

What's Next?

Strategies for Improving Compliance with Health Care Fraud and Abuse Laws

December 8, 2011

Welcome and Introductions

with Mary Jacoby,
Main Justice

Shifting the Paradigm: The New High-Tech Approach to Fraud Prevention

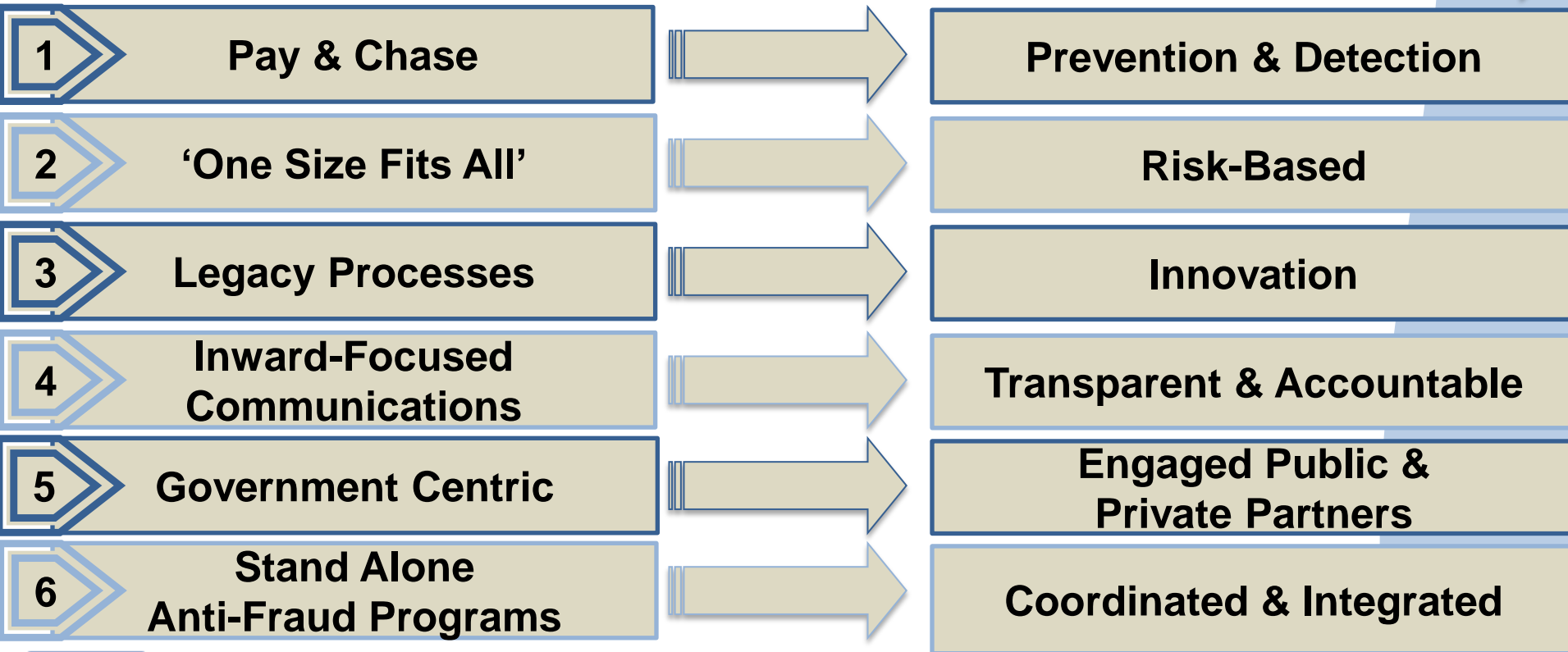
*Giving Pay and Chase a
Horse and Buggy Future*

