceed the one or two employees cut in the compliance department. ■

FTC grants 3-month delay of Red Flags Rule

Under pressure from the American Medical Association (AMA) and other health care trade groups, the Federal Trade Commission (FTC) has extended the May 1 deadline for compliance with the Red Flags Rule to August 1. Requiring that certain entities develop and implement written identity theft prevention and detection programs, the Rule applies to any institution considered a "creditor."

Basic elements. Under the Rule, identity theft prevention programs must: (1) include reasonable policies and procedures to identify the "red flags" — suspicious patterns, practices and activities — that may arise in the day-to-day operation of business; (2) be designed to detect the red flags identified for the business; (3) outline appropriate actions to be taken when red flags are detected; and (4) address how it will be re-evaluated to reflect new risks from the threat of identity theft.

Merely having a written policy on file is not sufficient to achieve compliance with the Rule. The identity theft program must be incorporated into the daily operation of the business. The program must include appropriate staff training and, if operations are outsourced, the program must address how the organization will monitor contractors' compliance.

Creditors. A creditor is defined by the FTC as "any person who regularly extends, renews, or continues credit." The FTC's position is that physicians who accept insurance or allow payment plans are creditors and are, therefore, subject to the Rule. Although the AMA and other groups have argued that the FTC's interpretation is inconsistent with the intent of the Rule, their efforts to persuade the FTC have been unsuccessful.

Physician practices who accept insurance or allow payment plans are covered by the Rule and must have adequate policies and procedures in place by August 1 or they could face a penalty of up to $2,500 per knowing violation.

Red flags. The FTC has identified a number of potential red flags, including: (1) alerts, notifications and warnings from a credit reporting company; (2) suspicious documents and personal identifying information such as an inconsistent address or nonexistent Social Security number; (3) suspicious account activity; and (4) notices of possible identity theft from other sources such as patients, victims of identity theft or law enforcement authorities. ■

FTC Report, Fighting Fraud with the Red Flags Rule: A How-To Guide for Business, March 2009; FTC Press Release, April 30, 2009

On The Front Lines

Lessons Learned from EMTALA Enforcement

by Joanna Conder

Although enforcement actions under the Emergency Medical Treatment and Active Labor Act (EMTALA) have been few in number, compliance officers can use a handful of court decisions and issuances from CMS to better understand EMTALA's core provisions. This article examines EMTALA's history and requirements. It also offers suggestions for compliance officers to incorporate as a part of ongoing monitoring and auditing efforts.

EMTALA has its origin in the Hill-Burton Free Care Program established in 1946 to provide federal grants to hospitals for modernization in return for providing uncompensated services for 20 years after receiving funds. Facilities that received funding were to provide services without consideration of race, color, creed, national origin, or ability to pay.

Enforcement responsibility ultimately fell to the Office of Civil Rights in the U.S. Department of Health and Human Services (HHS). Over the years, questions were raised about the effectiveness of enforcement, and Congressman "Pete" Stark introduced new legislation passed by Congress under its current title EMTALA that applied to all hospitals participating in Medicare, not just the Hill-Burton hospitals. It also was designed to fortify enforcement actions.

EMTALA continues with the same basic nondiscrimination principles of the Hill-Burton requirements, including making emergency care available to everyone regardless of their ability to pay.[1] The statute imposes a legal obligation on hospitals that participate in Medicare and operate an emergency department to provide appropriate medical screening and stabilization care to persons presenting themselves to the emergency room with an emergency medical condition or in active labor. Violations of EMTALA may result in monetary penalties of not more than $50,000 (or not more than $25,000 for hospitals with less than 100 beds) for each violation.

Nevertheless, notwithstanding few exceptions, EMTALA regulatory and legal enforcement actions continue to be limited. This is due in part to disagreement among the courts interpreting the statute. This lack of uniformity has limited EMTALA's effectiveness but at the same time has revealed areas of the law that have been causing confusion and are of interest to the government.

