

**Highlights of the Keynote Address Delivered by Daniel R. Levinson,
Inspector General of the Department of Health & Human Services,
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Health Care Reform Legislation

Compliance professionals should be asking questions as they prepare for health care reform.

- **Transparency:** Are you prepared to operate in a more transparent health care system?
- **Quality:** Are you focused on quality as a compliance issue?
- **Accountability:** Is your organization prepared for greater accountability?

[Some Questions Compliance Professionals Should Ask As They Prepare for Health Care Reform](#) (PDF)

New payment and delivery models require a fresh examination of fraud and abuse risk.

- The Patient Protection and Affordable Care Act of 2010 (PPACA) contains numerous provisions that encourage the evolution of delivery and payment models designed to improve quality and introduce new efficiencies through greater integration, collaboration, and coordination among providers.
- New payment and health care delivery models require a fresh examination of fraud and abuse risks.
- Existing fraud and abuse laws will remain important fraud-fighting tools, and we will continue to enforce them as written. Many new delivery and payment arrangements can readily be accommodated under the existing statutory and regulatory framework.
- As health care reform provisions are implemented, we at the OIG will need to work through the issues raised, as will your clients and organizations. Our mutual goal should be to develop such solutions as may be necessary to strike the right balance between protecting the integrity of the health care programs and fostering innovation that increases quality, efficiency, and cost effectiveness.

Many program integrity provisions in PPACA are consistent with OIG's health care integrity strategy and recommendations.

- Many program integrity provisions in PPACA are consistent with OIG's 5-principle strategy ("EPCOR") for combating fraud, waste, and abuse. These 5 principles are:

1. Enrollment: Scrutinize individuals and entities that want to participate as providers and suppliers prior to their enrollment in the health care programs.
 2. Payment: Establish payment methodologies that are reasonable and responsive to changes in the marketplace and medical practice.
 3. Compliance: Assist health care providers and suppliers in adopting practices that promote compliance with program requirements.
 4. Oversight: Vigilantly monitor the programs for evidence of fraud, waste, and abuse.
 5. Response: Respond swiftly to detected fraud, impose sufficient punishment to deter others, and promptly remedy program vulnerabilities.
- The PPACA program integrity provisions include authorities and requirements to:
 - strengthen provider and supplier enrollment standards and enhance screening;
 - address certain misalignments between Medicare and Medicaid reimbursements and market prices and create new links between payment and quality;
 - promote compliance with program requirements, including by requiring providers to implement compliance programs;
 - enhance program oversight, including by requiring greater reporting and transparency and by improving data access and coordination among government agencies; and
 - strengthen the Government's response to health care fraud and abuse through new enforcement authorities and tools.
 - The PPACA also increases funding for the Health Care Fraud and Abuse Control (HCFAC) program, which is OIG's primary funding stream. HCFAC draws funds from the Medicare Trust Fund to finance OIG's fraud-fighting activities such as:
 - Establishment of Medicare Fraud Strike Force teams;
 - Support of Civil False Claims Act investigations and enforcement;
 - Support of administrative enforcement activities;
 - Evaluations of Medicare contractor operations, services provided to nursing home residents, Medicare and Medicaid reimbursement for prescription drugs, and other issues;
 - Audits of payments to hospitals, home health agencies, Medicare Advantage plans, and Medicare Part D plans, among other providers;
 - Monitoring of providers under corporate integrity agreements; and
 - Issuance of advisory opinions and other guidance to the health care industry.
 - Historically, funding the HCFAC program has proven a wise investment. From its inception in 1997 through 2008, HCFAC Program activities have returned more than \$13.1 billion to the Federal Government through audit and investigative recoveries, with a return-on-investment (ROI) of \$6 for every \$1 invested in OIG, DOJ, and HHS activities through the HCFAC Account. HCFAC-funded activities have a further sentinel effect, which is not captured in ROI calculation.

