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Combining risk management and compliance assessments

by Catherine Hubbard, M.A., Contributing Editor

Assessing both risk and compliance under an enterprise-wide program can be complicated, but sizing up both regulatory compliance and quality of care efforts can reduce risk, improve the quality of patient care and reduce overall organizational expenses, according to Scott Jones, a principal partner and senior risk analyst for IntegraRisk, Carencro, La.

"Compliance and risk management can and should work hand in hand," he said during a Health Care Compliance Association audio conference on July 27.

Merger of risk management with compliance. Compliance programs and compliance officers are relative newcomers to many healthcare organizations, Jones said. While compliance departments frequently are focused primarily on reimbursement and billing related risks, traditional risk management departments usually are staffed and organized to manage liability claims related to malpractice, general liability claims or injury, worker's compensation and property and casualty, he explained. "Few organizations have completely merged the traditional risk management process with the newer regulatory compliance process," he said.

Improvement in quality of services. Jones recommended a proactive approach: "Proactive prevention is the best process we can establish," he said, emphasizing that this takes thorough communication, a common set of goals and standards, and dedication to improving quality. Through such an approach, risk reduction in regulatory compliance should improve the quality of services and protect organizations against costly investigations, lawsuits and settlements, he stressed.

Review current auditing and monitoring. Organizations should start by reviewing their current auditing and monitoring tools, before creating new processes and work for staff, said Jones. He recommended that facilities create a list of existing risk assessment processes, such as physical plant safety; tools for monitoring facility staffing, and processes for reviewing and assessing incomplete areas in medical records. Facilities should also examine coding and billing audit processes, refund and denial audit processes, management, and subcontractor management, he said.

Health care quality. Most organizations are beginning to understand that their compliance programs should address more than just billing concerns, Jones said, noting that substandard care can result in allegations of fraud or abuse just as improper billing can. "Quality is a key factor in both compli-

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ance and malpractice issues," Jones emphasized.

"Improving quality of care can provide better services for the patients we serve," he said, adding that Office of Inspector General (OIG) program guidance "is geared toward identifying and eliminating waste, fraud, and abuse, particularly when it is related to poor quality or sub-standard care."

Coupling of allegations. Moreover, he said, allegations for sub-standard care typically are coupled with allegations of improper billing and reimbursement schemes. Quality allegations can apply to understaffing, unclean facilities, or a lack of linens, food, medications and expected services. They also can apply to inadequate medical record documentation and provider visits with patients that are too brief. Failures such as these "frequently open the door for medical malpractice and general liability claims," said Jones.

Obtaining insurance. Not only can poor quality care lead to fraud and abuse allegations, but it also can affect both the cost and availability of insurance for healthcare organizations and individual providers, Jones said. Insurance providers are more cautious about risk exposure and more likely to charge high premiums for providers with perceived quality issues, he said. "Insurance underwriters are focused on a wide range of indicators when they assess risk - and the cost of insurance that is related to that risk," he said, recommending that organizations provide underwriters information on their quality focus. "This perception will affect premiums, deductibles, self-insured retentions, and even whether insurance coverage will be offered," he added.

Underwriter considerations. Underwriters may examine risk assessment reports from on-site assessments, off-site assessments based on documents and interviews, state license and certification reports, loss run reports from prior years, analysis of open claims, submissions data prepared by facilities and their insurance agents and news reports and other public information. "Underwriters are increasingly aware of regulatory compliance efforts by the OIG and the Department of Justice, and how frequently quality of care issues are cited in investigations," he said.

OIG program guidance. The OIG wants organizations to link traditional risk management and regulatory compliance to improve responsibility for billing claims and to improve quality of care, Jones said. "The concept is that proper accountability can regulate both how organizations provide services and how they bill for them."

Collaboration. Jones recommended breaking down the OIG program guidance into standards that can be scored, conducting a comprehensive liability risk assessment and relying on objective analysts who are knowledgeable about operations, risk, and compliance. "Risk assessment requires some independence to allow for objectively and the ability to honestly assess risk," he said.