Presented by Marc Smolonsky,
Associate Deputy Secretary, HHS

New Strategic Direction

Established Approach

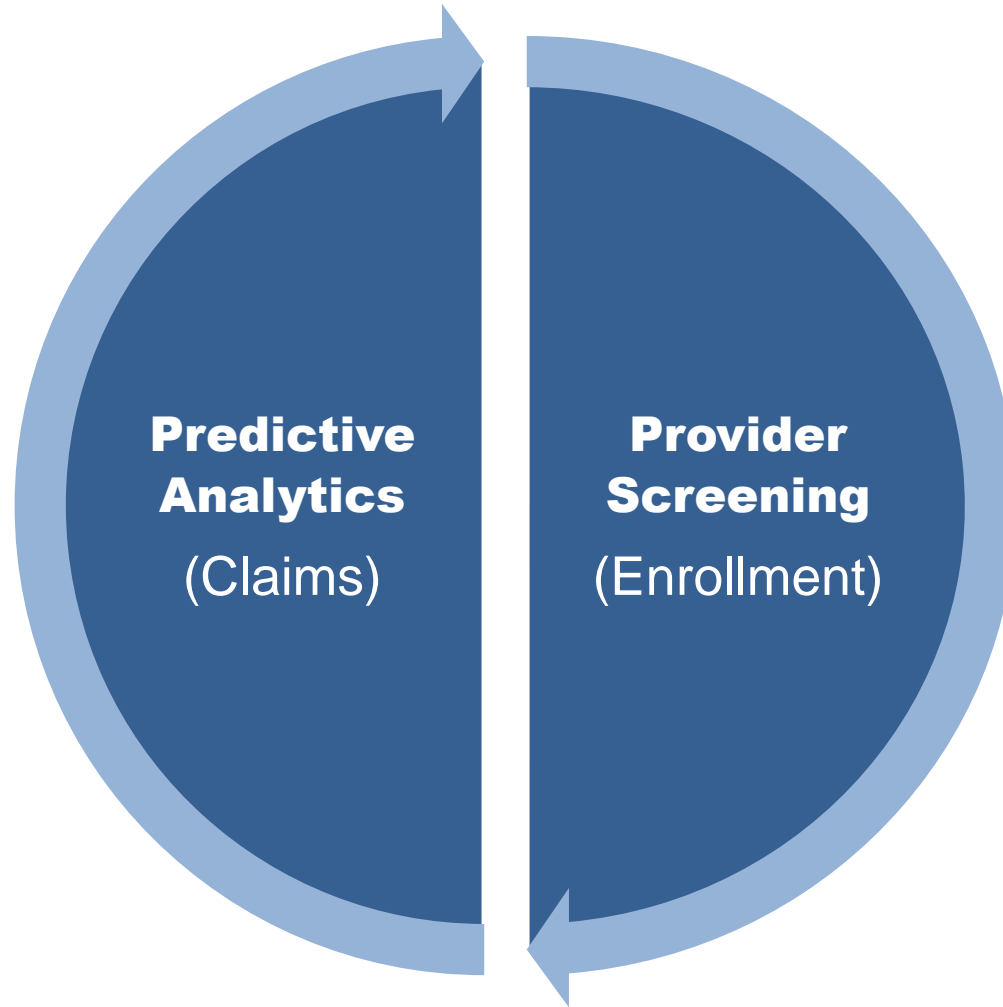
New Approach



National Fraud Prevention Program

- Prevents bad actors from enrolling in Medicare
- Prevents payment of fraudulent claims
- Prevents payment of improper claims with quick administrative action

