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GAO finds weaknesses in CMS oversight of clinical lab quality

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

CMS oversight of clinical lab quality is inadequate, according to a recent Government Accountability Office (GAO) report. In addition, the report cited a lack of data to identify the extent of serious quality problems and weaknesses in the complaint and enforcement processes, which also mask potential quality problems. Clinical lab oversight was delegated to CMS under the Clinical Laboratory Improvements Amendments of 1988 (CLIA) to address concerns about lab quality. Recent lab quality problems in several states prompted GAO's investigation into CMS oversight.

GAO stressed that lab oversight is critical because inaccurate or unreliable tests could result in improper treatment, unnecessary mental and physical anguish for patients, and higher health care costs. Clinical lab test are one of the most frequently billed Medicare procedures and affect an estimated 70 percent of medical decisions. As of December 2005, there were approximately 193,000 labs nationwide, GAO stated.

CLIA establishes personnel qualification, proficiency testing, quality control, quality assurance, and recordkeeping requirements. Labs may choose to have their surveys conducted by state survey agencies using CLIA inspection requirements or other survey organizations that use requirements equivalent to CLIA's.

Inadequate oversight. GAO concluded that CMS was inappropriately stressing education over regulation resulting in misleading data on trends in lab quality over time. For example, CMS instructed state surveyors in 2006 and 2006 to refrain from citing deficiencies at labs whose staff failed the proficiency test for interpreting Pap smears to allow labs and their staff to become familiar with the proficiency testing program. GAO also found that while CLIA requires proficiency testing quarterly, CMS conducts such testing only three times per year.

Insufficient data. The true extent of quality problems is unclear because CMS has incomplete data on deficiencies identified by state agencies prior to 2004, GAO stated. Investigators found a lack of straightforward linkage between CLIA requirements and the CLIA-equivalent requirements of some survey organizations, which makes it difficult to assess lab quality in a standardized manner

CMS responded to the accusation by citing its proficiency testing data, which showed a decrease in failures in recent years. The report, however, maintained that lab quality has not improved despite the proficiency testing results. Proficiency testing is used as an objective indicator of a lab's ability to consistently produce accurate test results and is conducted more frequently than surveys. Proficiency testing data showed that there has been an increase in testing failures for hospital labs. CMS argued that

Wolters Kluwer Law & Business

testing failures among physician office labs has decreased; however, the report stated that the improvement may be attributable to the increasing number of physician office labs performing only waived tests. Those office labs are not surveyed and do not participate in proficiency testing. The report stated that between 1998 and 2005, the percentage of labs subject to surveys and proficiency testing decreased from about 30 percent to about 19 percent, which accounts for CMS data suggesting lab quality has improved.

Weaknesses. Investigators believe that there are several key weaknesses in the survey process. GAO indicated that announced inspections allow labs to prepare, which may not result in an accurate reflection of the lab's day-to-day quality assurance process. In addition, the GAO, stated that the variability in the proportion of labs with deficiencies in 2004 suggests that surveys are not conducted in a consistent manner. Finally, the goal of educating lab workers during surveys may preclude the identification and reporting of deficiencies.

The GAO also noted that since one survey organization took steps to ensure that lab workers know how to file a complaint, the number of complaints that organization has received has increased significantly. This suggests that quality problems at labs inspected by other survey organizations may not be reported.

Finally, the GAO stressed that sanctions are not being used effectively as an enforcement tool. For example, between 1998 and 2004, 274 labs surveyed by state agencies had the same deficiency cited on multiple surveys. According to the GAO, however, only 30 of the 724 labs with repeat deficiencies had sanctions imposed.

In response, CMS maintained that some of the problems identified in the report were the result of a lack of staff and budget. The GAO discovered, however, that the fees collected from health care providers to fund the inspection program far exceeded the amount the agency spent, contributing to a $70 million surplus in the program's budget.

Recommendations. The GAO recommended that CMS improve lab oversight by:

(1) standardizing the reporting of survey deficiencies;
(2) working with survey organizations to ensure that educating lab workers does not preclude appropriate regulation, such as identifying and reporting deficiencies; and
(3) allowing the CLIA program to fully use revenues generated by the program to hire sufficient staff to fulfill it's statutory responsibilities.