However, Jones said risk managers, compliance officers and the facility's executives need to work together to implement a system-wide process. "All parties need to cooperatively work to develop processes that will address the needs of patients, the facilities, insurance underwriters and regulators," he said. Jones added that the support of senior administration or management "is essential to establishing an effective process. There must be buy-in at the senior level - even at the Board of Directors level."

CCH Washington Bureau, August 8, 2005

Proposed bill and establishment of committee advance health IT

by Sheila Lynch-Afryl, J.D., Contributing Editor

A proposed bill aimed at increasing health care provider use of Information Technology (IT), entitled the Better Healthcare Through Information Technology Act, was introduced by Senator Mike Enzi (R. —Wy.) and Senator Edward Kennedy (D. —Mass.) to accelerate the adoption of IT and implementation of a nationwide system of electronic medical records. The rate of use of IT is low even though the estimated savings from the use of an IT system is $140 billion.

Proposed savings. The higher savings level may cut the cost of a single family's health insurance policy by more than $700 per year. Senator

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Portfolio Managing Editor
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Coordinating Editors
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CCH Washington Bureau
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Designer
Kaveh D. Ryndak

Comments from readers are welcome and should be directed to Andra Popa at popaa@cch.com, Tel. 847-267-2476, Fax 847-267-2514. Customer service inquiries should be directed to 800-449-9525.

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NY Governor plans to fight Medicaid fraud and abuse

by Sheila Lynch-Afryl, J.D., Contributing Editor

New York Governor George E. Pataki revealed a new five-point plan to strengthen the state's ability to fight Medicaid fraud, waste, and abuse.

Among the measures included in Pataki's plan are:

- the creation of a Medicaid Inspector General (MIG), who will better integrate New York's Medicaid anti-fraud efforts;
- the appointment of former federal prosecutor Paul Schechtman to recommend long-term reform of the state's fraud efforts;
- push for federal approval of the state's pending request to join an existing federal Medicaid fraud detection program; and
- measures that will expand the use of existing state resources and agencies to combat fraud.

MIG functions. The function of the MIG will be to integrate and efficiently coordinate and utilize Medicaid anti-fraud resources currently scattered among several state agencies. The MIG will have broad authority to subpoena witnesses, administer oaths, examine witnesses under oath, and require the production of records deemed relevant or material.

The MIG also will work with federal and local government officials and will coordinate its activities with the Medicaid Fraud Control Unit, which is statutorily responsible for prosecuting all cases of alleged provider-based criminal Medicaid fraud, as well as the state Office of Welfare Inspector General, which is responsible for investigating and prosecuting cases of alleged recipient-based criminal Medicaid fraud.

In addition to the creation of the MIG position and the appointment of Schechtman, Pataki plans to leverage the clinical resources of the State University of New York medical schools to help review the medical necessity and appropriateness of services delivered to Medicaid recipients, and to further enhance the state's success in employing technology to detect and prevent Medicaid fraud, waste and abuse.

HHS Release, July 14, 2005

Medi-Cal HMO execs indicted for fraud

Gene' Stephens, J.D., Contributing Editor

The California Attorney General's Office (A.G.) has indicted two top executives of Tower Health, a health maintenance organization (HMO), with eight felony charges of grand theft, perjury, Medi-Cal fraud, and filing false corporate financial reports. The executives were indicted for allegedly siphoning more than $2 million of health care reimbursements that should have been disbursed to physicians who provided care to Medi-Cal patients. An additional $10 million was allegedly loaned to other companies owned by the executives, including loans to their family members. If convicted, the executives will face between nine and seventeen years in state prison, as well as maximum fines of up to $7.2 million.

