

# Immunization Program Manager's Meeting

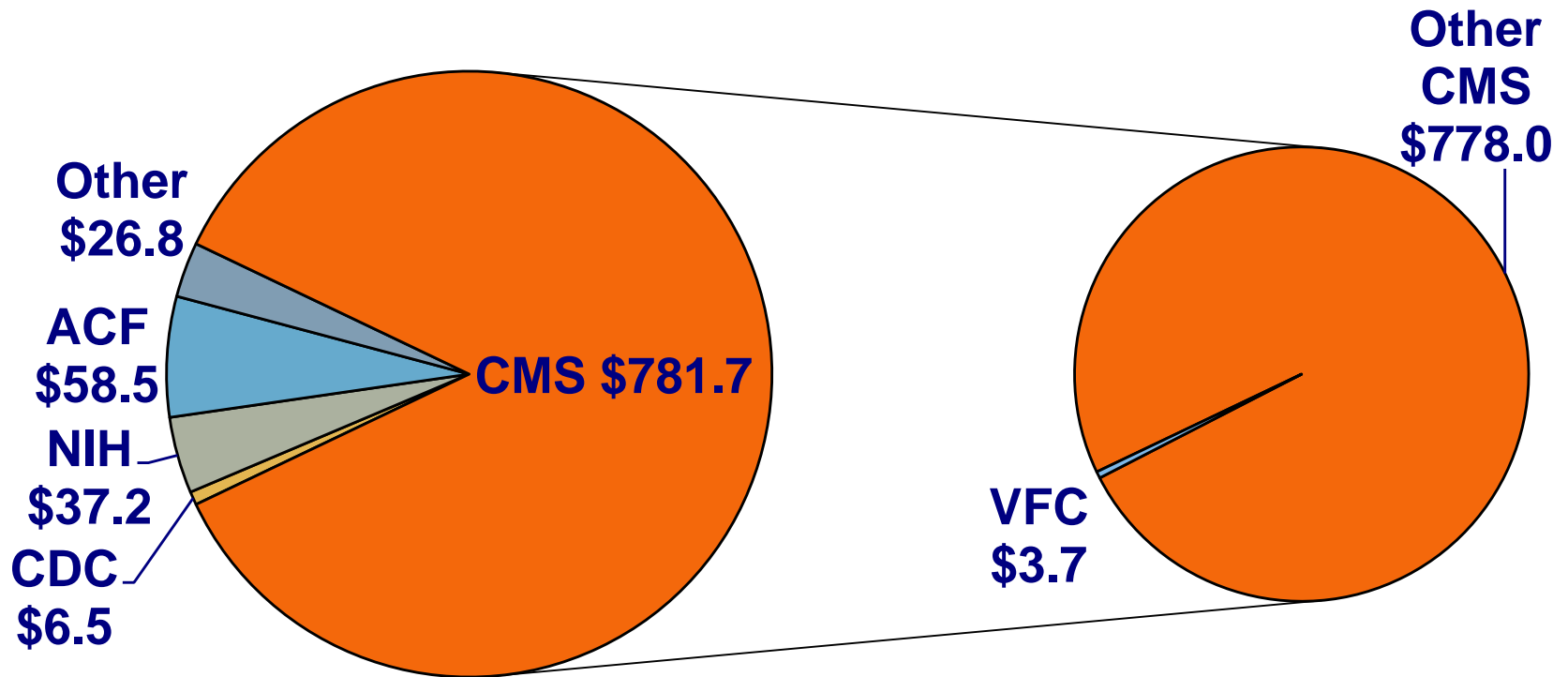


November 18, 2010

# OIG Mission

- ☞ To protect the integrity of HHS programs, as well as the health and welfare of the beneficiaries of those programs (mandated by Public Law 95-452 as amended)
- ☞ Report both to the Secretary and to the Congress program and management problems and recommendations to correct them
- ☞ Duties are carried out through a nationwide network of audits, investigations, inspections and other mission-related functions