Compliance officers should learn about EMTALA court decisions as they identify risk areas that might be the focus of future enforcement actions. Not only are there few court cases, but those that do exist are inconsistent regarding the interpretation of the statute's major provisions.

The Centers for Medicare & Medicaid Services (CMS) has attempted to clarify some parts of the provisions that caused confusion. Recently, the inpatient prospective payment system (IPPS) final rule clarified EMTALA requirements regarding hospital inpatients and proposed a flexible way for hospitals to meet EMTALA physician on-call requirements.[2] Nevertheless, case law continues to evidence significant problems with the interpretation of the scope of EMTALA's core provisions, such as medical screening, stabilization, and transfer requirements. Furthermore, courts disagree on the appropriate standard of care with respect to the duty to perform a medical screening. In some cases, the standard seems to be to provide a uniform screening to everyone; in other cases, even nonuniform treatment cannot be covered under EMTALA. No standard of care required under EMTALA threatens the quality of health care to the extent that the screening provided to a patient might be medically inadequate.

EMTALA requirements

In 2000, a Departmental Appeals Board (DAB) ruling seemed to limit the scope of EMTALA regarding screening and stabilization requirements in *Inspector General v. Bowen*.[3] The issue in the case was what action a reasonable physician should have taken in light of what he knew or should have known about the patient's condition when he or she came to the emergency department.

The DAB held that the EMTALA stabilization requirements apply only when a hospital determines through a medical screening examination that the individual has an emergency medical condition. Therefore, even if the doctor knew or should have known without conducting a medical screening examination that the patient had an emergency medical condition, the patient left the emergency department before the doctor could take any action consistent with the stabilization and transfer requirements. The court held that the doctor was not able to perform the appropriate screening procedure

to detect an emergency medical condition; therefore, without the emergency determination the stabilization requirement of EMTALA does not apply.

The interpretation of the stabilization requirement by the 9th Circuit Court of Appeals in *Bryant v. Adventist Health System* is what most courts are likely to follow today.[4] In *Bryant*, the patient was treated and discharged after being diagnosed with pneumonia. Later that day, the patient was asked to return to the hospital after a second physician's examination. After spending time in the intensive care unit, the patient was transferred to another hospital, where the patient had surgery and was eventually released and subsequently died. In this case, the appellate court decided that the duty to stabilize under EMTALA ended when the patient was admitted for inpatient care.

Based on this decision, EMTALA can now be interpreted in the following way: once an emergency medical condition is confirmed through medical screening, the hospital must treat that condition until the patient is stable. After the hospital provides appropriate examination and stabilizing treatment, anything else that happens to the patient as an inpatient or after discharge becomes a medical malpractice issue, not an EMTALA issue.

This interpretation was put into regulation in 2003 when, in the standalone final rule on EMTALA, CMS determined that a hospital's obligation under EMTALA ends when that hospital, in good faith, admits an individual with an unstable emergency medical condition.[5] Further, the IPPS final rule published in August 2008 clarified that a hospital with specialized capabilities does not have an EMTALA obligation to accept an appropriate transfer of an individual (who presented to the admitting hospital under EMTALA) to stabilize an emergency condition.[6] These provisions clearly narrowed a hospital's duties under EMTALA.

Standard of care

The medical screening requirement helps increase access to health care but at the same time may lower the quality of care as EMTALA does not establish a national standard of care. The statute only requires hospitals to develop and provide screening procedures to detect emergency medical conditions. In other words, a hospital itself determines what its screening procedures will be for people coming to the emergency room. This does not mean, however, that medical screening provided will be adequate and sufficient.

