REVENUE INTEGRITY WEBCAST SERIES, PART 4 – CORPORATE COMPLIANCE EFFECTIVENESS

April 20, 2016
Jim Sink
Principal
Jim is one of our national leaders for Healthcare Advisory Services. His professional career has focused exclusively in health care for more than 24 years, specializing in performance improvement, revenue integrity, reimbursement strategy and regulatory compliance. Jim has served as a partner/principal for 11 of his 16 years with RSM. Before RSM, he gained valuable experience serving the Big Four, a national health care system and the Medicare program. Jim serves multiple national/regional leadership roles ad responsibilities within RSM. Jim co-leads RSM’s national Revenue Cycle Practice with Steve LaFrance and co-leads RSM’s SE Region Health Care Industry (audit, tax and consulting) practice with Carlos Hernandez.

Greg Vetter
Director
Greg is a director in the Healthcare Consulting Practice with over 20 years of experience assisting clients in solving their business and information technology related challenges. While serving Providers and Payers, including some of the largest healthcare organizations in the Northeast, Greg has supported the IT, finance, compliance, and audit functions in achieving important business goals. The significant changes experienced by our clients in both the core patient care and management functions as well as the supporting business processes has provided the opportunity for complex projects which address significant business challenges.
Evan Carhart
Manager
Evan has over six years of ERM and internal audit experience. He has led the implementation of risk management frameworks and governance structures for public and private sector clients. He has also helped clients define their risk appetites. Evan is a member of RSM’s Governance, Risk and Compliance team established to develop ways to further enhance risk management methodologies, processes and tools for our clients.

Brian Green
Manager
Brian has more than 12 years of experience, both working for a large healthcare system, as well as a Big Four accounting firm within their advisory practice. He serves clients ranging from physician practices to large academic medical centers, with a concentration on various mid-revenue cycle functions ranging from Medicare DSH, wage index, medical education, Medicare cost report review/preparation and other performance improvement initiatives to help increase net revenue. Additionally, Brian’s experience includes assisting organizations with navigating the complex landscape around ICD-10 assessment/implementation.

Adam Harpool
Manager
Adam’s client service portfolio includes diverse information security, internal audit, enterprise risk management and compliance governance projects for health care clients ranging from hospital systems to pharmaceutical firms. He also holds national leadership roles in the RSM enterprise resource planning and governance, risk and compliance service lines. Adam is a Certified Information Systems Auditor and a member of the Healthcare Financial Management Association and the Institute of Internal Auditors. He has an MBA in corporate finance from Columbia Business School.

Carrie Furr
Manager
Carrie has more than 15 years of experience in the areas of information technology risk management, information privacy and security (HIPAA and HITECH), program and project risk management, project portfolio management, business continuity planning, offshore risk mitigation, program governance, regulatory compliance and clinical system implementation. Provided direct patient care in the following acute care areas: transplant (kidney, kidney-pancreas and liver), diabetes, labor & delivery and medical surgical units.
### Traditional Risk Management vs. ERM

<table>
<thead>
<tr>
<th>Traditional Risk Management</th>
<th>ERM</th>
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<tbody>
<tr>
<td>• Tactical, compliance focused</td>
<td>• Strategic, performance focused</td>
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<tr>
<td>• Silo-based processes</td>
<td>• Consistent risk management approach across the enterprise</td>
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<tr>
<td>• Business line or risk type view</td>
<td>• Holistic view of key risks</td>
</tr>
<tr>
<td>• Looks at risks individually</td>
<td>• Considers risk interactions</td>
</tr>
<tr>
<td>• Business decisions not closely linked to risks</td>
<td>• Business decisions based on a clear understanding of risks</td>
</tr>
<tr>
<td>• Driven by Risk Management and Internal Audit</td>
<td>• Driven by the board and owned by the business</td>
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<tr>
<td>• Supported by rules</td>
<td>• Supported by a “risk culture”</td>
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</table>
An ERM Framework should include:

- Risk governance
- Risk appetite setting
- Enterprise-wide risk management processes
  - Identification of risks
  - Assessment/measurement of risks
  - Monitoring of risks and actions to address risks
  - Management of risk through controls/risk responses
  - Reporting of risks and the status of action plans
- Integration with business decision-making
- Establishment of a strong risk culture
Risk Governance