The resulting investigation led the California Department of Managed Health Care to take possession of Tower Health to prevent patient enrollees from losing their health care. The investigation is one of over 850 criminal cases that the A.G. has prosecuted to prevent Medi-Cal fraud, a top priority for the administration. The A.G.'s health care fraud and abuse investigations led to a national award from the Department of Health and Human Services for having the top-performing health care fraud and elder abuse prosecutorial program in the country.

Department of Justice Press Release, July 20, 2005.

Health benefits company settles with physicians

by Barbara Leopold, J.D., M.S.

A commerical health benefits company, WellPoint, Inc., reached a settlement with over 700,000 physicians who alleged the company systematically reduced or denied payments in processing their claims. As part of the agreement, WellPoint, Inc. agreed to pay: (1) $135 million to physicians, (2) $5 million to a not-for-profit foundation whose mission is to promote higher quality healthcare and enhance care delivered to the disadvantaged, and (3) up to $58 million in legal fees. If approved by the court, the agreement will resolve two national lawsuits against two companies that merged to form WellPoint, Inc. ■

CCH Chicago Bureau, July 20, 2005.

On The Front Lines

Heightened government oversight in clinical trials: Non-FDA regulatory issues that sponsors should monitor

by Leesa Klepper, J.D.

Companies that sponsor clinical trials ("sponsors"), as well as the institutions and investigators who perform the studies, face enormous challenges today in the review, conduct and administration of such research. In addition to ensuring compliance with evolving federal regulations, these entities must also consider relevant ethical standards and changing cultural values as technology and science develop. Moreover, they must be ever mindful of heightened government oversight and scrutiny, especially in areas such as fraud and abuse and false claims, which have been somewhat underappreciated in the clinical trial context.

1. Increased government oversight

This article discusses recent federal and state governmental actions which suggest increased oversight and scrutiny of clinical trials, especially in areas such as fraud and abuse, false claims, and privacy. For example, just a few months ago, the government settled a case with a prestigious academic medical center involving allegations that the university violated the False Claims Act by, among other things, unlawfully billing Medicare for clinical research trials that were also billed to the sponsor of research grants. In addition, the risk areas recently identified by the Office of Inspector General of Health and Human Services ("OIG") – which provide valuable insight into federal enforcement priorities – include medical research activities and should considered by research participants when reviewing and developing clinical research programs. In addition, certain states have developed, or are in the process of developing, compliance obligations specific to the types of companies that sponsor clinical trials.

Such increased government attention suggests that research participants should review their clinical trial documents and policies in key areas to ensure compliance and minimize risk. This article addresses three areas of risk – physician compensation, clinical care costs, and privacy of medical records – and then discusses ways that such risks can be reduced in the written clinical trial agreement ("CTA"), which documents the respective rights and obligations of each party. The CTA plays an important compliance role by serving to minimize regulatory problems, preserve the quality of data and integrity of the research, and protect human subject participants.

2. Physician compensation

A. Legal and compliance issues

One of the most significant areas of risk in a research relationship involves physician compensation and research funding. Compensation from pharmaceutical or device companies to physicians for their participation in clinical research may be prohibited by the federal Anti-Kickback Law ("AKB") if intended to induce the purchase of items or services that will be reimbursable by a federal health care program.

The AKB prohibits any person from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, to induce the referral of an individual or the furnishing of or arranging for a good or service for which payment may be made under federal health care programs. The law punishes persons on both sides of a prohibited transaction. Violations are punishable by up to five years in prison, criminal fines, civil money penalties, and exclusion from participation in federal health care programs. The federal government has issued regulations, commonly known as safe harbors, that set forth certain provisions which, if fully met, will assure health care providers and other parties that they will not be prosecuted under the AKB. Although full compliance with these provisions ensures against prosecution under the AKB, the failure of a transaction or arrangement to fit within a specific safe harbor does not necessarily mean that the transaction or arrangement is illegal or that prosecution under the AKB will be pursued.