The 9th Circuit Court of Appeals ruling in *Jackson v. East Bay Hospital* shows that even medically inadequate screening, as long as the same screening is routinely given to all patients presenting similar symptoms, satisfies EMTALA requirements.[7] The issue in the case was whether a hospital violates EMTALA if it fails to diagnose the cause of a patient's emergency condition but treats the symptoms identified and concludes that the patient has been stabilized. The appellate court ruled that a hospital is not liable for failure to diagnose the physical cause of an emergency medical condition when it provided a screening examination that is comparable to that offered to other patients with similar symptoms, stabilized the symptoms, and concluded that the patient was stable. Therefore, the only standard that has emerged under EMTALA is that patients are entitled to be provided with uniform treatment within the hospital's capabilities; however, the statute does not specify what is medically adequate and sufficient treatment.

In *Summers v. Baptist Medical Center Arkadelphia*, a patient was treated differently from other patients and differently from the treatment prescribed by the hospital's normal screening process.[8] Therefore, the patient requested recovery under EMTALA. The 8th Circuit Court of Appeals ruled that the treatment was simply a physician's negligence that EMTALA does not cover. The appellate court also emphasized that it would almost always be possible to characterize negligence in the screening process as nonuniform treatment because any hospital's screening process presumably will include a nonnegligent response to symptoms or complaints presented by a patient. Therefore, instances of negligence in the screening or diagnostic process are not actionable under EMTALA. This ruling reduced the reach of EMTALA imposing a limited duty on hospitals.

The *Jackson* case shows that the "appropriate medical screening" requirement does not necessarily mean correct diagnosis as long as uniform screening procedures are applied. Therefore, this type of claim is not covered under EMTALA as the statute is not a remedy for federal malpractice actions. On the other hand, the *Summers* case shows that even nonuniform medical screening cannot be covered under EMTALA because it is considered to be a negligence claim.

Suggestions for compliance officers

EMTALA's past court rulings suggest the areas of regulatory and enforcement that are of interest to the federal government. Although some of those areas remain unclear, it is beneficial for hospitals to adopt good compliance practices. Based on what is known from the past court cases, compliance officers should do the following as part of ongoing auditing and monitoring:

- Review all EMTALA-related policies and procedures to ensure that the legal and regulatory requirements are addressed adequately.
- Identify any weaknesses in the policy documents that might put a hospital at risk of noncompliance or make it vulnerable for private cause of action.
- Verify the hospital is following its policies and procedures.
- Ensure appropriate medical screening procedures are applied uniformly to all people with similar symptoms pre-

On The Front Lines (cont.)

senting themselves in the emergency department. In other words, hospitals would have to be able to demonstrate that all patients were treated uniformly.

- Ensure the hospital provides an appropriate medical screening and does not compromise its own standards. Most enforcement actions resulting in civil monetary penalties have involved allegations that a hospital failed to provide appropriate medical screening examinations. ■

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1 42 U.S.C. §1395dd. Congress enacted EMTALA under Section 9121 of the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA) (Pub-LNo. 99-272), 100 Stat. 164-167, available at www.medlaw.com/statute.htm.

2 Final rule, 73 FR 161, 48434-49084, Aug. 19, 2008.

3 *Inspector General v. Bowen*, HHS Departmental Appeals Board, Doc. No. A-2000-7, CR 618, Dec. No. 1720, March 23, 2000, available at www.hhs.gov/dab/decisions/dab1720.html.

4 *Bryant v. Adventist Health System*, 289 F.3d 1162 (9th Cir. 2002).

5 Final rule, 68 FR 174, 53221, 53243, Sept. 9, 2003.

6 Final rule, supra n. 2.

7 *Jackson v. East Bay Hospital*, 246 F.3d 1248 (9th Cir. 2001).

8 *Summers v. Baptist Med. Ctr. Arkadelphia*, 91 F.3d 1132 (8th Cir. 1996).

Fraud and Abuse (cont.)

Fifth Circuit addresses restitution, sufficiency of pleadings

A federal appeals court issued two recent decisions related to Medicare fraud.