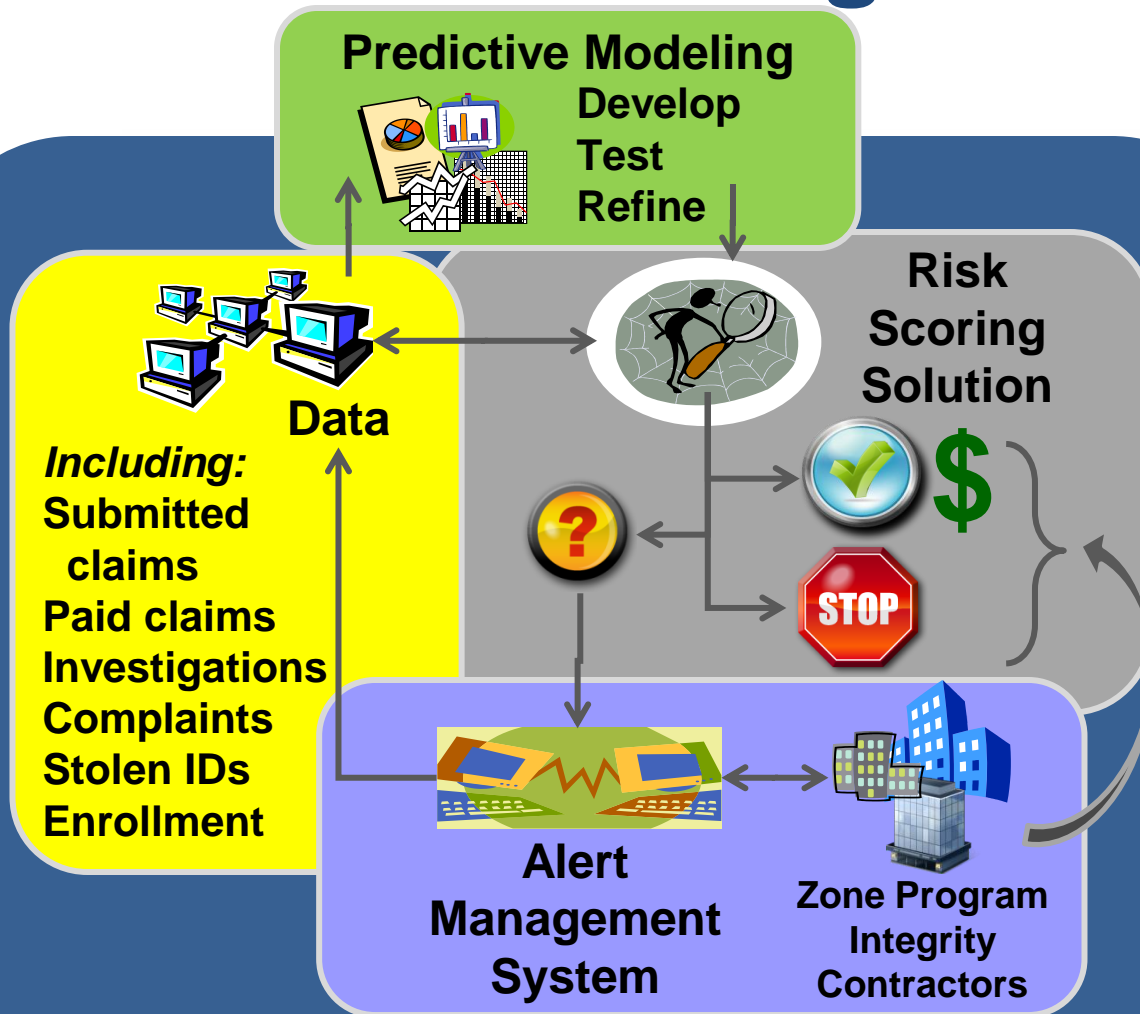
Two Concurrent Approaches



Fraud Prevention System

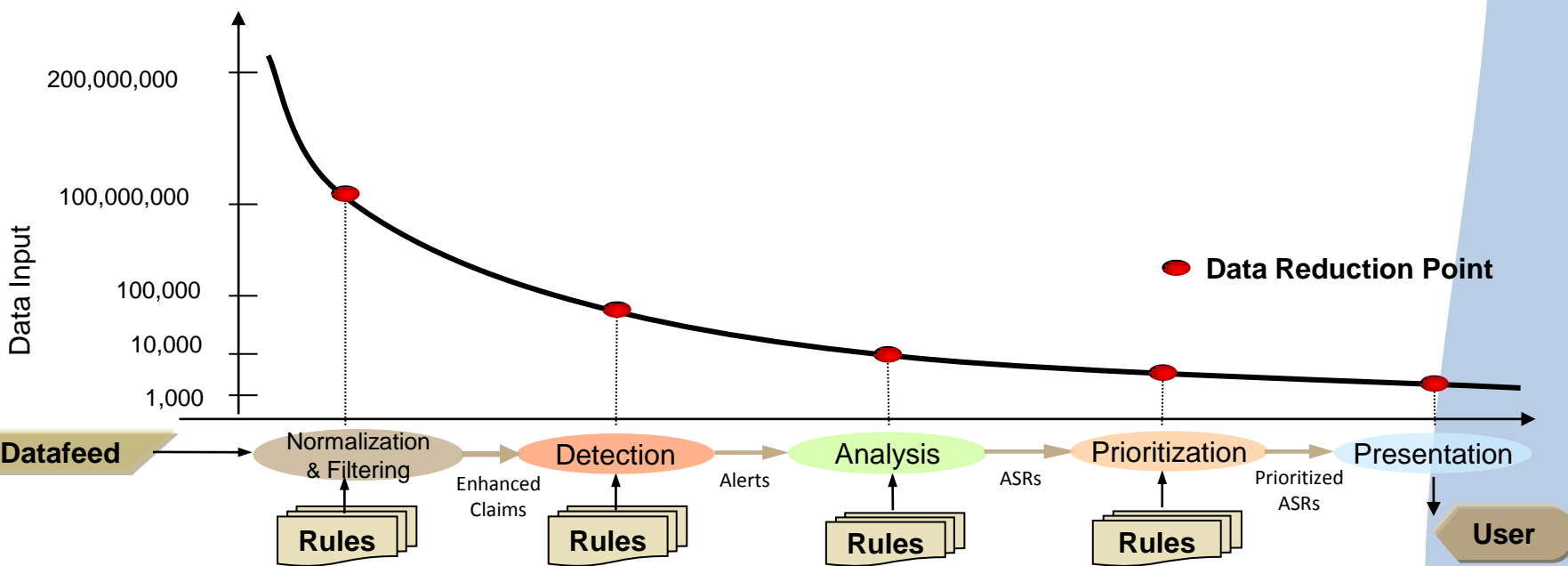
- Immediately transferable to Medicare FPS claims nationwide
- Based on demonstrated and effective technology while reducing necessary operational resources in half
- Exploring options to expand FPS-like technology to Medicaid

National Fraud Prevention Program



- ✓ Predictive modeling part of end-to-end solution that triggers effective, timely administrative actions by CMS
- ✓ Assures that analytics are effective (minimize false positives), efficient (return on investment), and risk-based
- ✓ Meets the requirements of Section 4241 of the Small Business Jobs Act of 2010

Data Reduction Approach



Fraud Prevention System

- Monitors 4.5 million claims each day
- Generates consolidated alerts on providers prioritized by risk
- Provides results to analysts and investigators
- Makes results available to CPI and law enforcement partners in a prioritized national view

Automated Provider Screening

- Validates data received from providers on enrollment applications against referential data
- Identifies applications of providers that may be high risk based on specific indicators

Provider Screening Lab

- Uses referential external datasets to validate information
- Identifies rules that could be used to effectively identify providers at high risk
- Uses predictive modeling to identify providers with the same characteristics as known fraudsters

National Site Verification Contractor

- Will perform site visits to verify information about providers and suppliers
- Will allow CMS to use this information, in conjunction with other data, to determine provider eligibility

Program Integrity Strategies

Yesterday

- Providers suspected of fraudulent activity are put on prepay review, sometimes indefinitely
- CMS initiates overpayment recovery
- Law enforcement determines if an arrest is appropriate

Today & Future State

- CMS will deny individual claims
- CMS will revoke providers for abusive billing
- CMS and contractors will use prepay review as an investigative technique
- CMS will address the root cause of identified vulnerabilities
- CMS continues to make referrals to law enforcement