Recently, the OIG has issued compliance program guidance that has called attention to research funding

as an area of potential risk under the AKB. For example, in 2003, the OIG issued its "Compliance Program Guidance for Pharmaceutical Manufacturers," which states, among other things, that contracts between pharmaceutical companies and a physician to provide research services could implicate the AKB. The OIG states that since research relationships involve the provision of something of value from a manufacturer to a physician who might prescribe the manufacturer's product, the manufacturer should examine whether it is providing the physician a valuable benefit with the intent to induce or reward referrals. The OIG instructs manufacturers to be certain that any provision of research grant funds is for bona fide research purposes. The OIG also suggests that contracts between manufacturers and physicians for research services be structured to fit within the "personal services" safe harbor to the AKB, whenever possible. The safe harbor provision requires that payments for research services be fair market value for legitimate, reasonable and necessary services.

The pharmaceutical and medical devices industry groups have also issued guidance related to relationships between manufacturers and physicians, including clinical trial arrangements, in order to ensure AKB compliance. For example, both the Pharmaceutical Research and Manufacturers Association (PhRMA) Code and the Advanced Medical Technology Association (AdvaMed) Code advise that arrangements between manufacturers and physicians should be for bona fide purposes and the services should be legitimate and specified in a written contract. In addition, certain states have set forth compliance obligations for drug makers and device manufacturers which will affect the conduct of clinical trials. For example, a new California law, which became effective on July 1, 2005, requires companies to comply with industry's voluntary guidelines and the OIG compliance guidance.

B. Implications for the CTA

Prudent sponsors and investigators, therefore, should ensure that the CTA is structured to meet the AKB safe harbor requirements and the industry guidelines. In particular, in the CTA: (a) the services to be provided should be clearly and specifically identified and costs should be allocated accordingly; (b) compensation should reflect the fair market value of the services provided; (c) compensation should not vary with the volume or value of referrals; and (d) the term of the agreement should be at least one year. The CTA should also address whether any payment will be made for screen failures or enrollees lost to follow-up and whether there is a process to return excess or unused funds, which could otherwise be seen as an improper benefit to physicians. It is important to remember that the OIG looks at compensation "in the aggregate" so all payment terms should be considered together and specified in the CTA.

The payment methodology and amount should also be set forth in sufficient detail to ensure that there is no improper inducement to refer patients (i.e., that no financial incentives exist to coerce patient participation). Payment to research institutions or individuals for purposes of increasing the numbers and/or rate of enrollment of people into research studies raise legal, as well as ethical, issues. Incentives include not only monetary payments but also reimbursements for travel or other expenses that may or may not be relate to the study. "Finder's fees," bonuses or other payments to increase enrollment may violate federal regulations, and compromise research integrity, and should be carefully considered and reviewed.

3. Reimbursement of clinical care costs

A. Legal and compliance issues

In addition to focusing on anti-kickback issues, the OIG intends to focus on whether Medicare payments for clinical trials are being made in accordance with program specifications. In its "Supplemental Compliance Program Guidance for Hospitals," issued on January 31, 2005, the OIG stated that hospitals should pay heightened attention to the risk of improper claims for clinical trials. The guidance states that the risks associated with the submission of claims in clinical trials may be "under-appreciated" by the industry. The guidance suggests that hospitals participating in clinical trials review the requirements for submitting claims for clinical trial patients and ensure that they are not submitting improper claims. Consequently, sponsors should be familiar with the compliance issues implicated by billing for clinical trial services and be able to appropriately document costs so that participating institutions may be properly reimbursed.

The submission of improper claims in clinical trials could subject an institution to scrutiny under the federal False Claims Act, which prohibits anyone from knowingly presenting, or causing to be presented, for payment to third-party payors (including Medicare and Medicaid) claims for reimbursed items or services, including drugs or services, that are false or fraudulent, claims for items or services not provided as claimed or claims for medically unnecessary items or services. The False Claims Act imposes civil and criminal liability on individuals and entities who submit, or cause to be submitted, false or fraudulent claims for payment to the government, and imposes penalties for a violation include three times the actual damages sustained by the government, plus

mandatory civil penalties of between $5,500 and $11,000 for each separate false claim.

