G-2 Compliance Report

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For Hospitals, Laboratories and Physician Practices

Quest to Pay $302 Million in Settlement

In one of the largest recoveries in a case involving a medical device, Quest Diagnostics Inc. (Teterboro, N.J.) has agreed to pay $302 million to the government to resolve charges that its subsidiary, Nichols Institute Diagnostics (NID), sold misbranded test kits and fraudulently billed Medicare, Medicaid, and other federal health programs, according to the Department of Justice (DOJ).

The settlement resolves both civil and criminal charges concerning the misbranding of NID's Nichols Advantage Chemiluminescence Intact Parathyroid Hormone Immunoassay (Advantage Intact PTH assay), a test kit that was used by laboratories throughout the United States to measure parathyroid hormone levels in patients, the DOJ said. NID stopped selling the kits in 2006.

The DOJ said NID entered a guilty plea April 15 in the U.S. District Court for the Eastern District of New York and agreed to pay a criminal fine of $40 million to resolve the felony charges against it. Quest also entered into a nonprosecution agreement with the federal government.

The companies jointly will pay $262 million plus interest to the federal government, and $6.2 million to various state Medicaid programs, to resolve a civil lawsuit brought under the False Claims Act. The company also has entered into a corporate integrity agreement with the Department of Health and Human Services' Office of Inspector General. *Continued on page 2*

Medicare Program Integrity Contractors Expected to Make Criminal Referrals to DOJ

New Medicare program integrity contractors are expected to generate criminal referrals to the Department of Justice (DOJ), as well as identify vulnerabilities that will be remedied at the administrative level, officials from the DOJ and the Centers for Medicare & Medicaid Services (CMS) said April 28 at a conference of health care compliance professionals.

The DOJ Deputy Chief Kirk Ogrosky said that his agency has met already with new zone program integrity contractors (ZPICs) and wants the new contractors to make law enforcement referrals based on billing aberrancies detected through data analysis. Ogrosky spoke at the Health Care Compliance Association *Continued on page 8*

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Lab Institute 2009
September 23-25, 2009
Crystal Gateway Marriott
Arlington, VA

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Quest to Pay $302 Million, *from page 1*

Quest said in an April 15 press release that, although it disagreed with the government's allegations and did not admit to any wrongdoing, it agreed to the settlement "to put the matter behind it."

Michael E. Prevoznik, senior vice president and general counsel of Quest, said the company "conducts its business with the highest standards of quality and integrity" and that it regards "NID's failure to meet [its] standards as unacceptable."

Prevoznik added that Quest "is strongly committed to fulfilling the terms of the [corporate integrity agreement] and already has in place many of the agreement's requirements."

Whistleblower Lawsuit Filed

The government's investigation was prompted by the filing of a qui tam, or whistleblower, lawsuit by Thomas Cantor in the U.S. District Court for the Eastern District of New York in 2004.

Cantor, a biochemist, alleged that Quest and NID had defrauded the government by causing health care providers to bill Medicare and other federal health care programs for faulty medical tests, as well as for unnecessary drugs and surgeries that followed inaccurate diagnoses caused by bad test results.

Cantor's lawsuit was kept under seal until April 15, when a federal judge approved the settlement, according to a press release from Phillips & Cohen LLP, Washington, D.C., which represented Cantor in the action. Cantor will share in the recovery and will receive about $45 million, the DOJ said.

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According to the Phillips & Cohen release, Cantor's primary reason for bringing the qui tam suit was to bring about the government investigation. "I felt very frustrated when I tried to stop the use of faulty tests on my own," he said.

After he presented to government investigators his evidence about the faulty tests and his concerns about the danger to dialysis patients, Cantor said a Federal Bureau of Investigation agent promised him that it would make NID stop. The government issued subpoenas to NID in October 2004, seeking documents related to the test kits.

Inaccurate Test Results

The tests targeted by Cantor and the government were used to determine the concentration of a parathyroid hormone, which, in turn, is used to determine how to treat dialysis patients, so accurate results are essential, the Phillips & Cohen release said. The inaccurate test results put the health of hundreds of thousands of dialysis patients at risk, it said.

"Dialysis patients and their doctors relied on the PTH test kits to determine treatment for these vulnerable patients," Erika A. Kelton, the Phillips & Cohen attorney who represented Cantor, said. "The health consequences of inaccurate

measurements of PTH in a dialysis patient can be serious, irreversible, and cause tremendous pain."

