

The Office of Inspector General (OIG) 2012 Annual Work Plan



Webinar Tips

- The audio for today's webinar is available via either the internet or telephone conference line
- Type questions into the Question box
- Information will be available after the webinar at www.cis-partners.com



Disclaimer

- CIS is a compliance consulting firm working primarily with Pharmaceutical Manufacturers to help them understand and meet requirements of Government Program participation.
- This presentation is being made by specific presenters, and reflects their industry experience on the topics at hand.
- In this webinar, CIS presents its view of an audit approach and methodology based upon available guidance.
- CIS does not represent the views or opinions of any specific federal government agency or the OIG. This webinar is not intended to provide specific interpretation of guidance.
- The content of this webinar does not represent legal opinion and does not necessarily reflect the advice of CIS.



Additional Resources

You may access the 2012 Work Plan directly from the following URL:

<http://oig.hhs.gov/reports-and-publications/archives/workplan/2012/Work-Plan-2012.pdf>

This webinar is part of our free Audit Webinar Series.

cis-partners.com/resources/webinars.html

Keep up with the latest industry developments with the Pharma Compliance Blog and monthly GP Forum

pharmacomplianceblog.com/blog/

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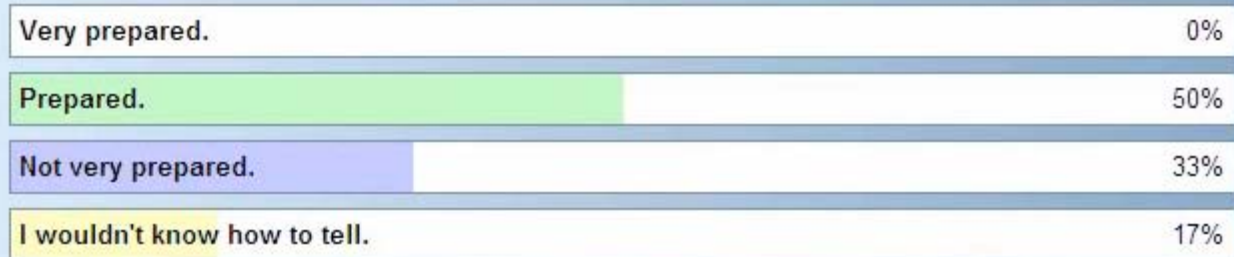
Check out the Healthcare Reform Beacon for a printer-friendly compilation of CIS insights

cis-partners.com/resources/cisnewsletters.html

QUICKPOLL

How prepared do you feel you are for a potential OIG Audit?

Poll Results (single answer required):





Today's Speakers



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By attending this complimentary webinar, you will have a better understanding of what the OIG will be focusing on in 2012 and what the Work Plan means for your company:

- Role of the OIG and its interaction with DOJ and States
- Purpose of the Work Plan
- History of the Work Plan
- How the Work Plan fits in the context of OIG focus on Medicaid integrity
- Brief background of the False Claims Act, and how it has been applied
- Summary of the 2012 Work Plan
- What you should be prepared to do – OIG Audit Readiness

Evaluating your Government Program compliance by a standard of “OIG Audit Readiness” is the best standard you can use to determine your level of compliance.

The Federal and State governments have placed a high level of importance on program compliance and “integrity,” especially Medicaid, PHS and VA, this scrutiny will continue as the programs grow and the government spends even more money on providing prescription drug benefits to Americans.

The OIG publishes its annual work plan to identify its focus in the upcoming year. Over the years, the work plan has gotten more detailed and specific. With staffing and budget for proactive audits, the nature of OIG audits continues to change, with increasing proactive inquiries and random audits.

Manufacturers must be aware of the risks, must ensure that they are OIG audit ready, and the annual work plan is one of the best ways to understand the focus of the OIG.