Medicare does not provide coverage for experimental or investigational items or services. Medicare will, however, cover the "routine costs" of "qualifying trials" and "reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials." "Routine costs" generally include all items and services that are otherwise generally available to Medicare beneficiaries and that are provided in either the experimental or the control arms of a clinical trial. Clinical trials often include tests or other items of services that are important to the scientific purposes of the study but are generally not offered as treatment to non-study patients, and such treatments are therefore not considered "routine" by Medicare. However, many clinical trials involve elements of care that are "routine" and will be covered by Medicare if the trial meets certain criteria (known as "qualifying criteria"), such as that the trial must have therapeutic intent and the purpose of the trial must be the evaluation of an item or service that falls within a Medicare benefit category, such as durable medical equipment. In addition, under federal regulations, providers should not bill insurers for specific treatments or items of costs that have been financed by research funding, even if those treatments or items would otherwise be reimbursable by insurers.

B. Implications for the CTA

Therefore, entities participating in clinical trials should ensure compliance with insurance coverage and billing rules for care received by patients enrolled in the trials. As a general matter, the CTA should clearly identify the clinical care costs that the sponsor is covering, as well as any costs that will be borne by other parties, whether Medicare or another third party insurer, the subjects, and the investigator. Specifically, before a clinical trial is conducted, the study design should be carefully reviewed by both the sponsor, investigator and institution to identify the treatments that will be solely conducted for purposes of the study. Such "study-only" treatments should not be billed and should be added to the research budget as non-insured patient care costs. The CTA should detail those clinical trial treatments that are not reimbursable by an insurer but will be covered by the sponsor as part of the research funding. The CTA should also specify in detail the clinical care costs that will be reimbursable by an insurer, including Medicare. (In general, the sponsor will not cover reimbursable costs.) If the CTA does not specify the purpose of funding, an insurer may claim that all clinical care costs were intended to be covered by the sponsor. In addition, the allocation of costs in the CTA should be consistent with the allocation of costs in any other documents, such as the research protocol or informed consent form.

4. The Privacy Rule and medical records

A. Legal and compliance issues

The standards for Privacy of Individually Identifiable Health Information ("Privacy Rule") issued pursuant to the Health Information Portability and Accountability Act of 1996 ("HIPAA") (PubLNo. 104-191) protect the privacy of individually identifiable health information and prohibit the use or disclosure of such information except as required or permitted by HIPAA.

While clinical trial sponsors may not be directly covered by the Privacy Rule, institutions and investigators are likely covered entities and required to be compliant with the Privacy Rule. Investigators' failure to comply with the HIPAA provisions could lead to patient complaints, government investigations, and loss of access to trial data. Therefore, it is advisable that CTAs address the Privacy Rule. Requiring investigators to comply with HIPAA will ensure that investigators have the ability to use and disclose protected health information necessary to conduct research, and that the sponsor will be able to obtain the results of that research.

B. Implications for the CTA

The OIG recently stated that it plans to conduct an assessment this year of universities' policies and procedures for protecting the privacy of medical records of research subjects. As a best practice, sponsors, institutions and investigators should develop a clear understanding of how they will share information and the privacy protections to be afforded to subjects' data. The CTA should include language that makes it clear that the HIPAA protections will be incorporated into the trial process. It is advisable for the CTA to include representations and warranties that address privacy and protect the sponsor's access to protected health information. For example, the CTA can include a representation that the investigator and institution will comply with HIPAA, obtain HIPAA authorizations and other consents, as required, and list recipients of protected health information on the consent form (including the sponsor, and, if relevant, any contract research organization or sponsor agents and employees).