Although CMS agreed generally that clinical lab quality should be strengthened, it disagreed that education was inappropriately stressed over regulation, expressed concern about how to identify and sanction labs with repeat deficiencies, and disagreed with the recommendation regarding increased proficiency testing. In his written response to the findings, CMS Administrator Mark McClellan stated that "while the GAO points to a recent increase in failures among some labs between 1999 and 2003, the overall performance of all labs has improved, especially when viewed over a longer period of time." ■

GAO Report, GAO-06-416, June, 2006.

Applicability of FDA's new informed consent exception explained

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

A Food and Drug Administration (FDA) interim final rule allowing the use of investigational *in vitro* diagnostic devices (IVDs) to identify chemical, biological, radiological, or nuclear agents without informed consent in certain emergency circumstances will likely impact HHS informed consent procedures related to human subject safety.

Accordingly, the HHS Office For Human Research Protections (OHRP) has issued a guidance for institutional review boards (IRBs), investigators, sponsors and funding agencies on how to determine whether HHS informed consent regulations are applicable to the activities covered by the FDA rule. The guidance helps to determine whether institutions conducting research activities covered by the FDA informed consent exemption would be engaged in nonexempt human subjects research. If an institution is engaged in a nonexempt human subject research that is either conducted or supported by HHS, then an OHRP-aiproved assurance of compliance is required.

OHRP guidance. The guidance clarifies that OHRP will not consider a lab to be engaged in nonexempt human subject research if: (1) the research involves minimal risk to the subject; (2) the waiver of informed consent will not adversely affect the rights and welfare of the subject; (3) the research could not be carried out without

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the waiver of alteration, and; (4) the subjects must be provided with additional pertinent information after participation, as appropriate. If, however, laboratory personnel are engaged in the analysis of identifiable private information derived from IVD devices to evaluate the safety and effectiveness of the device, then the OHRP will find that the lab is engaging in nonexempt human subject research and an OHRP-approved assurance of compliance must be completed. The guidance goes on to confirm that the stricter of the two regulations applies, however, if the FDA and HHS regulations disagree as to whether informed consent is waived. In that case, the HHS regulation will govern.

FDA informed consent exemption. Concerned that a delay in diagnosis caused by informed consent requirements during a potential terrorism event or other public health emergency could prove life threatening, the FDA created the exception to help ensure that individuals who may have been exposed to chemical, biological, radiological, or nuclear agents are able to benefit from the timely use of diagnostic devices, including those that are investigational.

The informed consent exemption is narrowly tailored and includes strict protocol. The exception applies only when IVD devices are used to test a specimen and the investigator is unable to obtain timely informed consent from the subject, or the subject's legally authorized representative(s), or when it is not feasible to obtain informed consent because, at the time the specimen was collected, it may not be known that an investigational device would need to be used on that specimen, and any delay in diagnosis could be life-threatening to the subject.

When an investigational device is used under these circumstances, the determinations of the investigator must be reviewed and evaluated in writing by a physician who is not participating in the clinical investigation within five working days after the use of the device. The evaluation also must be submitted to the institutional review board (IRB) within five working days. Additionally, investigators are required to disclose the investigational status of the device and any known performance characteristics in a report to the subject's health care provider and in all reports to public health authorities. The IRB is responsible for ensuring the adequacy of the information and that procedures are in place to provide the information to each subject. The rule expressly preempts any state informed consent law or rule different from the interim final rule. ■

HHS Guidance, June 7, 2006, Health Care Compliance Reporter ¶370,022.

Health Information Technology

Senate committee hears HIT update

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

HHS is giving the highest priority to fulfilling President Bush's commitment to promote widespread adoption of interoperable electronic health records (EHRs), according to Jodi G. Daniel, J.D., M.P.H. Director, Policy and Research Office of National Coordinator for Health Information Technology (ONC). Daniel gave her testimony on the progress of health information technology (IT) to the Senate Committee on Homeland Security and Government Affairs Subcommittee on Federal Financial Management Government Information and Information Security.

