

Hot Topics in Compliance

Recent Developments and What to Expect in the Year Ahead

New Jersey HFMA

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Overview

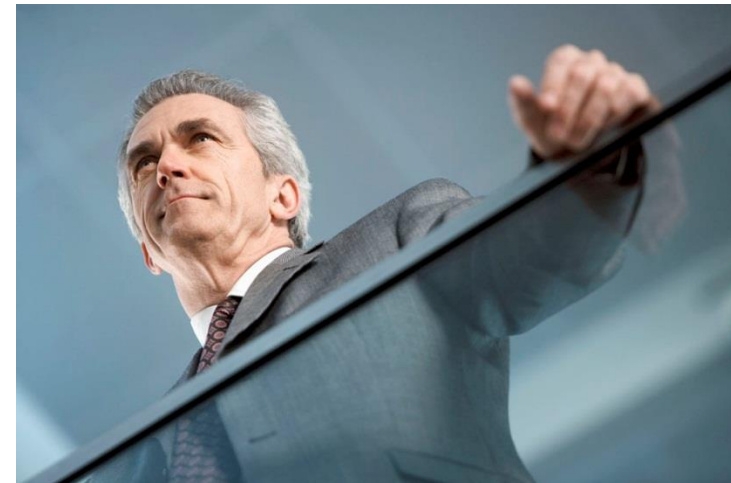
- Current regulatory environment
- Government enforcement
- Hot topics



Current Regulatory Environment

Many "Eyes" are watching...

- Medicare Administrative Contractors (MAC)
- Medicare Recovery Auditors (formerly "RA")
- Office of the Inspector General (OIG)
- Department of Justice (DOJ)
- Health Resources and Services Administration (HRSA)
- State Attorneys General
- Third Party Payors



Federal Enforcement Initiatives

Fiscal Year (FY) 2014 in review

- HEAT (Healthcare Fraud Prevention and Enforcement Action Team):
 - During FY 2014, Strike Force efforts resulted in the filing of charges against 228 individuals or entities, 232 criminal actions, and \$441 million in investigative receivables
 - March 2014: Halifax Medical Center, and its staffing agency (Halifax Staffing, Inc.) agreed to pay \$85 million to resolve allegations that Halifax entered into certain prohibited contracts with oncologists and neurosurgeons in violation of the Stark (physician self-referral) Law, resulting in the submission of false claims
 - May 2014: coordinated Strike Force teams across 6 cities, resulted in charges against 90 individuals for alleged participation in Medicare fraud involving over \$260 million



Sources: OIG Semiannual Report to Congress (April 1, 2014 – September 30, 2014); The Department of Health and Human Services and The Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2013

Federal Enforcement Initiatives

Fiscal Year (FY) 2014 in review (cont.)

- Medicare Wasteful Payments, Policies and Practices:
 - Approximately 1,600 Medicare Part D beneficiaries had questionable utilization patterns for HIV drugs in 2012, costing \$32 million; patterns may indicate beneficiary receives inappropriate drugs and diverts them for illegal sale
 - Pharmaceutical manufacturers have safeguards in place to prevent copayment coupons from being used to purchase drugs covered by Medicare Part D; this encourages Part D beneficiaries from buying a higher cost brand drug rather than a drug with equal effect but lower cost
 - Estimated that Medicare and its beneficiaries could have saved \$12 billion during CY 2012 through 2017 if CMS reduces hospital outpatient department payment rates for ambulatory surgical center (ASC)-approved procedures to the same level as ASC payment rates.
 - Medicare Part B would've saved more than \$100 million in 2011 if its rates for dispensing and supplying fees for certain drugs were aligned with Part D or State Medicaid rates

Federal enforcement initiatives are becoming “preventive” through use of technology