5. Conclusion

As research involving human subjects becomes increasingly scrutinized by the federal government and the public, sponsors, institutions and investigators will need to pay heightened attention to the terms of the clinical trial agreement, and also ensure that other clinical trial documentation, such as the protocol, HIPAA authorization, and informed consent form, are consistent with the agreement. In particular, in order to avoid violating federal regulations, as well as institutional policies, careful attention

On The Front Lines (cont.)

should be paid to terms such as those relating to compensation and budget, clinical care costs and reimbursement, and privacy of subjects' records. A revised clinical trial agreement that takes into consideration these heightened regulatory risks is crucial to successful research relationships and essential to product approval.

[1] See, e.g., The Washington Post, "Findings: Fear of Controversy Inhibits Research," February 11, 2005, Page A14, citing an article in the journal Science concluding that some scientists are thinking twice about doing or reporting certain research because of political and social controversy as well as legal restrictions.

[2] See, e.g., "University of Alabama-Birmingham Will Pay U.S. $3.39 Million to Resolve False Billing Allegations," Associated Press News Release, April 14, 2005.

[3] See 42 U.S.C. §1320a-7b(b).

[4] See 68 FR 23731, 23738 (May 5, 2003). The OIG notes that there is no substantive difference between remuneration from a pharmaceutical manufacturer or from a durable medical equipment provider or other supplier for purposes of the AKB.

[5] The OIG also notes that research-related contracts with physicians that originate through the sales and marketing departments (or that are offered in connection with sales of goods) are highly suspect. Relevant factors include whether the research is initiated or directed by marketing and sales agents, whether the research is reviewed by the manufacturer's science department, whether the research is unnecessarily duplicative or is not needed by the manufacturer for any purpose other than the generation of business, or whether the research is a pretense to promote a product. The OIG advises manufacturers to develop contracting procedures that separate the awarding of research contracts from marketing or promotion of the products. *Id.*

[6] See "Pharmaceutical Research and Manufacturers Association (PhRMA) Code on Interactions with Healthcare Professionals," issued in April 2002, *available at* <http://www.phrma.org>, and Advanced Medical Technology Association (AdvaMed) Code on Interaction with Health Care Professionals, issued in January 2004, *available at* <http://www.advamed.org>.

[7] See Senate Bill 1765, which passed the Senate and Assembly in August 2004 and was filed with the Secretary of State on September 30, 2004.

[8] See 70 FR 4858 (January 31, 2005). In this document, the OIG defines "hospital" broadly to include individual hospitals, multi-hospital systems, health systems that own or operate hospitals, academic medical centers, and any other organization that owns or operates a hospital.

[9] *Id.* at 4860.

[10] See National Coverage Decision, Sept. 19, 2000.

[11] See Medicare Coverage Issues Manual, §30-1.

[12] See the Medicare Coverage Issues Manual, §30-1 for a complete list of the requirements that must be met in order for a clinical trial to qualify for coverage under Medicare, and for a description of the qualification process.

[13] See Medicare Provider Reimbursement Manual, Section 504.1.

[14] Moreover, if the trial permits a waiver of a study patient's costs, such waiver should be carefully considered in accordance with the civil monetary penalty regulations prohibiting patient inducement. Federal law prohibits offering gifts and other inducements, including waivers of copayments, to beneficiaries that are likely to influence the beneficiary to order or receive items or services from a particular practitioner or supplier. See 42 U.S.C. §1320a-7a(a)(5). However, the OIG has indicated that it may propose a new exception for free goods or services, possibly including waivers of copayments, in connection with certain clinical trials sponsored by NIH or HHS. See OIG Special Advisory Bulletin, "Offering Gifts and Other Inducements to Beneficiaries," Aug. 30, 2002.

[15] Department of Health and Human Services, Office of Inspector General Work Plan Fiscal Year 2005, at 14. The OIG plans to issue a report on the privacy of research subjects' medical records in FY 2005.