In 2004, President Bush announced his commitment to the promotion of health IT and called for widespread adoption of EHRs within 10 years. The HHS Secretary established the position of National Coordinator for Health Information Technology later in 2004, to advance the President's vision, Daniel said.

The ONC works closely with CMS and other agencies and departments to avoid unnecessary duplication of efforts. In 2004, the ONC identified four major goals: (1) inform clinical practice by accelerating the use of EHRs, (2) interconnect clinicians so that they can exchange health information using electronic communication, (3) personalize care with consumer-based health records and better information for consumers, and (4) improve public health through advanced bio-surveillance methods and streamlined collection of data for quality measurement and research.

HHS action. Two critical challenges to realizing the President's vision for health IT are now being addressed: (a) interoperability and electronic portability of health information using information technology and (2) EHR adoption, Daniels said. Further, the gap in EHR adoption between large hospitals and small hospitals, between large and small physician practices, and among other

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On The Front Lines

Joint venture imaging centers, Part 2: Preferred structural and restructuring considerations

by Paul R. DeMuro, C.P.A, M.B.A, J.D., and Katherine A. Lauer, J.D., Contributing Editors

Structuring an imaging joint venture in a way that minimizes compliance risks, while still attracting participation among those likely to contribute to the venture's success, presents substantial challenges. Part 1 of this article identified and discussed compliance isses. The following discussion explains some of the ways that risks can be reduced through structuring.

The lowest risk of violating the Stark law and/or the state or federal anti-kickback statutes exists when a joint venture has only radiologists as physician investors, due to the radiologists' limited ability to refer patients to the joint venture, which in turn limits the possibility of over utilization.

When a joint venture does include physician investors, ideally the venture will require that the investors contribute cash in an amount that corresponds to each investor's ownership interest. Increasingly, however, imaging joint ventures are requiring investors only to guarantee a portion of the joint venture's debt instead of requiring a cash contribution, or some combination thereof. To avoid liability under the anti-kickback law, the debt guarantees for all investors should either be pro rata, with each investor guaranteeing an amount equal to his or its ownership interest in the joint venture, or joint and several among all investors. Nonphysician investors should not provide joint and several guarantees if physician investors are guaranteeing only their pro rata share of the debt. Such a structure could appear to provide excess or inappropriate value to the physician investors.

Each investor should execute a debt guarantee with the lending institution providing the loan. The parties should not rely upon an operating agreement's requirement that each investor guarantee his or her pro rata share of the joint venture's debt if only certain parties have formally guaranteed the debt with the lender. If a bank will not allow pro-rata guarantees from all investors, the need for requiring cash contributions becomes even more important to avoid the appearance of providing inappropriate value to physician investors. Joint ventures may seek to add new investors after formation by requiring debt guarantees. Although this may be appropriate in situations in which the initial investors contributed debt guarantees and the joint venture has outstanding debt, it may not be appropriate when the joint venture has no outstanding debt. In these instances, the new investors could be viewed as having received an ownership interest in the joint venture while not contributing or risking anything of value.

If debt guarantees are used, all expenses of the venture, including start up costs, should be paid out of the working capital loan guaranteed by the investors or out of cash contributions. Nonphysician investors should not be the only parties to pay legal or other costs related to setting up any joint venture. If structured otherwise, this could be viewed as providing remuneration to physician investors who are potential referral sources.

In this same vein, the form of contribution from each investor should be the same. It may be viewed as suspect to have joint ventures permit some investors to provide debt guarantees while other investors make cash contributions because debt guarantees are likely to be viewed as assuming less risk. When a joint venture permits differing forms of contributions, an independent consultant should be engaged to value the joint venture, and the investors that initially provided debt guarantees should be required to contribute cash that reflects their ownership interests, while the investors that provided cash contributions should be required to execute pro-rata debt guarantees. For those entities that required debt guarantees from new investors, but did not have any outstanding debt, an independent consultant should be engaged to value the joint venture and the investors who received an ownership interest by providing a debt guarantee when the joint venture did not have any outstanding debt. New investors should be required to contribute cash based upon the valuation that reflects their ownership interest.