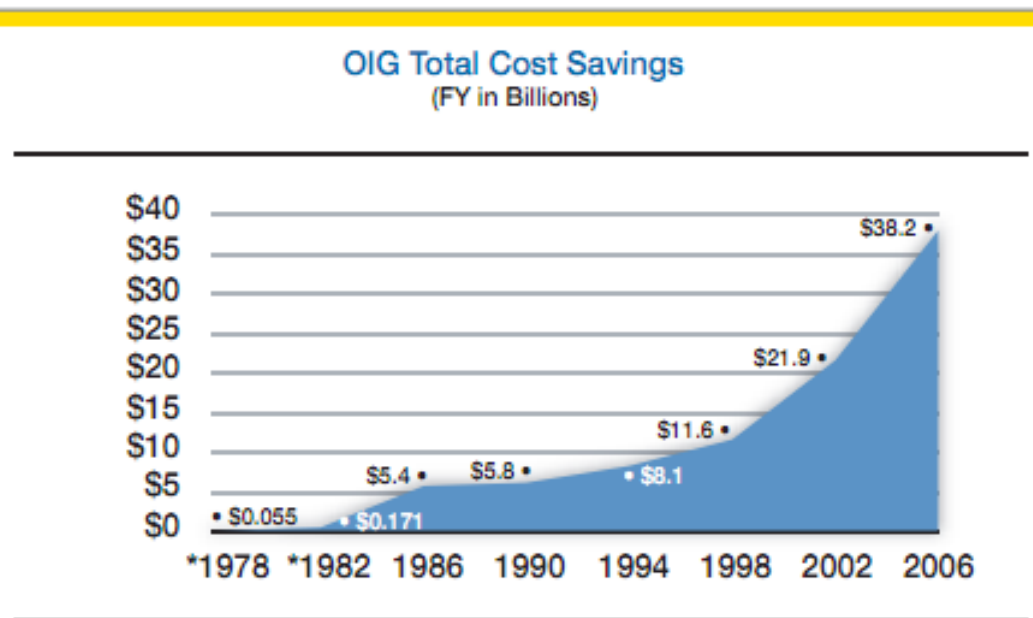
- OIG's mission is to protect the integrity of the Department of Health & Human Services (HHS) programs as well as the health and welfare of program beneficiaries
- HHS OIG is the largest Inspector General's office, with 1700 employees
- A majority of HHS OIG's resources are dedicated to oversight of Medicare and Medicaid
- OIG uses a collaborative approach, working closely with HHS agencies, Department of Justice (DOJ), and state governments

Purpose of the Work Plan

- Identifies the current focus areas and objectives for the fiscal year based on relative risks in the programs for which OIG provides oversight
- Considers:
 - Legislative, regulatory, and other directives for OIG
 - Congressional, OMB, and HHS management requests
 - HHS management and performance challenges
 - Collaborations with partner organizations
 - Management's actions to implement prior recommendations
 - Timeliness
- Actual initiatives may change over the course of the year, as new issues emerge

History of the Work Plan

- Deficit Reduction Act (DRA) of 2005, OIG was given the mandate & resources to perform program oversight more proactively
- Focus on program integrity has continued to evolve & become a focus of Federal and State enforcement agencies
- OIG estimates a \$17 to \$1 return on their audit activity in Pharma, with over \$7B recovered from Pharma since 2005
- The cost savings are even more impressive



The Work Plan in Context

- 1976 – HEW (later renamed HHS) OIG established
- 1986 – False Claims Amendments Act passed in response to concerns about fraud and abuse; strengthened the Act’s qui tam provisions
- 1995 – Operation Restore Trust initiated; 2 year partnership of State and Federal agencies – shared intelligence and coordinated enforcement
- 1996 – Health Insurance Portability and Accountability Act (HIPAA) enacted, established – and provided funding for – the Health Care Fraud and Abuse Control Program
- 1997 – First HHS OIG Work Plan published

The Work Plan in Context

- 2003 – OIG issued Compliance Program Guidance for Pharmaceutical Manufacturers
 - Integrity of data reported to the government identified as key risk area
- 2004 CMS Final Rule – Time Limitation on Recordkeeping Requirements Under the Drug Rebate Program
 - Established the 10-year rule (previously 3 years)
- 2005 King Pharmaceuticals CIA – based upon FCA, with no intent of wrong doing (DOJ issued press release)
 - Benchmark case with focus on Government Programs and expectation that Management should have *appropriate controls* in place

The Work Plan in Context

- 2005 DRA
 - Established budget for proactive audits
 - Promoted State FCAs
- 2005 Medicare Modernization Act (MMA)
 - Established certification requirements for ASP
- 2007 CMS AMP Rule
 - Established certification requirements for AMP, BP