Congressional Oversight Priorities

Key Fraud and Abuse Issues for the 112th Congress

Presented by Kim Brandt

Fraud and Abuse Key Focus in 112th Congress

- To date, at least 15 different hearings between the House and Senate focused on various aspects of fraud, waste and abuse
- Focus has been on:
 - Implementation of health reform anti-fraud provisions
 - Additional budget need for anti-fraud initiatives
 - Administration efforts to reduce improper payments

Permissive Exclusion

- Re-introduction of *Strengthening Medicare Anti-Fraud Measures Act* (H.R. 675) by Reps. Herger and Stark
 - Expands OIG authority to exclude from federal health programs:
 - Affiliated entity of sanctioned entity (e.g., parent company)
 - Individuals (e.g., owner or officer) controlling sanctioned entity or affiliated entity even if they leave entity before it is convicted or excluded
 - Proposals are included in Senate bill (S. 454)

Data Issues

- Sens. Grassley and Wyden introduced *The Medicare Data Access for Transparency and Accountability Act (DATA Act)* on April 7, 2011 to make Medicare claims and payment data available to the public
- *Physician Payments Sunshine Act* – CMS in process of implementing
- CMS currently implementing predictive modeling, use of commercial edit software, and continued development of the integrated data repository

Reducing Improper Payments

- Congress exercising vigilant oversight in ensuring CMS is reducing improper payments; Sens. Carper and Coburn are two of the more active advocates
- Focus on implementation of *The Improper Payments Elimination and Recovery Act of 2010*, which was introduced by Sen. Carper and Rep. Murphy and enacted in July 2010

Reducing Improper Payments

- What does this mean to you?
 - Increased focus on ensuring claims are paid properly
 - Contractor performance in identifying improper payments likely to be an area of scrutiny; document what you are finding and how you are addressing it
 - Greater emphasis on education and how CMS/contractors are ensuring providers submit claims correctly

CMS Contractor Oversight

- Conflict of Interest issues area key area of focus
 - Sens. Grassley, Baucus, Carper and McCaskill all have publicly opined on this
- Contractor operations and performance issues will continue to be closely monitored
- Discussion regarding changes to contracting structure (i.e., separating provider enrollment)

Enhanced Anti-Fraud Legislation

- *Strengthen Program Integrity and Accountability in Health Care Act of 2011* (S. 454) introduced by Sen. Grassley
 - Provides CMS more time to pay Medicare claims when fraud, waste and abuse suspected
 - Enhances coordination among federal agencies responsible for fighting medical identity theft
 - Prohibits Medicaid payments for illegal, unapproved drugs
 - Expands OIG permissive exclusion authority like in H.R. 675
 - Requires Medicare claims and payment data to be available to the public



Enhanced Anti-Fraud Legislation

- *Medicare and Medicaid Fighting Fraud and Abuse to Save Taxpayer Dollars Act (S. 1251) (FAST Act)* introduced by Sens. Coburn and Carper
 - Enacts stronger penalties for Medicare fraud
 - Curbs improper payments and establishes stronger fraud and waste prevention strategies to help phase out the practice of “pay and chase”
 - Curbs the theft of physician identities
 - Takes steps to help states identify and prevent Medicaid overpayments
 - Improves the sharing of fraud data across agencies and programs
 - Deploys cutting-edge technology to better identify and prevent fraud



Implementation of F/W/A Provisions of Health Reform

- Congress closely monitoring implementation of the following provisions:
 - Screening provisions
 - Application fees
 - Enrollment moratoria
 - Suspension of payments
 - Mandatory compliance programs
 - RACs for Medicaid and Medicare Parts C & D

Congressional Oversight

- Joint letter from Sen. Baucus and Hatch to OIG and CMS requesting quarterly reports beginning May 20, 2011 on spending and metrics related to implementation of various health reform provisions
- Closely watching to assess any negative impact on providers and to see which measures are most effective

Final Thoughts

- Health care reform will continue to be a key issue for the foreseeable future
- Entitlement reform and budget issues will also shape the debate
- Next two years are going to be very active and unpredictable but could end up having a significant impact on the health care system as a whole