• Reviews and approves risk strategies, frameworks and policies

• Reviews risk reports and recommends/monitors risk limits and action plans

• Oversees the implementation of the ERM framework/controls

ERM function
- Risk policies
- Incentives
- Capital adequacy

ERM committee
- Risk appetite
- ERM training
- Product/strategy review

ERM function

Board oversight

Risk committees
Development of a risk culture is critical to effective ERM

Ways to establish a risk culture that is supportive of risk management:

• “Tone at the top”
  – Reference the importance of risk management in organization’s objectives
  – Incorporate risk management into ongoing executive management communications
  – Exhibit the desired risk management behaviors

• Code of conduct or ethics

• Risk management factors included in incentive and performance evaluation plans
Risk Appetite

• An effective ERM program relies on the establishment and communication of the organization’s risk appetite
  – Helps employees to understand the specific risks that the organization is willing and not willing to take
  – Provides a means for ensuring that actual risk-taking is consistent with the organization’s risk-taking capacity
Risk Appetite

• There are many ways to define risk appetite:
  – Statements, such as “a zero tolerance for compliance risk” or “target debt rating of AAA”
  – Specific products, markets and/or customer segments that are outside of the company’s risk tolerance
  – Metrics that define risk thresholds, such as financial measures (e.g., ROE target) or limits (e.g., % of total risk exposure)

Are you able to articulate your organization’s appetite or tolerance for risk?
Risk Management Processes

- Risk management processes are grouped in different ways but generally include the following:

- Ideally, each of these processes should be ongoing rather than, for example, annual
### Example Health Care Risk Model

**Sample Health Care Risks**

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<tbody>
<tr>
<td>• Change Readiness</td>
<td>• Trustee Involvement</td>
<td>• Clarity of Mission &amp; Vision</td>
<td>• Attraction Retention</td>
<td>• Demographic Changes</td>
<td>• Information Security</td>
<td>• Reputation</td>
<td>• Plan &amp; Manage the Business</td>
</tr>
<tr>
<td>• Regulatory Reporting</td>
<td>• Authority/Accountability/Responsibility/Leadership</td>
<td>• Commitment to Mission</td>
<td>• Identify and Reward Key Skilled Employees</td>
<td>• Medical Technology Innovation</td>
<td>• Effectiveness of System Controls</td>
<td>• Patient Access</td>
<td>• Accounting</td>
</tr>
<tr>
<td>• Billing &amp; Reimbursement Compliance</td>
<td>• Decision Making Process</td>
<td>• Responsiveness</td>
<td>• Laws and Regulations</td>
<td>• Competitive Actions</td>
<td>• Compliance</td>
<td>• Patient Satisfaction</td>
<td>• Tax and Treasury</td>
</tr>
<tr>
<td>• Accreditation and Licensing</td>
<td>• Communications</td>
<td>• Alignment of Strategies to Overall Mission/Vision and Triple Aim</td>
<td>• Labor Relations</td>
<td>• Marketing/Public Image</td>
<td>• System Capacity</td>
<td>• Quality and Outcomes</td>
<td>• Funding Allocation</td>
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<tr>
<td>• Environmental</td>
<td>• Policy Administration</td>
<td>• Alignment of Org Processes</td>
<td>• Morale/Job Satisfaction</td>
<td>• Patients Requirements &amp; Satisfaction</td>
<td>• Use of Automated Systems</td>
<td>• Business Interruption/Catastrophic Loss</td>
<td>• Information Technology</td>
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<tr>
<td>• Tax-exempt status</td>
<td>• Organizational Structure</td>
<td>• Culture</td>
<td>• Ethics/Values</td>
<td>• Government/Political</td>
<td>• Competency of Process Team Members</td>
<td>• Compliance</td>
<td>• Risk Management</td>
</tr>
<tr>
<td>• Non-compliance</td>
<td>• Ethics and Fraud</td>
<td>• Structure</td>
<td>• Career Succession</td>
<td>• Range of Service</td>
<td>• Number of Platforms</td>
<td>• Profitability</td>
<td>• Procurement/Vendor Relations</td>
</tr>
<tr>
<td>• ACA</td>
<td></td>
<td>• Strategy</td>
<td>• Health and Safety</td>
<td></td>
<td>• Technology Selection Process</td>
<td>• Billing and Collections</td>
<td>• Outsourcing</td>
</tr>
<tr>
<td>• Security and Privacy</td>
<td></td>
<td>• Leadership Structure</td>
<td></td>
<td></td>
<td>• Obsolescence of Medical Technology</td>
<td>• Research</td>
<td>• Support Services</td>
</tr>
<tr>
<td>• Research Compliance</td>
<td></td>
<td>• Risk Mgmt Activities Support Achievement of Strategy</td>
<td></td>
<td></td>
<td>• Business Dev &amp; Tracking of Benefits Realization</td>
<td>• Revenue Cycle Performance</td>
<td>• Capital Projects</td>
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<tr>
<td></td>
<td></td>
<td>• Measurement</td>
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<td></td>
<td>• Complexity of Billing Systems</td>
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<td>• Manage Physical Assets</td>
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<tr>
<td></td>
<td></td>
<td>• Monitoring</td>
<td></td>
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<td></td>
<td></td>
<td>• Manage Regulatory Compliance</td>
</tr>
</tbody>
</table>
Using Risk Assessments