The False Claims Act in History

- Originally signed by President Lincoln in 1863 to combat war profiteering
 - Made it a crime to defraud the Federal Government through false statements or claims
 - Provided double damages against offenders, plus penalties for each false claim
 - Established *qui tam* provisions, though 1943 legislation virtually eliminated these provisions
- Expanded in 1986 with the False Claims Amendments Act
 - Increased damages and fines
 - Lowered the standard of proof
 - Reinstated the *qui tam* provisions and provided protection from employer retaliation

The False Claims Act in History

- 2008 Allison Engine case (Allison Engine v. U.S.)
 - Clarified and narrowed the scope of FCA liability – required *intent* and payment *by the [federal] Government*
- 2009 Fraud Enforcement and Recovery Act (FERA)
 - Expanded the scope of potential FCA liability narrowed by the Allison Engine case
 - Reinforced that intent is not required – “require no proof of specific intent to defraud”
 - “Actual knowledge”
 - “Deliberate ignorance”
 - “Reckless disregard”

The False Claims Act in Practice

- Civil Monetary Penalties
 - Up to \$10,000 *per false claim*
 - *Plus* triple damages
 - *And* court costs
- Key issues:
 - Off-label marketing of drugs
 - Kick-backs
 - Pricing violations (inflating prices, BP violations, nominal, Bona Fide Service Fee treatment)
- *Intent* of wrong-doing is not required for application of FCA

Recent Enforcement Actions

- 10/26/10 – GSK – adulterated drugs - \$600M
- 12/7/10 – Abbott/B. Braun/Roxane – false/inflated prices - \$421M
- 12/15/10 – Elan/Eisai – off-label marketing - \$214.5M
- 12/20/10 – Dey – false prices – \$280M
- 3/10/11 – AstraZeneca – off-label marketing - \$68.5M
- 5/4/11 – Serono – kick-backs - \$44.3M
- 6/23/11 – GSK – manufacturing violations - \$40.75M
- 8/24/11 – Par – inflated AWP – \$154M
- 9/15/11 – Watson – caused Medicaid to overpay – \$79M
- 9/15/11 – Sandoz – caused Medicaid to overpay – \$66M

Medicaid Integrity “In the News”

- Some clips from recent news articles about focus on program integrity...

Senate committee accuses companies of 'gaming of Medicare'

By Kelly Kennedy, USA TODAY

Updated 10/4/2011 7:55 AM

Administration targets improper health care payments

By Richard Wolf, USA TODAY

Updated 9/14/2011 3:02 AM

Inspector General: Audits, Legal Actions May Net Up to \$3.4 Billion

For Immediate Release
June 1, 2011

HHS, OIG Press:
202/619-1343



November 04, 2011

Government Targeting Pharmaceutical Executives with Renewed Enthusiasm

Semiannual Report to Congress – Fall 2011

- \$5.2B in expected recoveries, plus \$19.8B in savings
- 2,662 individuals/entities excluded from participation in Federal health care programs
- 723 criminal actions and 382 civil actions taken
- Medicaid's net costs for branded drugs are "much lower" than those of Medicare Part D
- Medicaid's net costs for these drugs increased at a lower rate than inflation
- State Medicaid agencies lack the information to prevent overpaying for products purchased under the 340B program
- Roughly half of the states had not identified a replacement for AWP to use in reimbursing drugs