Restitution. In one case, the court found that the amount of restitution a district court ordered to be paid was not excessive because the government did not have to prove that the beneficiaries who received power wheelchairs were in need of the devices. A durable medical equipment (DME) supplier pleaded guilty to a conspiracy that included participating in a scheme with a recruiter who solicited Medicare beneficiaries to see a doctor who signed false certificates of medical necessity that certified the beneficiaries needed a power wheelchair. The DME supplier paid the doctor kickbacks, provided the beneficiaries with the power wheelchairs and accessories and then billed Medicare. The DME supplier admitted he falsely represented to Medicare the beneficiaries were qualified to receive the wheelchair and accessories.

The amount of the loss in a government benefit case is the amount of the benefit received less the amount of benefit intended to be paid. The district court appropriately used the sentencing guidelines in imposing a sentence for health care fraud that required restitution in the amount of slightly more than $446,000. Since no evidence was offered to the district court that showed the beneficiaries actually needed a wheelchair, the district court did not err in finding the actual loss to Medicare was the total amount paid on those claims. Medicare would not have paid for the wheelchairs had it not been for the criminal activity.

Sufficiency of pleadings. In another case, the dismissal of a relator's complaint against a hospital and doctors for failing to plead fraud with particularity was reversed because the relator was able to sufficiently plead without including all the details of the claims. The relator was a doctor, who upon beginning work at a hospital learned of a preexisting arrangement among other doctors to bill for services not provided to patients. The doctor brought a *qui tam* suit against the hospital and individual doctors claiming that they submitted false claims to the government, and used false records to obtain payment while participating in a conspiracy to do so.

Although complaints brought under the False Claims Act must meet the heightened pleading standard, including presentment of a false claim, and "state with particularity the circumstances constituting fraud or mistake," whether the actual details of the false claim are required has not been previously decided. With regard to the presentment of a false claim, showing proof of the falsity of the claim but not the claim's exact contents suffices; therefore the relator's detailing of the scheme to submit a false claim was sufficient to infer that false claims were submitted, and details of the contents of the false bills were not needed. Because the relator was not required to plead with the same level of detail required to prevail at trial, the dismissal of his complaint was reversed. ■

U.S. v. Edet, 5th Cir., No. 08-10287, April 8, 2009, Health Care Compliance Reporter, ¶800,640; U.S. ex rel. Grubbs v. Kanneganti, 5th Cir., No. 07-40963, April 8, 2009, Health Care Compliance Reporter, ¶800,641

Health IT

Guidance on how to secure PHI and prevent breach harm issued by HHS

HHS has published a guidance identifying the technologies and methodologies that can be used to render protected health information (PHI) unusable, unreadable, or indecipherable to unauthorized individuals. The guidance should be used by covered entities under the Health Information Portability and Accountability Act (HIPAA) and their business associates to decide whether "unsecured protected health information" has been breached, thereby triggering the notification requirements specified in section 13402 of the Health Information Technology for Economic and Clinical Health (HITECH) Act, which was enacted February 17, 2009, as part of the American

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Recovery and Reinvestment Act of 2009 (PubLNo. 111-5).

The HITECH Act requires HHS to: (1) issue interim final regulations within 180 days of enactment requiring covered entities and their business associates to provide notification in cases of breaches of unsecured PHI; and (2) within 60 days of enactment, issue and annually update guidance specifying the technologies and methodologies that render PHI unusable, unreadable, or indecipherable by unauthorized individuals.

HHS is seeking public comment on the guidance and the breach notification provisions of the HITECH Act to inform the development of its interim final regulations and required guidance updates.

"Breach" defined. The breach notification provisions in the HITECH Act apply to HIPAA covered entities and their business associates that access, maintain, retain, modify, record, store, destroy, or otherwise hold, use, or disclose unsecured PHI.

"Breach" is defined by the Act as "the unauthorized acquisition, access, use, or disclosure of protected health information which compromises the security or privacy of such information, except where an unauthorized person to whom such information is disclosed would not reasonably have been able to retain such information."