Internal Audit assessments are generally used to:
• Determine the scope and frequency of audits
• Compare to business line assessments

Business Line assessments are used to:
• Prioritize risks across the organization
• Identify the top risks to the organization
• Identify appropriate responses to risks, as well as areas where the adequacy of controls is too low for the level of risk
• Drive risk-based monitoring processes

Avoid the “black hole” of risk assessment data!
Integrating ERM into Decision-making

• To be effective, risk management must be integrated into day-to-day business line activities and corporate decisions
  – Risk managers must be involved at the onset of strategy setting processes
  – Risks associated with new products should be considered and communicated to the board
  – Analysis of emerging risks and stress tests should influence business decisions
  – Risk information should be shared across the organization to avoid the same event recurring
Lessons Learned

• Tone at the top
• Crawl – walk – run
• Build on tools/processes in place
• Simplicity at the outset
• Culture – culture – culture
Affordable Care Act
ACA Requires an “Effective” Program

- Section 6401 of the ACA mandates that a “provider of medical or other items or services or supplier within a particular industry sector or category” shall establish a compliance program as a condition of enrollment in Medicare, Medicaid or CHIP.
- CMS has updated regulations for Medicare Advantage managed care and prescription drug (Part D) plan entities to adopt and implement an “effective” compliance program.
- CMS guidance includes a focus on first tier, downstream and related entities (FDRs).
- ACA also significantly expanded compliance risks for health care entities in a number of areas.
- The bottom line – establishing and operating an effective compliance program is a small cost compared to the potential penalties for not doing so!
7 Elements of an “Effective” Compliance Program
Based Upon OIG Guidance

- Written Policies
- Compliance Officer
- Compliance Training Program
- Effective Lines of Communication
- Enforcement of Disciplinary Guidelines
- Auditing & Monitoring
- Responding to Offenses
# Elements of an “Effective” Compliance Program

- Based on New York State OMIG guidelines (2011)

<table>
<thead>
<tr>
<th>1. Written Policies and Procedures</th>
<th>- Critical areas include code of conduct and governance of the compliance program</th>
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<tbody>
<tr>
<td>2. Designation of Compliance Officer</td>
<td>- Competency, seniority and independence in reporting structure</td>
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<tr>
<td>3. Training and Education</td>
<td>- Frequent risks include periodic assessments of training effectiveness and vendor/business associate training</td>
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<tr>
<td>4. Communication Lines to Compliance Officer</td>
<td>- Accessibility and avenues for anonymous reporting</td>
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</table>
Elements of an “Effective” Compliance Program (cont.)

- Based on New York State OMIG guidelines (2011)