Health Care Fraud Prevention and Enforcement Action Team (HEAT) Initiative

OIG is working closely with our HHS colleagues and DOJ and other law enforcement partners on coordinated efforts to fight fraud and abuse.

- OIG is integrally involved in one of the Administration's signature initiatives, the Health Care Fraud Prevention and Enforcement Action Team (HEAT). This is a joint effort by HHS and DOJ to leverage resources, expertise, and authorities to prevent fraud and abuse in Medicare and Medicaid.
- The HEAT task force, established by Secretary Sebelius and Attorney General Holder in May 2009, is an unprecedented partnership that brings together high-level leaders from both departments so that we can share information, spot fraud trends, coordinate prevention and enforcement strategies, and develop new fraud prevention tools.
- OIG contributes its expertise to HEAT by analyzing data for patterns of fraud, conducting investigations, supporting Federal prosecutions of providers who commit criminal and civil fraud, and pursuing administrative remedies, including program exclusions, as well as making recommendations to HHS to remedy program vulnerabilities and prevent fraud and abuse.
- Collaborating through HEAT is also resulting in improved access to Medicare data for law enforcement. Access to "real-time" claims data – that is, as soon as the claim is submitted to Medicare – is critical to identifying fraud as it is being committed. With "real time" knowledge, we would be better able to stop the fraud more quickly and to bring the perpetrator to justice and recoup the stolen funds before the criminal or the money disappears. Timely data are also essential to our agile response as criminals shift their schemes and locations to avoid detection.

Medicare Fraud Strike Force teams have proven successful for investigating and prosecuting fraud committed by sham providers masquerading as legitimate providers.

- The Strike Force model has proven especially effective for investigating and prosecuting fraud committed by sham providers masquerading as legitimate providers.
- The Medicare program is increasingly infiltrated by violent criminals, and our investigations are also finding an increase in sophisticated and organized criminal networks.
- Some of these fraud schemes are viral, i.e., schemes are replicated rapidly within geographic and ethnic communities.
- Health care fraud also migrates – as law enforcement cracks down on a particular scheme, the criminals may shift the scheme (e.g., suppliers fraudulently billing for DME have shifted to fraudulent billing for home health services) or relocate to a new geographic area.

- To combat this type of fraud, OIG and DOJ first launched their Strike Force efforts in 2007 in south Florida utilizing the expertise of staff from OIG, DOJ and the U.S. Attorney's Office for the Southern District of Florida, the FBI, and CMS to identify, investigate, and prosecute DME suppliers and infusion clinics suspected of Medicare fraud. Building on the success in south Florida, the Strike Force model was expanded to Los Angeles in March 2008. Today, Strike Force operations are in place in seven locations: South Florida, Los Angeles, Houston, Detroit, Brooklyn, Tampa, and Baton Rouge.
- Collectively, Strike Forces have resulted in approximately 270 convictions, indictments of more than 500 defendants, and more than \$240 million in court-ordered restitutions, fines, and penalties.
- We believe that our Strike Forces have had a marked sentinel effect. Though deterrence is difficult to quantify, claims data showed that during the first 12 months of the Strike Force (March 1, 2007, to February 29, 2008), claim amounts submitted for DME in south Florida, a particularly hot spot of DME fraudulent activities, decreased by 63 percent to just over \$1 billion from nearly \$2.76 billion during the preceding 12 months.

As part of HEAT, OIG is planning to conduct compliance training for providers in selected localities.

- OIG and the Department of Health & Human Services (HHS) are embarking on a new provider compliance training initiative. Stemming from the HEAT initiative, the goal of the project is to provide compliance training for providers, compliance professionals, and attorneys to assist the majority of providers and suppliers who want to do the right thing.
- We are in the early stages of planning for this initiative, which will unfold over the next year, so stay tuned for further announcements about this exciting initiative.

Roles and Responsibilities of Boards of Directors

Increasing links between payment and quality further increase Boards' responsibilities for ensuring quality of care.