# Expected HHS Outlays for FY 2011 (billions)



# Funding by HHS Agency

Agency	FY 2011 Outlays (billions)	Number of Programs	Major Programs
CMS	\$782	21	Medicare, Medicaid, CHIP
ACF	\$58	65	TANF, Foster Care, Head Start, Child Support
NIH	\$37	54	Medical Research
HRSA	\$9	78	Ryan White HIV/AIDS, Community Health Centers
CDC	\$7	37	Emergency Preparedness, Immunizations, HIV/AIDS, Chronic Disease Prevention
IHS	\$5	14	Treatment & Prevention, Health Professions Scholarships
SAMHSA	\$3	13	Substance Abuse Treatment, Mental Health Services
FDA	\$2	5	Food Safety, Drugs, Medical Devices
AoA	\$2	12	Transportation, Nutrition, Senior Centers
All Others	\$6	38	Departmental Operations
Total	\$911	337	

# Legal Authority

- ✎ Exclude individuals and entities engaged in health care fraud (SSA, § 1128m § 1156)
  - Program-related convictions
  - Patient abuse or neglect convictions
  - Licensing board disciplinary actions
  - Other actions that pose a risk to beneficiaries or programs
  
- ✎ Exclusions generally based on referrals from Federal and State agencies
  
- ✎ FY 2009 excluded 2,556 individuals and entities from participating in Federal health care programs

# Legal Authority

- ⌘ Levies civil monetary penalties based on the:
  - Submission of false or fraudulent claims
  - Offer, payment, solicitation, or receipt of kickbacks (SSA, §1128B(b))
  - Violations of the Emergency Medical Treatment and Labor Act of 1986
  - Items and services furnished to patients that fail to meet standards
  - Other conduct (SSA, §1128A)

# Legal Authority - ACA

- ✎ New authority to exclude providers/suppliers for false statements, misrepresentations in applications and enrollment
  
- ✎ Broadens civil monetary penalties for:
  - Ordering or prescribing by excluded provider
  - Failing to report and return known overpayments
  - Failing to grant timely access to OIG for audit or investigation
  - Knowingly including false statements, omissions on applications, bids for contracts

# Legal Authority

## ∞ False Claims Act

- Those who knowingly submit, or cause another person or entity to submit, false claims for payment of government funds are liable for three times the government's damages plus civil penalties of \$5,500 to \$11,000 per false claim. (31 U.S.C. § § 3729-3733)
- The law that allows citizens with evidence of fraud against government contracts and programs to sue, on behalf of the government, in order to recover the stolen funds
- Whistleblowers be awarded between 15 and 25 percent of the funds recovered

# Legal Authority

## ∞ Types of fraud prosecuted

- Billing for goods and services that were never delivered or rendered
- Billing for marketing, lobbying or other non-contract related corporate activities
- Performing inappropriate or unnecessary medical procedures to increase reimbursement
- Billing for work or tests not performed
- Double billing - Charging more than once for the same goods or service
- Upcoding - Inflating bills by using diagnosis billing codes for a more expensive treatment
- Billing for brand -- Billing for brand-named drugs when generic drugs are actually provided
- Charging for employees not on the job, billing for made-up hours
- Billing at doctor rates for work that was actually conducted by a nurse or resident intern
- Being over-paid for sale of a good or service and not reporting that overpayment
- Failing to report product defects/continuing to sell or bill the government for the product
- Billing for research not conducted; falsifying research data paid for by the U.S. government
- Winning a contract through kickbacks or bribes
- Billing for unlicensed or unapproved drugs

# Legal Authority

## OIG's Role

- Work with DOJ to develop and pursue Federal false claims against individuals and entities that defraud the Government
- Consider whether to invoke our exclusion authority based on the defendants' conduct
- When appropriate, we require defendants to implement corporate integrity agreements to ensure compliance with Federal health care program requirements