Breach notice requirement. After discovery of a breach of unsecured PHI, a covered entity must notify each individual whose unsecured PHI has been, or is reasonably believed to have been, inappropriately accessed, acquired, or disclosed.

After the discovery of a breach by a business associate, the business associate must notify the covered entity of the breach and identify the individuals whose unsecured PHI has been, or is reasonably believed to have been, breached.

The Act requires use of the following methods of notice:

- Written notice to the individual at the last known address by first-class mail or by e-mail if requested by the individual.
- If there is insufficient contact information, substitute notice, including, in the case of 10 or more individuals, conspicuous posting on the home page of the Web site of the covered entity or notice in major print or broadcast media.
- If the entity deems the situation urgent based on the possibility of imminent misuse of the unsecured PHI, notice by telephone or other method is permitted in addition to the above methods.
- Notice to prominent media outlets within the State or jurisdiction if a breach of unsecured PHI affects, or is reasonably believed to affect, more than 500 residents of that State or jurisdiction.
- Immediate notice to HHS by covered entities for breaches involving more than 500 individuals and annually for all other breaches.
- Posting by the Secretary on an HHS Web site of a list that identifies each covered entity involved in a breach in which the unsecured PHI of more than 500 individuals is acquired or disclosed.

Contents of breach notice. The Act requires that the breach notification include: (1) a brief description of what happened, including the date of the breach and the date of the discovery; (2) a description of the types of unsecured PHI that were involved; (3) the steps individuals should take to protect themselves from potential harm; (4) a brief description of what the covered entity is doing to investigate the breach, mitigate losses, and protect against further breaches; and (5) contact procedures for individuals to ask questions or learn additional information.

Rendering methods. The HITECH Act defines "unsecured protected health information" as PHI that is *not* secured through the use of a technology or methodology specified in HHS guidance. The guidance addresses methods for rendering paper or electronic PHI unusable, unreadable, or indecipherable and identifies (1) encryption and (2) destruction as the two acceptable methods.

- Electronic PHI has been *encrypted* as required by the HIPAA Security Rule by "the use of an algorithmic process to transform the data into a form in which there is low probability of assigning meaning without use of a confidential process or key" and the confidential process or key that might enable decryption has not been breached.
- The *destruction* method applies to both paper and electronic forms of PHI. Paper, film, or other hard copy media may be shredded or destroyed so that the PHI cannot be read or otherwise reconstructed. Electronic media must be cleared, purged, or destroyed consistent with National Institutes of Standards and Technology Guidelines, so that the PHI cannot be retrieved.

Comments sought on "limited data set" formats. HHS is considering whether PHI in "limited data set" form should be considered unusable, unreadable, or indecipherable for purposes of security breach notification. A "limited data set" is PHI from which the 16 direct identifiers listed in 45 C.F.R. § 164.514(e)(2) of the HIPAA Privacy Rule (i.e., name, address, Social Security number, and account number) have been removed. Even with the removal of the direct identifiers, however, the PHI is not entirely de-identified, according to 45 C.F.R. § 164.514(b) of the HIPAA Privacy Rule.

As a result, HHS is not making a decision as to whether limited data sets should be considered unusable, unreadable, or indecipherable and, therefore, not subject to breach notification. Instead, HHS is seeking comments on whether the risk of re-identification of a limited data set warrants its exclusion from the list of technologies and methodologies that render PHI unusable, unreadable, or indecipherable by unauthorized individuals.

Comments on the guidance must submitted to HHS on or before May 21, 2009. The guidance will apply to breaches that occur 30 days after publication of the forthcoming interim final regulations. ■

HHS Guidance and Request for Information, April 17, 2009

Quality of Care

Pilot project aims to reduce preventable hospital readmissions

CMS has selected 14 communities around the nation to participate in a pilot program aimed at eliminating unnecessary hospital readmissions. Under the Care Transitions Project, health care providers will work together to promote seamless transitions from the hospital to home, skill nursing facilities, or home health care.