If a nonphysician investor extends any loans to the joint venture, the loans should be repaid in full, with interest at a commercially reasonable rate. If the nonphysician investors provide capital contributions to a joint venture, the other investors should be required to make cash contributions equal to the amount contributed by the nonphysician investors, as adjusted by any difference in ownership interests to avoid the appearance that the structure of the venture favors physician investors.

Directorship agreements. To reduce regulatory risks, a joint venture should contract only with radiologists for directorship services. Compensation should be verified independently as fair market value and paid on an hourly basis with a monthly maximum. The agreement must be in writing and clearly set out the duties of the director.

"Earn-ins." Joint ventures should not permit physicians to become investors by "earning in," i.e. forgoing distributions for a certain amount of time until the amount distributed would equal the capital contribution required for their ownership interest. An earn-in structure could be viewed as risk-free for these investors. A regulator could argue that the physicians were never at risk of losing anything in exchange for their ownership interest in the joint venture.

The Office of Inspector General's (OIG's) Special Fraud Alert (see Health Care Compliance Reporter ¶520,010) regarding joint ventures identified as suspect certain financing structures in which physicians invest an amount of capital that is disproportionately small and return on investment is disproportionately large when compared with a typical investment in a new business enterprise.

Modalities. Locations should not have separate joint ventures set up for different types of imaging services, or modalities. When this has occurred, an independent consultant should be engaged to value each joint venture. The joint ventures should then be merged into one entity with investors receiving an ownership interest in the resulting entity based upon the valuations.

Percentage lease agreements and purchased service agreements. It is preferred that joint ventures not enter into percentage lease agreements and/or purchased service agreements for diagnostic services with potential referral sources because it can be argued that such arrangements involve the payments for the referral of business. This does not preclude a nonphysician investor from entering into equipment leases or management agreements.

Management fees. Management companies with ownership interests in imaging joint ventures should receive a management fee and/or a billing fee from the joint venture in exchange for services provided, and such fees should be accounted for and paid before investors profits and distributions are calculated and paid. When this is not the case, a regulator may take the position that referral source owners were receiving remuneration, i.e., free management services, for their referrals.

Retirement. A joint venture's operating agreement should not require a physician owner to redeem his/her ownership interest upon retirement from the practice of medicine in the service area. A government entity may view such a requirement as evidence that the physician's ownership interest was based upon his/her referrals.

Recommendations and considerations for new joint ventures in this increasingly hostile regulatory climate

Taking into account the issues discussed above, and particularly in light of the increased regulatory activity aimed as imaging joint ventures, we recommend that new imaging joint ventures be structured consistent with the following guidelines.

Capital Contributions:

(1) To minimize the amount of risk with respect to the Stark law, and the state and federal anti-kickback statutes, each investor should contribute cash in an amount that is directly proportionate to his or her ownership interest and not related to the volume or value of referrals provided by the physician investor.

(2) Debt guarantees, in addition to cash contributions, may be acceptable as long as the guarantees are pro rata with each investor guaranteeing a share of the entity's debt that directly corresponds to each investor's ownership interest or joint and several for all investors. Each investor should execute a debt guarantee directly with each lending institution that provides a loan to the joint venture.

Distributions:

- All distributions to investors should be directly proportionate to each investor's ownership interest.

Multiple Modalities:

- All multiple modalities should be encompassed in one joint venture

Selection of Investors:

- Investors should be selected irrespective of their ability to refer patients to the joint venture. For example, investment opportunities should be marketed to either all physicians in the community regardless of their ability to make or influence referrals; or only nonreferral sources (radiologists).

Marketing:

- Joint ventures should develop written marketing policies and procedures. At a minimum, these policies and procedures should include a discussion that providing anything of value to a potential referral source could implicate federal and state anti-kickback statutes and the Stark law. This include gifts, entertainment, and professional courtesy discounts as well as social events sponsored or hosted by a joint venture such as meals, sporting events, theatrical events and/or receptions.
- Under the non-monetary compensation exception to the Stark law, items of value may be provided to a potential referral source and his or her immediate family members, however, the total value of such business courtesies may not exceed $322 per calendar year (as adjusted annually pursuant to the Stark non-monetary compensation exception). No benefits may be offered or provided as an inducement to refer patients or business or as a reward for such referrals. In addition, business courtesies should not be extended to a potential referral source who solicits it.
- A tracking mechanism to monitor compliance with the annual nonmonetary compensation limit should be created. A "Business Courtesies Log" or something similar should be enacted for each joint venture to monitor all nonmonetary items of value provided to potential referral sources.