# Legal Authority

- ☞ Health Insurance Portability and Accountability Act of 1996
  - Coordinating Federal, State and local enforcement efforts targeting health care fraud
  - Providing industry guidance concerning fraudulent health care practices
  - Establishing a national data bank to report final adverse actions against health care providers

# Office of Audit Services

- ✎ Examines the performance of HHS programs, grantees and contractors in implementing their responsibilities and provides independent assessments of HHS programs and operations
  - Shelf life extension program: determine whether CDC is complying with the Shelf Life Extension Program, managed by FDA, to extend the expiration dates on Strategic National Stockpile drugs in lieu of destroying expired drugs and replacing them
  - Planned start: November 2010
  - Final report: November 2011

# Office of Evaluation and Inspections

- ∞ Conducts national program evaluations to provide HHS, Congress and the public with timely, useful and reliable information
- ∞ Reports recommendations to improve program operations, save Federal dollars, and protect beneficiary well-being
- ∞ Oversees the activities of the Medicaid Fraud Control Units in 49 states and DC
  - MFCUs investigate and prosecute Medicaid provider fraud and incidents of patient abuse and neglect that occur in Medicaid-funded facilities

# Office of Evaluation and Inspections

## ∞ On-going studies:

- VFC: Storage and Management of Vaccines in accordance with Operations Guide, including required FDA temperature ranges
- Radiological and Nuclear Preparedness: extent states/localities have developed and exercised their response plans
- Preliminary work and study design completed for both studies
- Entrance conference: November 2010 for both studies
- Final report: November 2011

# Office of Investigations

- ∞ Conducts and coordinates criminal, civil and administrative investigations of fraud and abuse related to HHS programs and operations

# Office of Counsel to the IG

- ∞ Provides legal support for all OIG activities
- ∞ Initiates and litigates actions seeking civil monetary penalties and the exclusion of health care programs because of fraudulent or abusive conduct
- ∞ Issues advisory opinions on the application of fraud and abuse laws to health care business arrangements
- ∞ Promotes industry compliance with fraud and abuse laws by conducting public outreach and issuing guidance addressing voluntary compliance programs

# OIG Activities

- ∞ Conduct audits, investigations and evaluations relating to all HHS funded and administered programs and operations
- ∞ Coordinate activities to promote the economy, efficiency and effectiveness in HHS programs, and to prevent and detect fraud in those programs
- ∞ Review legislation and regulations and make recommendations to promote economy, efficiency, and effectiveness
- ∞ Keep the Secretary and Congress informed about deficiencies in agency programs and possibilities for corrective action

# OIG Activities

- ∞ Conduct or facilitate administrative sanctions for fraud against HHS programs and operations
- ∞ Provide guidance to health care industry regarding fraudulent practices
- ∞ Establish a national data bank to receive and report final adverse actions against health care providers
- ∞ Provide security and protection to the HHS Secretary
- ∞ Investigate violations of interstate non-payment of child support

# OIG Activities

- ∞ Conduct financial statement audits under the Government Management Reform Act of 1994 and the Chief Financial Officers Act of 1990
- ∞ Conduct information systems reviews required by the Federal Information Security Management Act
- ∞ Provide oversight for non-Federal audits required under the Single Audit Act

# 6-Month Accomplishments for FY 2010

- ⌘ \$3.1 billion in expected recoveries
- ⌘ 1,935 individuals and entities excluded from participating in Federal health care programs
- ⌘ 293 criminal actions against individuals or entities that engaged in crimes against HHS
- ⌘ 164 civil actions, including False Claims and unjust enrichment lawsuits filed in Federal district court

# Recovery Act

- ✎ 2008 risk assessment of CDC assessed the risk for public health emergency preparedness and response as high
- ✎ Assessed Recovery Act spending and implementation plans and conducted risk assessments for:
  - Evidence-based clinical and community-based prevention strategies (\$650M)
  - Section 317 immunization program (\$300M)
  - Healthcare associated infection reduction strategies in states (\$50M)