- The Fraud Prevention System applies predictive analytic technology to claims prior to payment to identify aberrant and suspicious billing patterns
- In its second year of implementation, the Fraud Prevention System:
 - Generated leads for 469 new fraud investigations
 - Provided new information for 348 existing investigations
 - Stopped, prevented, or identified \$210.7 million in payments
 - Results are a **\$5 to \$1** return on investment, almost double the value of the first year of the program

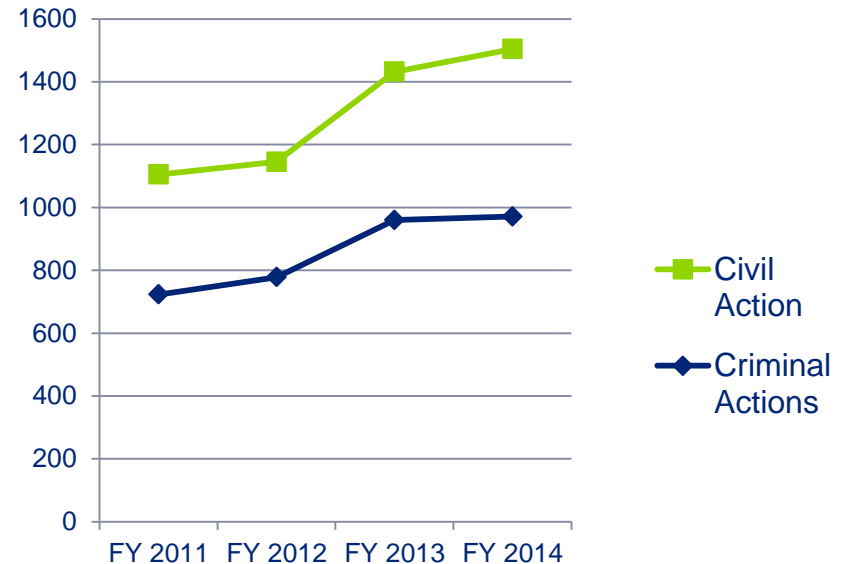
Source: Information on the fraud prevention accomplishments under the Affordable Care Act at <http://www.stopmedicarefraud.gov/fraud-rtc06242014.pdf>.



Rise in OIG Criminal and Civil Actions

Per the OIG's Fall Semiannual Reports to Congress for Federal FY 2014, criminal and civil actions against all HHS programs are on the rise.

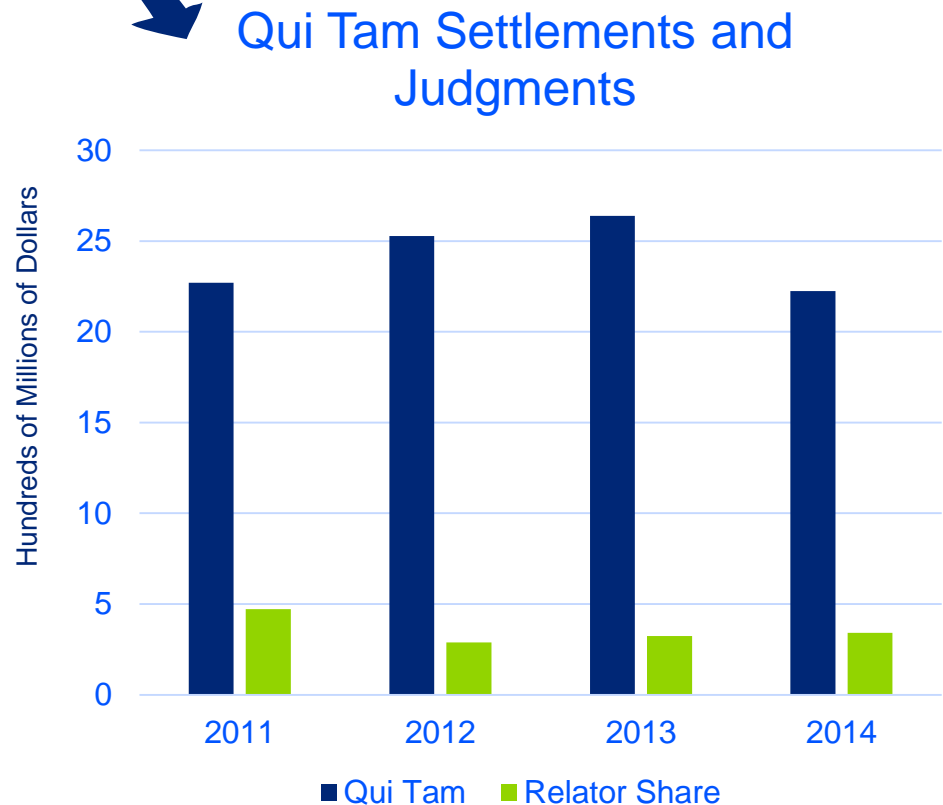
| Year | Criminal Actions | Civil Actions |
|---------|------------------|---------------|
| FY 2011 | 723 | 382 |
| FY 2012 | 778 | 367 |
| FY 2013 | 960 | 472 |
| FY 2014 | 971 | 533 |