Managed Care Plan Considerations:

- Managed care plans are seeking to require certain things of joint venture imaging centers as noted above. Expectations also might include taking Medicare and Medicaid patients.

The Budget Reconciliation Act of 2005 ("BRA")

- The BRA ties payment of IDTFs for most imaging services (except diagnostic and screening mammography) to either what is paid by an outpatient department in the applicable geographic area, or the level set by CMS under its new multiple imaging policy. For 2006, this policy cuts Medicare payment by 25 percent for the second technical component of service performed on a Medicare patient on the same day or a contiguous body part when the imaging service is from the same group of codes. In 2007, the payment cut is 50 percent for the second technical component.

OIG's focus on contractural joint venture arrangements

In addition to the issues presented by ownership joint ventures, the OIG has expressed through a special advisory bulletin its concern about the proliferation of so-called "contractual joint ventures." The bulletin focused on contractual joint ventures that use a combination of "shell" entities and subcontracting arrangements with providers of related health services to disguise illegal kickbacks. (See Health Care Compliance Reporter¶ 520,024). The issues to consider in this regard include:

- Is a healthcare provider in one line of business (owner) expanding into a related health care business by contracting with an existing provider of a related item or service (e.g. manager/supplier) to provide the new item or service to the providers existing patient population?
- Does the owner operate the new line of business itself?
- Does the owner commit substantial financial capital, or human resources to the venture? Or does it merely contract out substantially all the operations of the new business?
- Are noncompetition covenants involved?
- Is the owner's actual business risk minimal because of the owner's ability to influence substantial referrals to the new business?
- Is the manager/supplier an established provider of the same line of services as the owner's new line of business?
- Does the manager/supplier take its share in the form of payments under various contracts with the owner?
- Do aggregate payments to the manager/supplier typically vary with the value of volume of business generated for the new business by the owner?

Thus, even when a formal joint venture structure is not adopted, those developing imaging centers should be aware of their contractual arrangements and strive to structure them to minimize the risk of OIG scrutiny.

Conclusion

It remains to be seen whether the current opposition by health plans and hospitals and increased scrutiny by state and federal regulators will put a damper on the boom in imaging joint venture growth. While the regulatory risks can be formidable, the rewards of these ventures can be significant. Potential venturers should be motivated to develop structures that continue the possibility of financial rewards, while mitigating against compliance risks. ■

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Health Information Technology (cont.)

healthcare providers also must be addressed. This adoption gap has the potential to shift the market in favor of large players who can afford these technologies, and can create differential health treatments and quality.

ONC is meeting these challenges by: (1) harmonizing health IT standards; (2) promoting the certification of health IT products to assure consistency with standards; and (3) addressing variations in privacy and security policies that can pose challenges to interoperability; and (4) developing a prototype, nationwide, Internet-based architecture for sharing of electronic health information. The Secretary established a federal advisory committee, the American Health Information Community, charged with making recommendations regarding the federal government's role in responding to those challenges.

Stark and anti-kickback. Last October, CMS proposed regulations that support adoption of e-prescribing and EHRs. The proposed regulations would create exceptions to the "physician self-referral" law to allow hospitals and certain health care organizations to furnish hardware, software, and related training services to physicians for e-prescribing and EHRs, particularly when the support involves systems that are "interoperable." In addition, the Office of Inspector General announced proposed safe harbors for arrangements involving the donation of technology for e-prescribing and EHRs that would be exempt from enforcement action under the federal anti-kickback statute.