Michael F. Hertz, acting assistant attorney general for DOJ's Civil Division, said: "Pursuing the case was particularly important in light of the potential for adverse health consequences to beneficiaries of federal health care programs."

Quest said in an April 15 press release that, although it disagreed with the government's allegations and did not admit to any wrongdoing, it agreed to the settlement "to put the matter behind it."

U.S. Attorney for the Eastern District of New York Benton J. Campbell agreed, saying: "The American public has the right to expect medical device manufacturers to make accurate claims in their labeling, especially when the failure to meet those claims could indicate that the performance of the device is suspect."

"In order to safeguard public health, and when appropriate, to recover taxpayer dollars, the government will vigorously investigate allegations that a manufacturer knowingly sold medical devices, such as test kits, that were materially unreliable or provided significantly inaccurate results," Campbell said.

Criminal Charges

The civil lawsuit alleged that NID made, marketed, and sold the Advantage Intact PTH kit and another kit, the Bio-Intact PTH test kit, despite knowing that some kits produced materially inaccurate and unreliable results, according to the DOJ.

NID's conduct resulted in the submission by clinical laboratories of false claims for reimbursement to federal health care programs and in the submission by medical providers of false claims for reimbursement for unnecessary treatments and procedures, it said.

The criminal charges, by contrast, focused solely on the Advantage Intact PTH kit. The information filed against NID alleged that the test often produced elevated results, but the marketing materials that NID distributed described the product as having "excellent correlation" to a proven assay, the DOJ said.

Additionally, the directional insert for the kit, in a section titled "Accuracy," described a study in which the Advantage Intact PTH Assay produced results nearly identical to those produced by the proven assay when used to test PTH levels in samples of human blood. Contrary to those claims, however, NID knew as early as May 2000 that its kit was not consistently providing such results, the DOJ said.

As part of the guilty plea, NID admitted that in or about May 2000 and at various times thereafter, the company knowingly, intentionally, and with intent to mislead introduced into interstate commerce the Advantage Intact PTH Assay, which was misbranded, the DOJ release said.

Finance Committee Leaders Propose Program Integrity, Enforcement Activities

New health care reform proposals from Senate Finance Committee Chairman Max Baucus (D-Mont.) and committee ranking member Chuck Grassley (R-Iowa) would require Medicare and Medicaid providers to adopt compliance programs and would increase penalties for fraud against the federal health care programs as part of broad changes to ramp up program integrity efforts.

The proposals also called for greater scrutiny by the Centers for Medicare & Medicaid Services (CMS) of providers and suppliers seeking to participate in the Medicare program and for an improved database that could cull information from across health care programs and provide better information to law enforcement and oversight agencies.

The Finance Committee leadership released the 48-page set of policy options April 28, calling for sweeping changes to the way Medicare operates, including a shift from volume-based purchasing to value-based purchasing and paying bonuses to primary care doctors. The document contains numerous proposals that could be included in a final health care reform bill.

Baucus and Grassley met with Finance committee members April 29 to solicit feedback on the reform options and to begin crafting legislation. Baucus has said he intends to mark up health care reform legislation in June with the aim of securing Senate passage by the August congressional recess.

The health care policy options regarding compliance plans would require Medicare and Medicaid providers to develop compliance programs as a condition of participation.

No other details were provided about the proposal. The federal government does not require such plans of Medicare or Medicaid providers, and only New York mandates that Medicaid providers implement compliance programs.

New Sanctions Proposed

In addition, Baucus and Grassley proposed adding new sanctions and safeguards to the Medicare and Medicaid programs to give CMS and law enforcement agencies greater ability to address compliance problems.

In particular, the proposal called for giving CMS the ability to suspend payments to providers during investigations and to extend the use of civil monetary penalties (CMPs) in cases where providers fail to report violations. However, the senators also said the CMP law should be amended to "relieve the burden" on charitable and other "innocuous" programs currently covered by the statute.

The proposals also called for greater penalties for providers who submit false claims to federal health care programs and for violations of the Emergency Medical Treatment and Labor Act, but also would amend the law to allow the Health and Human Services Office of Inspector General to waive its mandatory exclusion authority in cases where excluding a provider would impose hardship on beneficiaries or the federal health care program. The proposal would also strengthen provider enrollment oversight.

COMPLIANCE PERSPECTIVES

Budget Proposal Includes Increase for Fraud Fighting

President Obama's detailed budget proposal for fiscal year 2010, submitted to Congress on May 7, would boost funding for the Department of Health and Human Services to $879 billion and includes an additional $311 million in funds for eliminating fraud and abuse in federal health care programs.