- As part of the movement to improve outcomes and reduce health care costs, Medicare and Medicaid are beginning to link hospital payments to the quality of care. In addition to financially rewarding hospitals that improve care, Medicare and some other public and private insurers also are starting to refuse payment for preventable errors.
- A shift toward paying based on quality is also reflected in the Health Care Reform legislation, which contains multiple provisions linking payment to quality. These provisions affect physicians, hospitals, hospices, nursing homes, and others. The new payment systems are designed to reward value and quality and may require health care providers to implement new systems to track and accurately report performance measures.

- Quality assumes a heightened importance not only as a patient care concern, but also as a payment concern. As the link between payment and quality of care grows, Boards will need to be involved in the oversight of the care provided by their health care institutions.

OIG is committed to assisting Boards in meeting their compliance and quality responsibilities.

- OIG and the Health Care Compliance Association (HCCA) have co-sponsored two roundtables focused on engaging Boards on quality of care in their institutions. Resources resulting from these roundtables are available on our Web site (<http://oig.hhs.gov>).
 - “Driving for Quality in Long Term Care,” January 2008.
 - “Driving for Quality in Acute Care: A Board of Directors Dashboard,” March 2009.
- OIG and the American Health Lawyers Association (AHLA) have jointly published three guides addressing these issues:
 - Corporate Responsibility and Corporate Compliance (2003)
 - An Integrated Approach to Corporate Compliance (2004)
 - Corporate Responsibility and Health Care Quality (2007)
- The publications focus on defining the Board’s duty of care in the post-Sarbanes-Oxley and health care regulatory compliance environment. They are intended as educational information, not mandates. The AHLA-OIG Corporate Responsibilities Series recently have been reissued by The Governance Institute.

Individual Accountability

OIG is focused on holding Responsible Corporate Officials accountable for health care fraud.

- Under the “responsible corporate officer” doctrine, corporate officers are subject to both civil and criminal liability for corporate violations of statutes affecting public welfare.
- Liability as a responsible corporate officer does not turn upon a corporate officer’s approval of wrongdoing, but rather on whether the officer had, by reason of his or her position in the corporation, responsibility and authority either to prevent, or promptly correct, the violation at issue, and the officer failed to do so. *United States v. Park*, 421 U.S. 658, 673-674 (1975).
- The doctrine has been applied extensively in a variety of criminal cases involving public welfare statutes. For example:
 - OIG recently excluded the chairman of a large nursing home chain for his responsibility in the alleged provision of substandard care to residents of his facilities, including failure to protect residents from accidents, neglect, and abuse, exacerbated by chronic understaffing.

- OIG excluded for 12 years the CEO, General Counsel, and Chief Medical Officer of Purdue Frederick based on their misdemeanor convictions related to misbranding of oxycontin.

OIG is pursuing those individuals who solicit kickbacks, in addition to the payers of kickbacks.

- The payment of kickbacks to physicians can distort medical judgment, result in medically unnecessary care, and contribute to the rising cost of health care.
- OIG is using our civil monetary penalty authority to pursue cases against physicians who receive kickbacks from health care providers, including durable medical equipment suppliers, pharmaceutical companies, and medical device manufacturers.
- Specifically, OIG may exclude and impose a civil monetary penalty of \$50,000 for each kickback, plus 3 times the amount of each kickback against any individual or entity that engages in kickbacks.

Conflicts of Interest

Systems to ensure that the independence and integrity of health care providers and medical researchers are maintained are essential.

- The public's trust in the health care system rests on the belief that decisions affecting our health and wellbeing are made with integrity and in the best interest of the patient. That trust is undermined if the health care provider, clinical researcher or institution of higher learning allows a financial relationship with the health care industry to create a conflict of interest.
- If conflicts of interest are undetected or are disclosed but not appropriately dealt with, the result can be serious enough to damage reputations and raise public concern about the integrity of research and patient care.
- If undetected, the public may suffer numerous potential harms: people who volunteer in trials may be subjected to unnecessary risk or deprived of beneficial therapies; unsafe or ineffective drugs or devices may enter the US market; patients may receive inferior therapies when safer or more effective therapies are available; and the public may waste limited Medicare and Medicaid dollars to pay for this inappropriate treatment.