Health Care Fraud Enforcement in Broader Context

Presented by Ted Ruger,
University of Pennsylvania Law School

Health Care Fraud Enforcement in Context

\$4 billion

US government
recovered from health
care fraud enforcement

\$80-250 billion

Health care fraud
estimated by FBI

\$2.5 trillion

Health care spending



MAIN JUSTICE
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Health Care Fraud Enforcement in Context

\$509 billion

Annual Medicare
spending

\$507 billion

Ten year savings from
PPACA Medicare
payment reforms

Health Care Fraud Enforcement in Context

\$500 billion

Annual prescription
drug spending

\$55 billion

Annual Medicare Part D
drug spending

\$42 billion

Estimated annual savings
from shift to generics

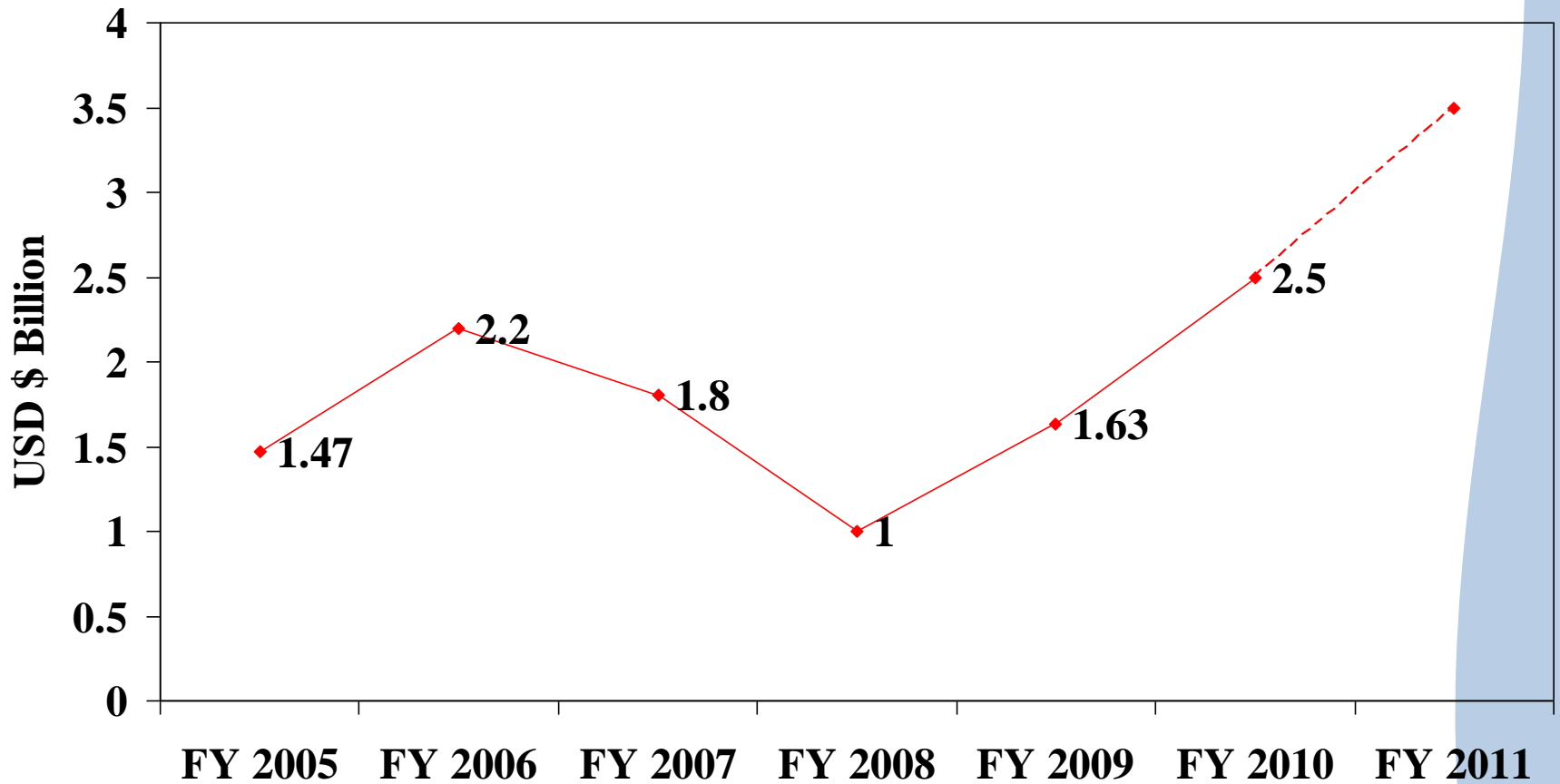
Rethinking Strategies to Reduce Fraud and Abuse