Consistent with the budget outline released in February, the proposal establishes a Heath Care Reform Reserve Fund of $635 billion over 10 years, supported in part by a reduction of $309 billion in Medicare and Medicaid spending over the same period. The administration states that savings will be achieved in three areas to finance the reserve fund: "aligning incentives toward quality, promoting efficiency and accountability, and encouraging shared responsibility."

Some of the more significant health care provisions in the budget are highlighted below:

- **Enhancing Medicare and Medicaid Integrity.** The FY2010 budget proposal invests $311 million in discretionary resources to strengthen program activities within the Medicare and Medicaid programs, with particular emphasis on greater oversight of the Medicare advantage and the Medicare Prescription Drug program. These funds will augment existing mandatory resources for combating health care fraud and abuse. Moreover, the additional funding will better equip the federal government to minimize inappropriate payments, pinpoint potential weaknesses in program integrity oversight, target emerging fraud schemes by provider and type of service, and establish safeguards to correct programmatic vulnerabilities, according to budget documents.

- **Hospital Payments Linked to Quality.** Under the budget proposal, hospitals would have five percent of their base operating payments linked to performance on specified quality measures, phasing to 15 percent by 2015. Payments not earned back would be split equally between a pool to fund additional hospital quality incentive payments and the Medicare Trust Fund. The administration estimates this will reduce program spending by $12 billion over 10 years.

- **Reduction of Readmission Rates.** The budget proposal aims to reduce hospital readmission rates by adjusting payments for targeted conditions and procedures by 30 percent for hospitals with readmission rates exceeding the 75th percentile, if the patient is readmitted within 30 days of discharge due to

Contracting reform will transform Medicare claims processing from 40 cost-based contracts to 15 performance-based, competitive contracts (plus four specialty contractors).

complications or related diagnosis, beginning in 2012. Public reporting of readmission rates would start in 2013.

- **Contracting Reform.** The administration requests $65.6 million to implement contracting reform, a reduction of $43.3 million below FY 2009. CMS is winding down transitions and is on track to complete contracting reform before the 2011 target set in the Medicare Modernization Act (MMA). Contracting reform will transform Medicare claims processing from 40 cost-based contracts to 15 performance-based, competitive contracts (plus four specialty contractors).
- **MIPAA Implementation.** The proposal includes $81.6 million to implement the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA). This funding will supplement appropriation provided in the mandatory legislation for implementation.
- **Survey and Certification.** The FY 2010 survey and certification request is $347 million, a $54 million, or 18 percent, increase over FY 2009. At this funding level, CMS will establish more frequent surveys of health care facilities. Survey frequencies have steadily declined in recent years, potentially compromising the safety and quality of care provided to beneficiaries, notes the budget proposal.

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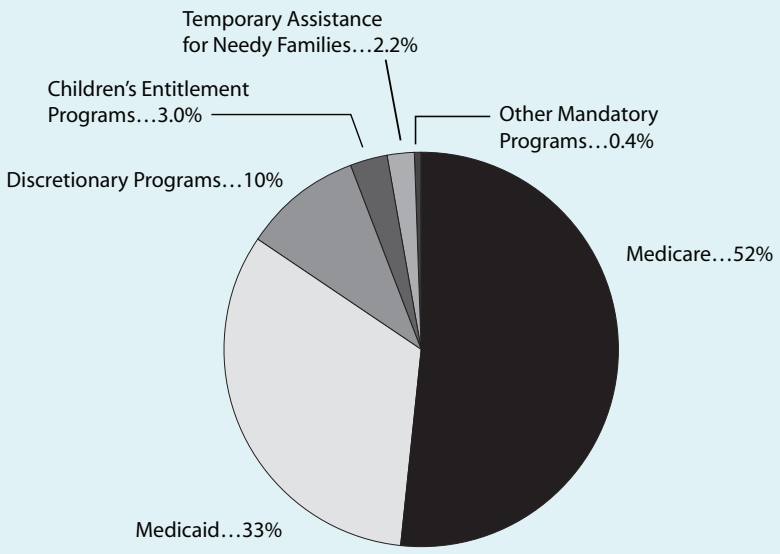
- **Bundling Post-Acute Care.** The budget proposes bundling Medicare payments for inpatient hospital services and post-acute care provided within 30 days of discharge, beginning in 2013. A single payment would be made to hospitals to cover the cost of both acute and post-acute care services.
- **Physician-owned Hospitals.** The budget proposal would prohibit new physician-owned hospitals from seeking reimbursement for services furnished to beneficiaries referred to the hospital by a physician with a financial interest in the hospital. Existing physician-owned hospitals would be grandfathered if they meet certain criteria, but would be prohibited from expanding.
- **Physician Reimbursement.** The budget proposal includes $311 billion over 10 years to reflect anticipated action from Congress to prevent future cuts in Medicare reimbursement for physicians. Congress has enacted temporary legislative patches to prevent scheduled cuts, the result of a flawed payment formula, almost annually. The budget documents state that this should not be future policy and that the payment system needs to be reformed. The administration says it will continue to consider other options, including an assessment of whether physician-administered drugs should be removed from the payment formula.
- **Physician Bonus Eligible Organizations (BEOs).** The proposal would enable physicians to form voluntary groups that coordinate care for Medicare beneficiaries. BEOs would receive incentive payments if they improve the quality of care for patients and produce savings.
- **Competitive Bidding for Medicare Advantage (MA) Plans.** The budget would establish a competitive bidding system in which MA payments would be based