Whistleblower Activity Continues

| Year | Reports Made |
|--------------|--------------|
| 2011 | 417 |
| 2012 | 415 |
| 2013 | 503 |
| 2014 | 469 |
| Total | 1,804 |

- Qui tam reports made have continued at a steady pace since 2011
- Settlements awarded from qui tam reports increased from 2011 to 2013 but dropped slightly in 2014 to \$2.22 billion
- Relator share awards have remained fairly constant in the past few years, with awards totaling \$342 million in 2014



Top 10 Health Care Fraud Issues in 2015

BNA's Health Care Fraud Report

According to *BNA's Health Care Fraud Report*, the following are the top issues to watch in 2015:

1. Increased in False Claims Act cases involving Stark issues, Medicare Advantage and managed care and pharmaceuticals
2. Increase in prosecutions of health-care executives
3. Increase in cases alleging fraud within the insurance exchanges
4. Expansion of fraud enforcement into Medicare Part C and Part D
5. Increased scrutiny of Open Payments data and the CMS Part B database
6. Increase in litigation resulting from the publication of the final 60-day repayment rule
7. Growth in state False Claims Act enforcement
8. Growth in state Medicaid enforcement
9. Increased use of CMS enforcement tools, such as payment suspensions and moratoria
10. Increase in data breach and cybersecurity investigations

New Corporate Integrity Agreements

| Organization Name | Date |
|---------------------------------------------------------|------------|
| Good Shepherd Hospice | 02/11/2015 |
| Irwin County Hospital | 02/09/2015 |
| Daiichi Sankyo, Inc. | 01/12/2015 |
| CareAll, Inc. | 11/13/2014 |
| Borio Chiropractic Health Center and Joseph Borio, D.C. | 11/05/2014 |
| Ocean Dental, P.C. | 11/04/2014 |
| Dignity Health | 11/03/2014 |
| DaVita HealthCare Partners Inc. | 10/27/2014 |
| Community Health Systems | 08/19/2014 |
| Tri-County Ambulance | 08/14/2014 |
| Mid Hudson Medical Group, P.C. | 05/16/2014 |
| CVS Caremark Corporation | 04/01/2014 |
| American Family Care Inc. | 03/21/2014 |
| Saint Joseph London | 03/20/2014 |
| Halifax Hospital Medical Center | 03/14/2014 |

Deeper Dive on Some Recent CIA's

Physician Arrangements

Infirmity Health Systems, Inc. \$24.5 Million violation (July 14)

- Federal whistle-blower lawsuit that claimed its clinics routinely overpaid doctors to refer their radiology patients to hospitals
- Whistleblower was a physician (2008), received \$4.4 M
- Case centered upon incentives paid to physicians for referrals
- Signed Corporate Integrity Agreement
 - http://oig.hhs.gov/fraud/cia/agreements/Infirmity_Health_System_07182014.pdf
 - 5 year commitment
 - Legal IRO required
 - Focus Arrangement obligations