Research institutions, health care providers, and the Federal Government are examining how to best identify and manage potential conflicts of interest.

- Some institutions have taken a proactive approach to identifying and managing conflicts of interest through new policies and procedures. For example:
 - The owner of two research hospitals affiliated with the Harvard Medical School imposed restrictions on outside pay for two dozen senior officials who also sit on the board of pharmaceutical or biotechnology companies.
 - Stanford University announced plans to develop new continuing medical education (CME) programs for doctors that will be devoid of the drug industry influence that has often permeated such courses. Stanford received a \$3 million grant from Pfizer, and, according to the plan, Pfizer will have no say in how the grant dollars will be spent.
 - The University of Miami has become one of the first in the country to offer an online, searchable database revealing its doctors' relationships with outside businesses.
- Monitoring conflicts of interest continues to garner significant attention by HHS. In the 2009 HHS Agency Financial Report, my office continued to list Ethics Program Oversight and Enforcement, including conflict-of-interest issues, as a Top Management Challenge.
- On May 8, 2009, HHS issued an Announcement of Proposed Rulemaking (APRM) to gather input from interested stakeholders regarding revisions to the Federal financial conflict-of-interest rules issued in 1995 (42 CFR Part 50, 45 CFR Part 94).

OIG's enforcement and oversight work has addressed conflict of interest issues related to payments by pharmaceutical and device manufacturers, CME, and oversight of HHS-funded and HHS-regulated research.

- Cases involving illegal marketing of prescription drugs have included conflict-of-interest issues. For example:
 - In 2004, Pfizer paid \$430 million to resolve charges relating to the off-label promotion of Neurontin. The Government alleged that the company engaged in illegal promotion schemes, including one that corrupted the physician education process by fraudulently sponsoring medical education events on off-label Neurontin uses. These educational events were purportedly independent, but in reality they were developed and produced with extensive input from Pfizer regarding topics, speakers, content, and participants, with the ultimate goal of promoting off-label sales.
 - In 2007, Jazz Pharmaceuticals' subsidiary, Orphan Medical Inc. (Orphan), agreed to pay \$20 million to settle charges that it had illegally marketed Xyrem for off-label uses. The Government alleged that these off-label promotion schemes included paying a psychiatrist tens of thousands of dollars for speaking engagements that promoted off-label indications. Some of these speaking

engagements were characterized as independent CME programs, when in fact they were promotional events approved by Orphan's marketing department.

- Industry-sponsored CME can also implicate the criminal anti-kickback statute when it is used to channel remuneration to physicians.
- OIG has pursued several cases where companies provided funding purportedly for “educational support,” but that in reality constituted payment of kickbacks. For example:
 - In 2006, Medtronic paid \$40 million to the Government and entered into a Corporate Integrity Agreement to settle a range of allegations that it illegally paid spine surgeons to promote and use its spinal implant devices. The improper payments allegedly included lavish travel, lodging, and entertainment for physicians and their guests to participate in “discussion groups” that were of no or limited substance.
- OIG has identified deficiencies in oversight of conflicts of interest among researchers receiving grants from the National Institutes of Health (NIH).
 - For example, conflict-of-interest reports the NIH received from grantees did not provide specific details about the nature or amount of the financial conflict of interest. Further, when researchers submitted information regarding their financial interests, we found that grantee institutions did not routinely verify it.
- As at NIH, vulnerabilities that OIG has identified in the Food and Drug Administration's (FDA) oversight of conflicts of interest provides further evidence that conflicts of interest might not be properly addressed.
 - For instance, conflict-of-interest information submitted to FDA by clinical trial sponsors lacked specific details necessary to confirm that conflicts of interest were properly reported and addressed by clinical trial sponsors. Further, we found that 42 percent of marketing applications were missing financial information.