on the average of plan bids submitted to Medicare. MA benchmarks would be set equal to the average MA plan bid in each county. Bids would be weighted by plan enrollment in the previous year.

- **Imaging Services Payments.** To control costs and guard against potential waste and abuse, the budget would require prior authorization from radiology benefit managers (RBMs) for the use and payment of advanced imaging services provided to Medicare beneficiaries.
- **Medicaid Drug Rebates.** The budget would increase the savings to Medicaid from brand-name drug rebates paid by drug manufacturers by increasing the rebate amount payable to states from its current level of 15.1 percent to 22.1 percent of average manufacturer price. It also would authorize states to collect rebates from drug manufacturers on drugs provided through Medicaid managed care organizations (MCOs) and plans. Currently, under an MCO arrangement, manufacturers are not required to pay the statutory rebates on drugs purchased by MCOs for Medicaid beneficiaries.
- **Health Privacy.** The budget proposal includes $41 million for the Office for Civil Rights (OCR), an increase of $1 million over FY 2009. Key priorities for OCR include ensuring understanding of and compliance with the HIPAA privacy rule; implementing additional privacy protections for genetic information; promoting adequate privacy protections in health information technology; and enforcing the confidentiality protections afforded to patient-safety information.
- **Advancing Comparative Effectiveness Research.** The FY 2010 budget proposal supports HHS-wide comparative effectiveness research, including $50 million within the Agency for Healthcare Research and Quality (AHRQ). This research will improve health care quality by providing patients and physicians with state-of-the-science information on which medical treatments work best for a given clinical condition. The Recovery Act provided $1.1 billion for comparative effectiveness research. Agencies will continue utilizing these funds in FY 2010.

Composition of Proposed FY 2010 HHS Budget ($879 Billion in Outlays)



- **Enhancing Health Care Information Technology.** The budget proposal advances the president's health IT initiative and accelerates the adoption of health information technology and the utilization of electronic health records. The Office of the National Coordinator for Health Information Technology (ONC) will continue its current efforts as the federal health IT leader and coordinator.

Criminal Referrals, *from page 1*

Annual Compliance Institute in Las Vegas.

Ogrosky said the DOJ uses data analysis from CMS contractors to launch investigations but that those investigations do not always uncover actual fraud. In some cases, higher-than-expected utilization rates for a provider or in a particular region are legitimate, but the DOJ investigates the unusual patterns because of the potential that fraud is being committed.

Data previously have come from program safeguard contractors (PSCs), and as ZPICs replace PSCs, the DOJ will work with the new contractors.

Ogrosky said he expects to see referrals from recovery audit contractors (RACs) and was surprised that the DOJ received "zero" referrals from RACs during the demonstration projects. "As a matter of statistics, we'd think there would be something," he said of what he expected to see from RAC reviews.

The DOJ senior legal analyst and investigator Peggy Sposato agreed. "We think there would be at least one," she said, also speaking at the HCCA conference.

RAC Reviews

RACs began their contracts earlier this year and, as with ZPICs and PSCs, will conduct reviews based on data analysis, CMS Program Integrity Group Director Kimberly Brandt said April 27 at the conference. RACs will alert providers to their review areas—by posting issues on their Web sites—before widespread reviews are conducted, Brandt said.

Providers are encouraged to have a single point of contact for the RAC in their region and should respond to RAC requests for medical records within 45 days, even if the response is to request an extension. Failure to respond within the time frame will result in claim denials, Brandt cautioned.