# Recovery Act

- ∞ Assessed internal controls over award process for:
  - Section 317 immunization program (A-04-09-01067)
  - Healthcare associated infection reduction strategies (A-04-09-01064)
  - Evidence-based clinical and community-based prevention strategies controls not audited – spending/implementation plans not approved by OMB in time for this body of preventive work

# Recovery Act

- ∞ Assessed the internal controls over the grant-award process used to award Recovery Act funds and to determine whether the controls have been suitably designed
  
- ∞ Control objectives:
  - **Authorization and approval:** transactions authorized and executed by persons acting within the scope of their authority
  - **Accuracy, completeness, and validity:** transactions should be consistent with originating data, fairly represent economic events that actually occurred, and not omitted
  - **Physical safeguards and security:** secure and safeguard vulnerable assets and limit access to resources and records to authorized individuals
  - **Error handling:** errors detected at any stage of processing should receive prompt corrective action and reported to the appropriate level of management
  - **Segregation of duties:** key duties and responsibilities should be divided among different people to reduce the risk of error or fraud

# Recovery Act

- ∞ The internal controls over the grant- and contract-award processes used to award Recovery Act funds, as described by CDC management, are suitably designed to provide reasonable assurance that the specified internal control objectives would be achieved if the described internal controls were complied with satisfactorily and applied as designed
  - Applications tracked electronically
  - No single person prepares the funding opportunity announcements, reviews the application, and selects the fundable applications
  - Established policies and procedures
  - Checklists used to ensure administrative requirements are addressed, including whether grant was funded in rank order
  - All Notices of Awards includes terms and conditions
  - Reviews excluded party lists and other related sources prior to awarding a grant
  - Grantee's expending more than \$500,000 are subject to an independent audit

# Affordable Care Act

- ⌘ Reviewed Patient Protection and Affordable Care Act for CDC programs with authorized and appropriated funds
- ⌘ Assessed the Prevention and Public Health Fund (4002)
  - Expanded and sustained prevention and public health programs
  - Improve health
  - Restrain growth in private and public sector health care costs

# CDC Funding – FY 2010

- ⌘ \$6.9B – annual Federal appropriations, includes the 317 immunization budget (\$562M)
- ⌘ \$3.6B – Vaccines for Children
- ⌘ \$191M – Affordable Care Act

# Affordable Care Act

## ☞ CDC's funding

- \$191M in 2010
- \$499M in 2011

## ☞ Uses for 2010 funding

- \$7.5M – fellowships
- \$20M – epidemiology
- \$30M – HIV
- \$32M – communities putting prevention to work
- \$25M – children's health insurance program reauthorization act

# Affordable Care Act

## Approach

- Internal control audits
- Risk assessments
- GAO reports
- Federal Information Security Management Act (FISMA) audit
- Funding opportunity announcements
- Listings of contracts and grants for FY 2010
- Interviews with CDC officials

# Affordable Care Act

- ⌘ No spending or implementation plans for ACA – no guidance on how to spend ACA monies – increases risk that grant funds used for unintended purposes – one state, for example, used non-ACA grant funds to cover budget shortfall
- ⌘ One ACA already awarded improperly – funds awarded to a grantee that applied for a different grant in which it was deemed ineligible

# Affordable Care Act

- ☞ CDC officials interviewed stated that their programs rely extensively on contractors
- ☞ Four recent contracting audits showed that CDC did not have adequate policies and procedures to ensure compliance with Federal Acquisition Regulations
- ☞ Allegations on grants mismanagement, problems with stockpiling inventory

# Affordable Care Act

- ∞ Assess internal controls for awarding ACA grants
- ∞ Determine whether CDC's ACA grants comply with grants administration requirements and terms and conditions of the Funding Opportunity Announcements
- ∞ Determine whether CDC and its grantees (State health departments) comply with the requirements of the Vaccine for Children Program