The full text of the testimony is located at www.hhs.gov/asl/testify/t060622a.html. *HHS Testimony, June 22, 2006.* ■

IT bill advances despite opponents' privacy concerns

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

The controversial Health Information Technology (IT) Promotion Act of 2006, which promotes the use of health information technology through implementing government standards and provides safe harbors for private funding for acquisition of IT systems, was approved by the House Committee on Ways and Means. A similar version was adopted by the Energy and Commerce Committee. Opponents argue that the bill ignores privacy concerns and the need for patient control over medical records.

Elements. According to Ways and Means Chairman Bill Thomas (R-Calif.), the bill would "remove legal barriers that currently prevent the private sector from efficiently coordinating information and technology, leveraging private - not public - dollars to promote health IT." Specifically, the bill would:

- codify the Office of the National Coordinator for Health Information Technology and delineate its responsibilities in coordinating federal health information technology efforts;
- allow entities to provide physicians with hardware, software, or related services used for the electronic exchange of clinical health information;
- enable private sources of funding to finance physician adoption of electronic health records systems without running afoul of the fraud and abuse statutes;
- prohibit the use of volume or value of referrals as a quid pro quo for the provision of health IT;
- require the Secretary of HHS to conduct a study on the impact of variation between state and federal security and confidentiality laws;
- require the Secretary to adopt the new ICD-10 coding system;
- require the Secretary to adopt or reject proposed modifications or additions to existing coding and transaction standards within 90 days if the National Committee on Vital and Health Statistics (NCVHS) recommends the change;
- require the development of a strategic federal plan to coordinate implementation efforts for health information technology standards, transaction standards, and new coding systems;
- ensure that the development of electronic health records are coordinated with ongoing efforts to implement electronic transaction standards developed under the Health Insurance Portability and Accountability Act (HIPAA); and
- require the Secretary of HHS to take steps that expedite the provision of telehealth services across state lines by taking a closer look at state licensure issues.

The Energy and Commerce Committee's version, the "Better Health Information System Act of 2006," drops the requirement to adopt the ICD-10 coding system and the requirement to study and make recommendations to provide consistency in state and federal privacy and security laws.

Opposition. According to Deborah C. Peel, M.D., Chairman, Patient Privacy Rights Foundation, "neither version of this HIT bill gives patients control over who can access their medical records, or the right to opt out of electronic systems. That leaves all Americans vulnerable to companies and individuals who want to use this very private information for reasons unrelated to health care or payment." Amendments offering greater privacy protections were voted down along party lines in both committees.

The growing concern over the lack of privacy protections cuts across the political and ideological spectrum. Organizations including the Christian Coalition, the American Civil Liberties Union, Family Research Council and Consumer Action, have urged Congress to include a number of privacy protections in the legislation including:

- recognizing a patient's right to medical privacy;
- giving patients control over who can access their health information across electronic health information networks;
- giving patients the right to opt-in and opt-out of electronic systems;
- giving patients the right to segment sensitive information;
- requiring audit trails of every disclosure of patient information and allow patients to review those disclosures;
- requiring that patients be notified of suspected or actual privacy breaches;
- providing meaningful penalties and enforcement for privacy violations;
- denying employers access to employees' medical records; and
- preserving stronger privacy protections in state laws.

Although the Patient Privacy Rights Foundation supports the implementation of electronic medical records to improve health care and reduce costs, it argues that ironclad privacy and security protections should be in place first.

"We are puzzled why the House can reach bipartisan agreement on bills to afford Americans protections of their financial data and to prevent identity theft, and yet not reach bipartisan agreement to protect patient's medical records," Peel said.

According to the Foundation, there is reason to worry about the lack of privacy protections. National research shows that Americans will avoid treatment, be less than truthful about symptoms, omit critical medical data, and delay care if they are compelled to share their medical records over electronic health networks without adequate privacy safeguards.

Peel argues that while victims of identity theft can ultimately straighten out their records, "victims of medical privacy abuses will live with the consequences such as loss of jobs or insurance, discrimination, being denied access to schools, or getting sick because they've avoided health care for the rest of their lives."

Although the bill was approved in the committees, House republicans have said they plan to hold off on the legislation after the Congressional Budget Office projected that the bill would increase direct spending and reduce revenues. ■

House Ways and Means Committee Press Release, June 15, 2006, Patient Privacy Rights Foundation Press Release, June 16, 2006.