<table>
<thead>
<tr>
<th>Element</th>
<th>Description</th>
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<tbody>
<tr>
<td>5. Disciplinary Procedures</td>
<td>Policy on sanctions; fair and consistent enforcement</td>
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<tr>
<td>6. Identification of Compliance Risk Areas and Non-compliance</td>
<td>Periodic quality assessments; key role of internal and external audit</td>
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<tr>
<td>7. Responding to Compliance Issues</td>
<td>Prompt, fair, thorough and impartial investigations; process to identify and refund overpayments</td>
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<tr>
<td>8. Policy of Non-intimidation and Non-retaliation</td>
<td>Appropriate preventative controls in place (e.g., training on retaliation, avenues to report, exit interview questioning)</td>
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</table>
The False Claims Act (31 U.S.C. §§ 3729–3733, also called the "Lincoln Law") is an American federal law that imposes liability on persons and companies (typically federal contractors) who defraud governmental programs. It is the federal government's primary tool in combating fraud against the government. The law includes a qui tam provision that allows people who are not affiliated with the government, called "relators" under the law, to file actions on behalf of the government (informally called "whistleblowing" especially when the relator is employed by the organization accused in the suit). Persons filing under the Act stand to receive a portion (usually about 15–25 percent) of any recovered damages. As of 2012, over 70 percent of all federal government FCA actions were initiated by whistleblowers. Claims under the law have typically involved health care, military or other government spending programs, and dominate the list of largest pharmaceutical settlements. The government recovered $38.9 billion under the False Claims Act between 1987 and 2013 and of this amount, $27.2 billion, or 70 percent, was from qui tam cases brought by relators.

The Penalty for Non-compliance

• Abuse/fraud recoveries totaled $4.3 billion in 2013

• CMS seen as targeting those without a compliance program in audits and enforcements
FALSE CLAIMS ACT
History

- Lincoln Law
- World War II changes – lessened effectiveness
- 1986 revision – Amendments strengthened Act
History (cont.)

- **Qui Tam Provisions**—Truncated version of the Latin Phrase “Qui Tam pro domino rege quam pro se ipso in hac parte sequitur,” which translates as “He who sues on behalf of the King as well as for himself”
- Rooted in common law
- Endorsed by the founders
- Approved by the courts
Facts Around FCA

• 1986 and 2014
  - $44 Billion recovered
  - $4.7 Billion paid to whistleblowers
  - Over 50 percent of recoveries and majority of largest settlements from health care-related entities

• 4 types of claims
  - Classic
  - False documentation
  - Conspiracy to engage
  - Reverse false claim
Burdens of Proof

• 3 Burdens of proof
  - Individual presented or caused to be presented a claim for payment or approval or a document to facilitate payment of false claim
  - Claim and/or document was proven to be false or fraudulent
  - Individual or organization knew the claim to be false/fraudulent or acted with blatant disregard of the truth or falsity of the claim
    • Note 1 – If these three elements are present, a violation of the FCA has occurred, even if the government never actually makes a payment or suffers a loss
    • Note 2 – Individual/organization does not have to act with specific intent to fraud in order to be liable, as long as the submission was “knowing”

• Knowing vs. intent
Whistleblowers’ Role

• 2015 – 80 percent of money returned to the federal government under the FCA originated from whistleblowers

• Also called relator

• Customary awards are between 15-30 percent of overall money recouped, plus legal fees and “other” compensation

• Typical statute of limitations is six years
Example

- Penalties range from $5,500 to $11,000 for each false claim submitted
- Organization ABC submitted 3,683 false claims resulting in an increase in payment of $130,719
  - Organization was found liable under the FCA and penalized 3x amount of damages equaling $394,157
  - Civil action resulted in $5,000 for each claim resulting in additional $18,415,000
• 32 states have enacted FCA
• 7 municipalities
• Securities and Exchange Commission (SEC)
• Commodity Futures Trading Commission (CFTC)
• Internal Revenue Service (IRS)
2016 OIG WORK PLAN
SUMMARY OF THE OIG 2016 WORK PLAN

Executive Summary

On November 2, 2015, the Office of Inspector General (OIG) published and described OIG’s new and revised corporate compliance risk areas and providing policy development. Compliance officers should prioritize to ensure they include the pertinent risks. There are several new and revised areas of focus for replaced medical devices, Medicare Services (“CMS’s”) validation of hospital-submitted provider-based status. Significant new focus areas include the level of the Medicare hospice benefit, skill mix, and the oversight of ambulatory services. It is important to understand the implications of physician home visits and the impact of this focus on delivery and value-based purchasing in FY 2016 and beyond.

A complete copy of the Plan may be accessed on the OIG’s website. A summary of OIG’s key FY 2016 hospital audit activities is included.

Medicare Hospital Audit Activities

Significant new and revised hospital risk areas include:

- Medical device credits for replaced medical devices were made in accordance with the replacement of implanted devices.