Leesa Klepper is an attorney in Washington, D.C., where she specializes in health care law and policy, and constitutional law. She has represented hospitals, academic medical centers, research organizations, and biotechnology companies on a wide variety of health care regulatory and legislative matters, including clinical (human) research. She is currently an adjunct Professor at American University Washington College of Law. Previously, she served for three years as Counsel to the U.S. Senate Judiciary Committee for Senator Patrick Leahy. She can be reached at leesa_klepper@hotmail.com.

Trends (cont.)

Enzi stated that the proposed bill "will bring the government and the private sector together to make healthcare better, safer and more efficient by accelerating the adoption of IT."

Community Established. To develop standards and achieve interoperability of health information, the Department of Health and Human Services (HHS) previously established the American Health Information Community (Community). As a public-private collaboration, the Community will provide a forum for public and private interests to recommend actions to accelerate the widespread application and adoption of electronic health records and other health IT. The draft charter for the Community was posted on the HHS web site and the notice of the formation of the Community was published in the *Federal Register.*

"Our health care system is saturated with inefficiency," HHS Secretary Mike Leavitt said. "Until we adopt modern information technology practices--like electronic health records, e-prescribing, and systematic adverse drug event reporting--we will have no cost-effective medical care in this country, and we will have far too many medical errors. The American Information Community will accelerate the development of standards necessary for the modernization we need."

The Community will be governed by the Federal Advisory Committee

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Trends (cont.)

Act and will have up to 17 members appointed by the Secretary of HHS. These members will include officials from HHS and representatives from other approrpiate federal agencies, state government, and the private sector. Members will serve two-year terms.

Public sector. The Secretary will appoint eight members from the federal government, including HHS, Department of Veterans Affairs, Department of Defense, Department of Commerce, Department of the Treasury, Office of Personnel Management, and one from the state government.

Private sector. Private sector members will be selected from the following stakeholder groups:

- Consumer and Privacy Interests;
- Purchasers;
- Third-Party Payers;
- Hospitals;
- Physicians;
- Nurses;
- Ancillary Services (e.g., laboratories and pharmacists); and
- Information Technology Vendors.

HHS Release, July 14, 2005;
US Senate Release, June 20, 2005.

Quality of Care

Congress, CMS to reward quality Medicare services

by Catherine Hubbard, M.A., Contributing Editor

The Centers for Medicare and Medicaid Services (CMS) wants to work with Congress to revise payment incentives in the Medicare program, according to Herb Kuhn, director of CMS' Center for Medicare Management. Speaking at a July 27 Senate Finance Committee hearing, Kuhn said the current system reimburses providers on a per-service basis, actually rewarding physicians for providing more, not better, services. "There is not necessarily a financial incentive built into our payment systems to provide the best care," he said.

Kuhn said that by delivering higher quality and more efficient care, physicians can lose money. "It costs them at the end of the day," he said. He added that Congress may need to consider new legislation to enable CMS to rework payment systems."We may need additional authority," he said.

Committee Chairman Charles Grassley (R. -Iowa) said, "Until we pay providers more for providing better quality care we are not going to see the improvements we want."

Grassley and ranking member Max Baucus (D. -Mont.) have introduced the Medicare Value Purchasing Act of 2005 (S. 1356) to enable Medicare to proceed with value-based purchasing. "Our bill starts with paying for the reporting of quality measures. It then moves to a system of paying for quality, gradually changing Medicare into a system that rewards quality over volume,"Baucus said.

"Change to Medicare's payment systems is urgently needed," said Mark Miller, executive director of the Medicare Payment Advisory Commission (MedPAC), noting that MedPAC in its March report recommended linking payments with performance in the areas of Medicare Advantage plans, home health agencies, hospitals, physicians and dialysis facilities.

In some areas, such as dialysis, Miller said, Medicare already has the information it needs to start measuring performance. In other areas, including physician care, Medicare still needs time to develop quality measures, he said. For a start, he said, Medicare could measure how a physician office's information technology works and then could spend a few years developing broader quality measures. "It is achievable," he said. ■

CCH Washington Bureau, August 8, 2005