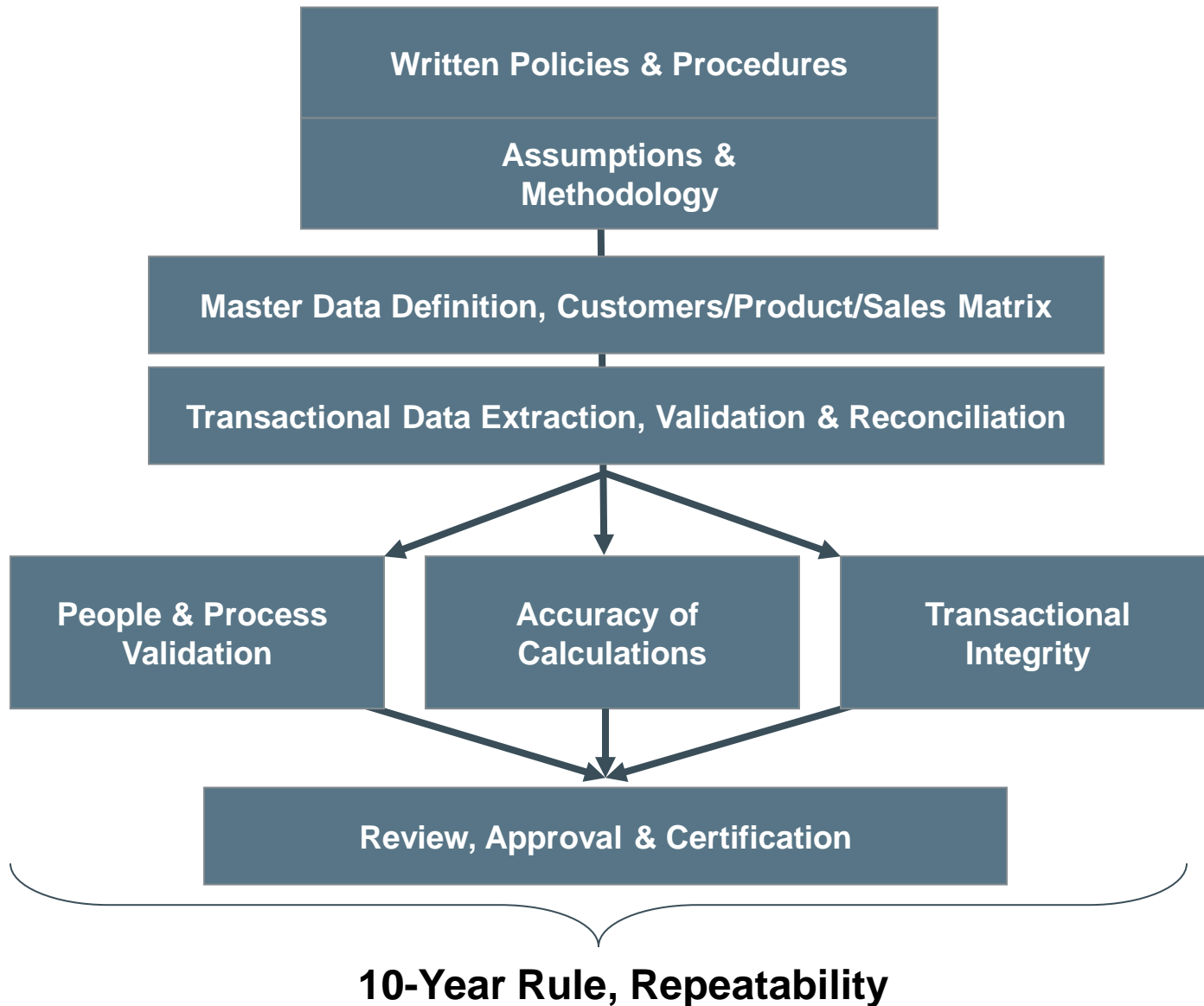
2012 Work Plan Key Focus Areas

- AMP compliance
- Identification of new formulations of existing drugs
- Federal Upper Limits
- Off-Label use of prescription drugs in Medicaid & Medicare
- Changes in prices of Part D drugs
- Potential changes to Medicare reimbursement methodologies
- Medicaid claims from Medicaid Managed Care Organizations
- Part D Coverage Gap data quality
- Accuracy of Part D Coverage Gap payments

- Demonstrate that you have attempted to self-identify compliance gaps and that you have a plan in place to mitigate identify gaps and continually improve GP compliance
 - Establish a specific action plan and timeline to build more effective compliance
 - Demonstrate understanding of the government's view of risk and implement measures to identify & mitigate issues, including voluntary disclosures

- GP Audit
 - Evaluate overall GP compliance
 - Policies and procedures in place
 - Procedures and systems align to and adhere to your policies and procedures
 - Methodologies are accurate
 - Calculations are accurate and can be repeated
 - Does not have the traditional “bar of materiality” of a finance-driven audit
 - Requires business intelligence about Government Programs

Auditing GP Processes and Systems



Some Core Questions

- Can you demonstrate the accuracy of your methodologies, especially in this “sub-regulatory” environment?
- Do you have a COT Schema and are you following it?
- Do you have written policies and procedures?
- Can you demonstrate that your people, processes and systems are aligned to your documentation?
- Do you reconcile your data to the general ledger?
- Can you demonstrate the accuracy of your calculations?
- Are you “audit savvy” and “audit ready?”

Questions and Answers



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Thank you

Thanks for Attending



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