Inpatient Medical Necessity

Dignity Health – October 30, 2014

- Appointment of Service Area Compliance Officers
- Service Area Compliance Committees
- Must submit to OIG all documentation reviewed and actions taken related to oversight of compliance program
- Board resolution of compliance with CIA and if cannot achieve reasons why
- Certifications:
 - Executive Leadership (9)
 - Operations Leadership (15)
 - CFO; with annual report submission
- Inpatient admission Medical Necessity
- Risk Assessment and Internal Review Process

Nason Medical Center – CIA Management Certifications

In addition to the responsibilities set forth in this CIA for all Covered Persons, certain Nason employees (Certifying Employees) are specifically expected to monitor and oversee activities within their areas of authority and shall annually certify that the applicable Nason department is in compliance with applicable Federal health care program requirements and with the obligations of this CIA. These Certifying Employees shall include all employees with management responsibilities. Such employees include, but are not limited to, the following positions: the Billing Manager; Director of Human Resources; Medical Director; Nason Medical Center Manager and CEO; Laboratory Director; Radiology Director; Business Administration Manager; Accounting Director; Director of Business Analysis; and Bankfield CEO.

Nason Medical Center – CIA Management Certifications (cont.)

“I have been trained on and understand the compliance requirements and responsibilities as they relate to [insert name of department, and/or facility], an area under my supervision. My job responsibilities include ensuring compliance with regard to the [insert name of department, and/or facility] with all applicable Federal health care program requirements, obligations of the Corporate Integrity Agreement, and Nason policies, and I have taken steps to promote such compliance. To the best of my knowledge, except as otherwise described herein, the [insert name of department] of Nason is in compliance with all applicable Federal health care program requirements and the obligations of the Corporate Integrity Agreement. I understand that this certification is being provided to and relied upon by the United States.”

Recent Medical Necessity Cases with Cardiac Procedures

All involving incentives to Physicians

- Kings and Daughters Medical Center (May 2014)
 - \$40.9 million settlement
 - 5 year CIA
- Saint Joseph's London (January 2014)
 - \$16.9 million settlement
 - 5 year CIA
- Adventist Health Systems/West and St Helena Hospital Napa Valley (Jan 2015)
 - \$2.25 million settlement

Case Based on CMS Physician Payments Data

The government announced it had joined two lawsuits against Qamar (Florida Physician) and his physician group, the Institute for Cardiovascular Excellence, alleging they performed unnecessary, invasive heart testing and paid patients kickbacks by waiving their copayments and deductibles for the services.

Greg Kehoe, an attorney for Qamar with Greenberg Traurig, said in a statement Monday that “Qamar practices under the highest medical and ethical standards” and “will defend himself vigorously against these baseless allegations.”

In 2012, Qamar collected more Medicare dollars—\$18 million—than any other cardiologist in the country, according to one of the lawsuits. That ranking was based on data made public last year that reveals Medicare Part B payments to individual physicians and physician practices by the CMS. The data was released after a federal judge ruled in May 2013 against a 1979 prohibition on the disclosure of such data.

Update on Recent Government Audit Activity

Examples of recent Medicare Payments, Policies and Quality

Hospitals – Postacute Care Transfer Policy

- Medicare inappropriately paid hospital inpatient claims subject to its postacute care transfer policy, resulting in overpayments of \$19.5 million over a 4 year span
- Common Working File (CWF) edits related to postacute care transfer were not working properly
- OIG recommended that CMS correct the CWF edits, educate hospitals on the importance of reporting the correct patient discharge status codes on transfer claims, direct Medicare contractors to recover the \$19.5 million in identified overpayments, and direct Medicare contractors to identify any transfer claims on which the patient discharge status was coded incorrectly