McGUIREWOODS

Legal Alert

Return to Resource Center

Highlights from the 2016 OIG Work Plan

December 9, 2015

The Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) has released its Work Plan for Fiscal Year 2016. This annual work plan provides valuable insights into OIG’s planned areas of focus for investigation and enforcement activities in the coming year. You can find our review of last year’s work plan here.

Below is our annual review of key observations on this year’s work plan. The work plan contains a number of additional areas and is worth reading to understand specific concerns in areas not mentioned below.

1. Ambulatory Surgical Centers – Certification and Quality Oversight. A new addition to the areas typically discussed in an OIG Work Plan is a section on Medicare’s oversight system for ambulatory surgical centers (ASCs). Specifically, OIG indicated it would focus on oversight of the state agencies that handle Medicare certification surveys and ASC accreditation organizations. An on-site survey is required for ASCs to be Medicare-certified. ASCs that do not meet these criteria may choose to have their certification surveys completed directly by Medicare, in which case the surveys are performed by the
About the HHS OIG

Their Responsibilities:

• Protect the integrity of U.S. Department of Health and Human Services (HHS) programs and operations and the well-being of its’ beneficiaries
• Focus is on programs related to the money appropriated to the OIG

How They Operate:

• The OIG program is shaped by legislative and budgetary requirements and adheres to professional standards
• Conducts audits, investigations and evaluations with assistance from OIG counsel and management
About the HHS OIG

What They Accomplish (Expected FY 2015):

• Recoveries of more than $3B
• Savings of about $20.6B
• Exclusions of 4,112 individuals and entities
• 925 criminal actions against individuals or entities that engaged in crimes against HHS
• 682 civil actions
Creating the Work Plan

Factors Considered in Planning:

- Mandatory requirements
- Requests made
- Top management and performance challenges facing HHS
- Work performed by partner organizations
- Management’s action to implement recommendations from previous reviews
- Timeliness
Work Plan Structure

- Medicare Part A and Part B
- Medicare Part C and Part D
- Medicaid program
- CMS-related legal and investigative activities
- Public health reviews
- Human services reviews
- Other HHS-related reviews
- Affordable Care Act reviews
- Recovery Act reviews
## OIG Work Plan – Highlights of New Areas of Focus

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<td>• Medical device credits for replaced medical devices</td>
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<td>• Medicare payments during MS-DRG payment window</td>
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<tr>
<td>• CMS validation of hospital-submitted quality reporting data</td>
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<tr>
<td><strong>Nursing Home</strong></td>
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<tr>
<td>• Skilled nursing facility prospective payment system requirements</td>
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<td><strong>Medical Equipment and Supplies</strong></td>
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<tr>
<td>• Orthotic braces-reasonableness of Medicare payments compared to amounts paid by other payers</td>
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<tr>
<td>• Osteogenesis stimulators-lump sum purchase versus rental</td>
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<tr>
<td>• Orthotic braces-supplier compliance with payment requirements</td>
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<tr>
<td>• Increased billing for ventilators</td>
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<tr>
<td><strong>Other Providers and Suppliers</strong></td>
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<tr>
<td>• Ambulatory surgical centers – quality oversight</td>
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<tr>
<td><strong>Other Providers – Billing and Payments</strong></td>
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<tr>
<td>• Physicians-referring/ordering Medicare services and supplies</td>
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<tr>
<td>• Anesthesia services-non-covered services</td>
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<td>• Physician home visits-reasonableness of services</td>
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<td>• Prolonged services-reasonableness of services</td>
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<tr>
<td>• Histocompatibility laboratories-supplier compliance with payment requirements</td>
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<tr>
<td><strong>Other Part A and Part B Program Management Issues</strong></td>
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</tr>
<tr>
<td>• Accountable Care Organizations (ACOs): Strategies and promising practices</td>
<td></td>
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<tr>
<td>• Medicare payments for unlawfully present beneficiaries in the United States and incarcerated beneficiaries-mandated reviews</td>
<td></td>
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<tr>
<td>• CMS management of the ICD-10 implementation</td>
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# OIG Work Plan – Highlights of New Areas of Focus