Brandt noted that CMS will require RACs to pay for inpatient hospital records that they request as part of reviews, and she reminded compliance officers that CMS has established a limit on the number of records RACs can request.

Groups Urge Regulatory Framework for Personalized Medicine

To advance personalized medicine, Health and Human Services Secretary Kathleen Sebelius will need to create and implement a reasonable and responsible regulatory framework for genetic tests and other advanced medical diagnostics, according to a recent letter to Sebelius from research and patient advocacy organizations.

Regulatory oversight of genetic testing needs to "strike the right balance between assuring patient safety and embracing policies that encourage the incorporation of rapidly advancing scientific methods and knowledge," the letter said. A regulatory framework would advance personalized medicine—that is, determining which drug will be used to treat a patient based on the patient's genetic makeup. The coalition that signed the letter includes patient advocates, health care policy researchers, and business groups such as the Huntington's Disease Society of America Inc., National Venture Capital Association, and

Citizens for Quality Sickle Cell Care Inc. The letter was announced May 5, but is dated April 30.

The coalition also said the new regulatory oversight policies must be clearly stated and publicly vetted before they are implemented. The new regulatory framework should "put patients first, be grounded in science, appropriately [provide incentives for] innovation, and be fully consistent with established statutes," the group said.

All advanced diagnostic tests, which currently are subject to different levels of regulatory scrutiny under Food and Drug Administration policies, should be regulated using consistent risk-based standards recognizing the unique aspects of each, say the groups.

While accurate, reliable, and timely genetic testing offers enormous promise to help shape our health care system to meet the challenges of the 21st century, "poor quality testing can harm patients and waste scarce resources," the letter said.

Physicians are already using genetic tests—currently available clinically for some 1,500 diseases or conditions—to diagnose disease, to predict an individual patient's risk of future disease, and to guide decisions about further diagnostic procedures and choices among therapeutic options, the letter said. "Advanced diagnostic testing is becoming the standard of care for many diseases," the group told Sebelius.

The letter noted that in 2007, then-HHS Secretary Michael Leavitt "charged his Advisory Committee on Genetics, Health, and Society to make recommendations for appropriate oversight of advanced diagnostic testing." According to the letter, the committee "engaged in vigorous debate and generated many thoughtful recommendations. We believe that now is a critical time to move to the next stage—to create and implement a reasonable and responsible regulatory framework for advanced diagnostic tests."

Seeking Stronger Lab Oversight

The letter outlines three goals the HHS secretary should adopt in crafting a framework of genetic testing oversight:

- All advanced diagnostic tests, which currently are subject to different levels of regulatory scrutiny under Food and Drug Administration policies, should be regulated using consistent risk-based standards recognizing the unique aspects of each. Scientific capabilities at HHS and FDA may need to be enhanced and strengthened to accomplish this goal.
- Sebelius should establish a publicly accessible registry that includes the name of the laboratory performing a specific test, the name of the laboratory or company that developed the test, and information to support claims about how useful the test is in obtaining the correct results and improving clinical care.
- Oversight of clinical laboratory quality, currently the job of the Centers for Medicare & Medicaid Services, should be strengthened to make sure that the information provided by genetic and other advanced diagnostic tests is accurate, reliable, and timely. The FDA and CMS should review their respective oversight roles to avoid unnecessary duplication.

"The importance of this issue to patients is clear from the large number of patient advocacy groups who signed onto this letter," Sharon Terry said. Terry is the chief executive officer of the Genetic Alliance and a board member of the Coalition for 21st Century Medicine, both of which signed the document.

Lab Groups Weigh In

In a separate letter dated April 29, 10 national clinical laboratory and pathology organizations urged Sebelius to take leadership in having her department advance personalized medicine by striking a balance in regulation of genetic and molecular testing.

"Genetic testing currently accounts for a relatively small but rapidly growing proportion of aggregate health care expenditures. However, it forms the cornerstone of personalized medicine, delivering the right drug to the right patient at the right time," they write. "Consequently, it is vital for us to maintain a regulatory environment that will foster and encourage development of this nascent field, delivering important benefits to patients, while protecting the public from unnecessary risks of harm."

The groups advocate a regulatory model that they say will allow genetic and molecular testing to "fulfill its potential for patient care and health care cost savings." They offered to help shape a regulatory model for personalized medicine that:

- Improves the interagency coordination between CMS and FDA;
- Utilizes CLIA to regulate clinical laboratory testing services;
- Avoids overlapping and potentially conflicting regulatory requirements that impede innovation;
- Provides a publicly transparent genomic test registry for tests that are classified as high-risk with stakeholder involvement on definitions and the relevant information to be included in the registry; and
- Allows for a participatory approach that draws on the expertise of all industry stakeholders.