Project locations. Communities in the following regions have been selected to participate: Providence, Rhode Island; Upper Capitol Region, New York; Western Pennsylvania; Southwestern New Jersey; Metro Atlanta East, Georgia; Miami, Florida; Tuscaloosa, Alabama; Evansville, Indiana; Greater Lansing, Michigan; Omaha, Nebraska; Baton Rouge, Louisiana; Northwest Denver, Colorado; Harlingen, Texas; and Whatcom County, Washington.

State QIO leaders. Each of the communities will be led by a state Quality Improvement Organization (QIO). Each QIO will be required to work with partners, including health care providers, consumers and other stakeholder groups, to implement the following: (1) hospital and community system-wide interventions; (2) interventions that target specific diseases or conditions; and (3) interventions that target specific reasons for admission.

Local solutions. Project participants will attempt to determine, within their communities, why hospital readmissions occur and how patients transition between health care settings. Using that information, they will develop local solutions and strategies to reduce the number of readmissions. CMS will gauge the project's success by monitoring the rates at which patients in these communities return to the hospital. The Project will continue in all 14 communities through summer 2011.■

CMS News Release, April 13, 2009

In the News

$302 million global settlement reached

Quest Diagnostics Incorporated and its subsidiary, Nichols Institute Diagnostics (NID), have entered into a global settlement resolving criminal and civil claims relating to NID's Nichols Advantage Chemiluminescence Intact Parathyroid Hormone Immunoassay, a test that was used by laboratories throughout the country to measure parathyroid hormone (PTH) levels in patients. As part of the criminal resolution, NID pleaded guilty to a felony misbranding charge in violation of the Food, Drug and Cosmetic Act and will pay a criminal fine of $40 million. Quest has entered into a non-prosecution agreement. As part of the civil settlement, Quest and NID also will pay $262 million plus interest to resolve False Claims Act allegations relating to the Advantage Intact PTH assay and four other assays manufactured by NID that allegedly provided inaccurate and unreliable results. Quest will pay various state Medicaid programs approximately $6.2 million to resolve similar claims. Quest has also entered into a Corporate Integrity Agreement. The whistleblower will receive $45 million.

U.S. Department of Justice Press Release, April 15, 2009

PT firm resolves billing fraud charges

Interstate Rehabilitation LLC, of Glendale, California, a physical therapy company that contracts with hospitals to operate physical therapy departments, as well as its owners and operators, have paid the government $233,345 to resolve allegations that they caused the submission of false claims to Medicare. Interstate Rehabilitation and its owner/operators agreed to pay the settlement without admitting any wrongdoing and the government is dismissing the lawsuit. The complaint alleged that the company improperly billed Medicare for services that were to be provided by licensed physical therapists, when in fact they were not. The services were allegedly provided to patients at skilled nursing facilities at southern California hospitals, which caused the facilities to submit false claims for payment to Medicare. The action was brought by two former employees who will split 16 percent of the settlement.

U.S. Attorney's Office Press Release, Central District of California, No. 09-047, April 13, 2009

Widespread South Florida drug fraud

Although just 2 percent of Medicare beneficiaries live in South Florida, the area accounted for 17 percent of the program's total spending on inhalation drugs in 2007 because of potential fraud. An Office of Inspector General (OIG) report found that in 2007 Medicare spent $143 million on drug claims to treat respiratory illnesses in Miami-Dade County – more than 20 times the amount spent in the Chicago area, which is home to twice as many beneficiaries. The report also found that Medicare spent $4,400 per beneficiary on inhalation drugs in South Florida compared with $815 per beneficiary in the rest of the country. According to the report, two-thirds of all Medicare beneficiaries in South Florida who have submitted claims for inhalation drugs did not have an office visit with the prescribing physicians in the previous three years.

OIG Report, No. OEI-03-08-00290, April 2009