## Medicare Part C and Part D

<table>
<thead>
<tr>
<th>Area</th>
<th>Focus Areas</th>
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<tbody>
<tr>
<td>Medicare Advantage</td>
<td>- Medicare Advantage organization practices in Puerto Rico</td>
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<tr>
<td>Part D Prescription Drug</td>
<td>- Medicare Part D beneficiaries’ exposure to inappropriate drug pairs</td>
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<tr>
<td>Program</td>
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<tr>
<td>Sponsor Compliance With Part D</td>
<td>- Medicare Part D eligibility verification transactions</td>
</tr>
<tr>
<td>Requirements</td>
<td>- Part D pharmacy enrollment</td>
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<td></td>
<td>- Increase in prices for brand name drugs under Part D</td>
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<table>
<thead>
<tr>
<th>Medicaid Program</th>
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<tbody>
<tr>
<td>Medicaid Prescription Drug Reviews</td>
<td>• Specialty drug pricing and reimbursement in Medicaid</td>
</tr>
<tr>
<td>Other Medicaid Services, Equipment and Supplies</td>
<td>• Express lane eligibility</td>
</tr>
<tr>
<td>Quality of Care and Safety of Beneficiaries</td>
<td>• State agency verification of deficiency corrections</td>
</tr>
</tbody>
</table>
| State Payments to Managed Care Entities  | • Medical loss ratio-recoveries of MCO rebates from profit-limiting arrangements  
                                        | • Review of states’ methodologies for assigning Managed Care organization payments to different Medicaid FMAPs  
                                        | • Managed long-term care reimbursements                     |
OIG Work Plan – Highlights of New Areas of Focus

CMS-Related Legal and Investigative Activities:

- Resolves civil and administrative health care fraud cases and negotiates and monitors corporate integrity agreements (CIAs).
- Issues fraud alerts, advisory bulletins and advisory opinions.
- Develops regulations within its scope of authority.
- Provides compliance program guidance
- Investigates allegations of fraud, waste and abuse in all of the departments’ programs with the largest area of investigation around matters related to Medicare and Medicaid
Public Health Reviews:

- These reviews generally include the review of the following public health agencies:
  - Centers for Disease Control and Prevention (CDC)
    - CDC-oversight of the Select Agent Program
  - Food and Drug Administration (FDA)
    - Controls over networked medical devices at hospitals
    - FDA-tobacco establishment compliance with the Family Smoking Prevention and Tobacco Control Act
  - Health Resources and Services Administration (HRSA)
    - HRSA-compliance with Maternal, Infant and Early Childhood Home Visiting (MIECHV) requirements
  - Indian Health Service (HIS)
    - HIS-charge card program review
  - National Institutes of Health (NIH)
    - NIH-control over subcontracting of NIH grant and contract work
  - Substance Abuse and Mental Health Services Administration (SAMHSA)
Human Services Reviews:

• Focus will be on human services program preparedness for emergencies and disasters and will be prioritizing work on the sufficiency and training of medical staff for disasters and severe infectious diseases and oversight of expenditures and adherence to safety standards

• Includes the Administration for Children and Families (ACF) and Administration for Community Living (ACL)

• New focus area will include:
  – Foster care – States’ protocols for the use and monitoring of psychotropic medications for children in foster care
  – States’ implementation of guardian ad litem requirements
Other HHS-Related Reviews:

• There are financial, performance and investigative issues that go across HHS programs that the OIG works to address department-wide matters; these include financial statement audits and information systems reviews

• New focus area will include:
  – Office for Civil Rights’ oversight of the security of electronic protected health information
Affordable Care Act Reviews:

- The OIG will continue to assess the department’s implementation and operation of ACA programs and progress toward achieving program goals.

- Work will be prioritizing work in three main areas: the health insurance marketplaces, including financial assistance payments, Medicare and Medicaid reforms and grant expenditures for public health programs.

- New focus areas will include:
  - Consumer Operated and Orientate Plan Loan Program – CO-OP compliance with requirements and CMS monitoring activities
  - Allowability of contract expenditures
  - Rollup of state-based marketplace eligibility determination audits and CMS oversight
  - Medicare reviews
OIG Work Plan – Highlights of New Areas of Focus

Recovery Act Reviews:

- The OIG will conduct financial oversight activities funding through the Recovery Act to ensure that HHS agencies and grantees used the funds that they received for their intended purposes and in accordance with established requirements.
THE POWER OF BEING UNDERSTOOD

AUDIT I TAX I CONSULTING
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