Fraud & Abuse

Tenet settles FCA allegations for $900 M

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

Tenet Healthcare Corporation Tenet has agreed to pay $900 million over a four-year period, plus interest, to resolve allegations of unlawful billing related to outlier payments, physician financial arrangements, and coding issues, according to Assistant Attorney General Peter D. Keisler of the Civil Division and U.S. Attorney Debra Wong Yang of the Central District of California in Los Angeles..

Under the agreement, Tenet will pay:

- more than $788 million to resolve claims arising from Tenet's receipt of excessive "outlier" payments resulting from hospitals' inflating their charges substantially in excess of any increase in the costs associated with patient care and billing for services and supplies not provided to patients;
- more than $47 million to resolve claims that Tenet paid kickbacks to physicians to get Medicare patients referred to its facilities and billed Medicare for services that were ordered or referred by physicians with whom Tenet had an improper financial relationship; and
- more than $46 million to resolve claims that Tenet engaged in upcoding.

CIA. Tenet also has reached an agreement in principle with the Office of Inspector General to enter into a multi-year corporate integrity agreement (CIA). Under the agreement, OIG will not exclude Tenet hospitals or entities from any federal health care program provided Tenet executes an acceptable CIA, which the company expects to do within 90 days. Tenet will maintain its existing compliance program, but will retain an independent review organization to provide an external review of the company's ongoing compliance in the areas of Medicare coding, physician financial relationships, setting of hospital charges and quality of care. ■

Department of Justice News Release, June 29, 2006; Tenet News Release, June 29, 2006.

In the News

FDA to integrate adverse event reporting systems

The Food and Drug Administration (FDA) plans to establish a single electronic system for collecting adverse event information on drugs and medical devices, according to Randy Levin, director for health and regulatory data standards. The agency plans to establish a website where patients, physicians and manufacturers will have an easy way to report adverse events. In addition, it will allow FDA to transfer information from one system to another, Levin said. "We're trying to harmonize adverse event reporting ...to allow our different systems to coordinate with each other." Currently, several systems are isolated and do not understand a common language, Levin explained. He described the present systems as silos, stating that under the new system, a single report that applies to two products can be sent at once to both products, which will improve efficiency. Levin predicted that the new system will be "very beneficial." Although there's no set timetable for getting the website up and running, he said the FDA is "actively working on it."

CCH Washington Bureau, June 23, 2006.

Dietary supplement adverse event bill approved

The Senate Health, Education, Labor and Pensions Committee on June 28, 2006, approved by unanimous consent the Dietary Supplement and Nonprescription Drug Consumer Protection Act (S.3546), a bill to mandate the reporting of serious adverse events related to the consumption of dietary supplements. The bill introduced by Sen. Orrin Hatch (R-Utah) would require any manufacturer, packer, or distributor whose name appears on the label of a nonprescription drug or dietary supplement marketed in the United States to submit to the HHS Secretary any report received of a serious adverse event associated with a drug or product. A "serious adverse event" is an event that results in a death, life-threatening experience, inpatient hospitalization, persistent or significant disability or incapacity, or congenital anomaly or birth defect; or an event that requires a medical or surgical intervention to prevent one of those outcomes.

CCH Washington Bureau, June 28, 2006.

DRA proof of citizenship requirement challenged

A class-action lawsuit was filed on June 28, 2006, challenging the constitutional validity a new provision under the Defecit Reduction Act of 2006 (PubLNo 109-171) that requires Medicaid recipients to prove their citizenship to receive benefits. The plaintiffs claim that the law harms those who can't produce citizenship documents, even though there is no doubt they are American citizens. The people at greatest risk of losing Medicaid coverage due to their inability to present passports, birth certificates, or other special documents are seniors in nursing homes, people with mental or physical disabilities, disaster victims, and people not born in hospitals (sometimes due to racial discrimination, especially in the South) who never had birth certificates. The plaintiffs' attorneys expect to seek an immediate hearing so that the law can be prevented from going into effect on July 1, 2006.

CCH Washington Bureau, June 28, 2006.