OIG: Medicaid Programs Improperly Spent Money on Lab Services

Medicaid programs in eight of 11 states examined by the Department of Health and Human Services Office of Inspector General (OIG) spent $1.3 million in fiscal years 2005 and 2006 on potentially improper payments for outpatient clinical diagnostic laboratory services for Medicare beneficiaries who are also entitled to some Medicaid benefits, the OIG said in a report released April 10.

The memorandum report, *Potential Improper Medicaid Payments for Outpatient Clinical Diagnostic Laboratory Services for Dual-Eligible Beneficiaries* (OEI-04-07-00340), examined the 10 states with the highest Medicaid payments for all clinical diagnostic laboratory services for dual eligibles, including California, Florida, Illinois, Ohio, Mississippi, New Jersey, New York, North Carolina, Tennessee, and Texas. The report said the state of Washington was also included, after discussions with CMS.

Dual eligibles are beneficiaries who are enrolled in Medicare Part A and/or Part B and are also entitled to some Medicaid benefits.

Only Illinois, Mississippi, and New Jersey did not use Medicaid to improperly pay for lab tests during the years examined. The amounts of potentially improper payments ranged from $5,482 in California to $794,580 in Texas, according to the report.

"State Medicaid programs should not pay for any portion of outpatient clinical diagnostic laboratory services that were provided on an assignment-related basis to dual-eligibles who are enrolled in Medicare Part B," OIG said in the report.

Over 6 Million Dual Eligibles

According to the report, over half of the potentially improper payments corresponded to five Current Procedural Terminology (CPT) codes, including complete and automated differential white blood cell count, comprehensive metabolic panel, urinalysis (nonautomated with microscopy), and HIV-1 quantification. One code, collection of venous blood by venipuncture, accounted for almost 30 percent of the improper payments.

As of January 2006, there were more than 6 million dual eligibles nationwide, the report said. For those beneficiaries, services covered by both Medicare and Medicaid are paid first by Medicare. Any remaining balance is covered by Medicaid up to the state's payment limit.

Dual eligibles can receive clinical diagnostic laboratory services in different settings, such as independent laboratories, physicians' offices, hospitals, and clinics, according to the report, and after such services are rendered, providers submit payment claims to Medicare using CPT codes, which determine how much Medicare will pay.

The OIG said the report was issued in final form because it contains no recommendations.

The full report is available at *http://www.oig.hhs.gov/oei/reports/oei-04-07-00340.pdf*.

Dubious Distinction: Florida lawmakers April 29 approved Medicaid anti-fraud bills (S.B. 2658, S.B. 1986) that would designate Miami-Dade County as a "health care fraud area of special concern" and provide new licensure requirements for home health agencies, durable medical equipment providers, and health care clinics. Among other things, S.B. 2658 and S.B. 1986 would establish additional licensure requirements, including requiring a $500,000 surety bond for nonimmigrant aliens who have controlling interest in one of the covered businesses. They also would make it a third-degree felony to offer skilled services that require licensure and to file a false or misleading license or renewal applications.

Conflicts of Interest: An Institute of Medicine report April 28 recommends new regulations and voluntary practices to increase disclosure of physicians' and scientists' relationships with drug and device companies and to ban gifts from industry to doctors. The report said the Department of Health and Human Services should coordinate the development and funding of a research agenda to study the impact of conflicts of interest on the quality of medical research, education, and practice and to examine the positive and negative effects of conflict of interest policies on these outcomes. The report, *Conflict of Interest in Medical Research, Education, and Practice*, also recommends educating staff at academic medical centers and teaching hospitals on how to avoid conflicts of interest.

OIG Clears Proposal: A proposed arrangement in which residents would be billed for ambulance services in their home villages regardless of which fire department provides the emergency medical services (EMS) would not constitute grounds for imposing civil monetary penalties, the Department of Health and Human Services Office of Inspector General said in an advisory opinion (No. 09-03) posted April 30. While the proposed arrangement potentially could generate prohibited payments under the anti-kickback statute, the OIG said it would not impose administrative sanctions on the three villages in connection with the proposed arrangement. The advisory opinion is available at *www.oig.hhs.gov/fraud/docs/advisoryopinions/2009/AdvOpn09-03.pdf*.

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