Presented by Patrick Morrissey,
King & Spalding

The Problem

- As federal healthcare spending continues to rise rapidly, the number of fraud and abuse investigations and settlements between the regulated health care industry and the federal government is growing at an even faster rate

Health Care Fraud Judgments and Settlements



Record Health Care Fraud Recoveries by DOJ

*“The Department of Justice has never been more aggressive – or more successful – in the anti-fraud battle as it has in the last two years. Indeed, since January 2009, the [DOJ has] opened more health care fraud matters, secured larger fines and judgments, negotiated higher settlements, and recovered more than **\$8.5 billion** for the taxpayers in health care fraud cases – this is a record, representing more health care fraud monies recovered than in any other two-year period in the history of the Department of Justice.”*

- Assistant Attorney General Tony West (Statement before the Senate Appropriations Subcommittee, Feb. 15, 2011)



Top 5 Settlements



\$3 Billion (2011 - tentative)



\$2.3 Billion (2009)



\$1.4 Billion (2009)



\$900 Million (2006)



\$875 Million (2001)

A DOJ Priority

DOJ Annual Awards

#1



#2



Fundamental Premise

- The government should be vigilant to ensure that taxpayers' resources are expended appropriately and not subject to fraud, waste and abuse
- At the same time, if the enforcement systems continue to generate multi-billion dollar settlements and do not focus on influencing activities before they occur, the system will always be prone to abuse

How Should the Current System Be Changed?

- Recognize the complexity of federal healthcare programs
 - Social Security Act
 - Medicare Parts A, B, C and D
 - Medicaid
 - Federal Drug Price Reporting Laws
 - FFDCA
 - Universal application of the False Claims Act
 - Breadth of the Anti-Kickback Statute

How Should the Current System Be Changed?

- Spend less money, reduce the complexity of laws, and/or provide greater clarity around the government's interpretation of the laws
 - Seek to prevent fraud and abuse from occurring before an investigation is launched
 - Consider establishing additional Advisory Opinion Processes that are binding and staffed with experts who are capable of responding quickly

How Should the Current System Be Changed?

- Aggressively incentivize positive behavior
 - Establish new safe harbor for entities demonstrating robust compliance programs
 - Amend the U.S. Attorneys Manual and OIG Guidance to better recognize the existence of rigorous compliance programs

How Should the Current System Be Changed?

- Enhance due process for regulated individuals and companies
 - Analyze how often the government threatens debarment in a settlement discussion
 - GAO report?
 - Reliance upon advisory opinions to mitigate prosecutorial risk

One Way to Advance Progress

- While the government should continue to pursue fraud and abuse settlements, policymakers have an opportunity to address problematic behavior before it occurs
 - Potential Solution: Create a meaningful FDA Advisory Opinion Process
 - Permit inquiries into ambiguous, fact-sensitive questions
 - Ensure adequate staffing within the Agency
 - Potentially fee-based (PDUFA reauthorization?)
 - Enumerated statutory goals: e.g., hard deadlines on responses
 - Practical tool designed to bridge the gap between regulatory and enforcement authorities

Discussion

Thank You!