Selected OIG recoveries September 2014 – February 2015

| Provider | Date | Focus | Claims Reviewed | Erroneous Claims | Overpayment Recovery |
|-------------------------------------------|------------|------------------|-----------------|------------------|----------------------|
| University of North Carolina Hospitals | 2/2/2015 | I/P & O/P claims | 192 | 59 | \$ 452,000 |
| Beth Israel Deaconess Medical Center | 1/29/2015 | I/P & O/P claims | 3 | 20 | \$ 483,000 |
| Iowa Methodist Medical Center | 1/27/2015 | I/P & O/P claims | 216 | 36 | \$ 216,000 |
| Ochsner Medical Center | 12/29/2014 | I/P & O/P claims | 107 | 51 | \$ 396,000 |
| Boone Hospital | 12/10/2014 | I/P & O/P claims | 202 | 105 | \$ 407,000 |
| University of Missouri Health Center | 12/5/2014 | I/P & O/P claims | 159 | 24 | \$ 189,000 |
| Queen's Medical Center | 10/27/2014 | I/P & O/P claims | 174 | 49 | \$ 319,000 |
| Oregon Health & Science University (OHSU) | 10/27/2014 | I/P & O/P claims | 45 | 57 | \$ 2,400,000 |
| Avera McKennan Hospital | 10/22/2014 | I/P & O/P claims | 227 | 35 | \$ 174,000 |
| Methodist Healthcare – Memphis Hospitals | 10/22/2014 | I/P & O/P claims | 102 | 48 | \$ 353,000 |
| Hackensack University Medical Center | 10/22/2014 | I/P & O/P claims | 138 | 62 | \$ 352,000 |
| Yale-New Haven Hospital | 10/20/2014 | I/P & O/P claims | 79 | 113 | \$ 1,700,000 |
| Mission Hospital | 10/2/2014 | I/P & O/P claims | 144 | 48 | \$ 443,000 |
| Orlando Health | 9/26/2014 | I/P & O/P claims | 143 | 75 | \$ 1,400,000 |
| Genesis Medical Center | 9/4/2014 | I/P & O/P claims | 286 | 71 | \$ 434,000 |
| Cox Medical Center | 9/4/2014 | I/P & O/P claims | 177 | 33 | \$ 302,000 |

Source: <https://oig.hhs.gov>; Section 8L of the Inspector General Act, 5 U.S.C. App., requires that OIG post its publicly available reports on the OIG Web site.

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OIG Work Plan

FY 2015

OIG 2015 Work Plan



OIG added two new compliance risk areas to the FY 2014 plan:

- Review of Hospital Wage Data
 - Review hospital controls over the reporting of wage data used to calculate wage indexes for Medicare payments; hospitals must accurately report wage data to CMS annually to develop wage index rates
- Adverse Events in Long-Term Care Hospitals
 - Examine national incidence of adverse and temporary harm events for Medicare beneficiaries receiving care in long-term care hospitals; OIG will identify factors contributing to the adverse events, determine the extent to which the events were preventable, and estimate associated costs to Medicare

OIG 2015 Work Plan (cont.)



Some hospital audit activities to highlight that are continuing to be examined following the FY 2014 plan are:

- New inpatient admission criteria
 - Determine the impact of new inpatient admission criteria on hospital billing, Medicare payments, and beneficiary payments, and determine how billing varied among hospitals in FY 2014
- Medicare costs associated with defective medical devices
 - Review Medicare claims to identify the costs resulting from additional utilization of medical services associated with defective medical devices and determine the impact of the cost on the Medicare Trust Fund
- Comparison of provider-based and free-standing clinics
 - Determine the difference in payments made to the clinics for similar procedures, and assess the potential impact on the Medicare program of hospitals' claiming provider-based status for such facilities

OIG 2015 Work Plan (cont.)



Hospitals—Billing and Payments

- Outpatient evaluation and management services billed at the new-patient rate
 - Determine if Medicare outpatient payments for E/M services for clinic visits billed at the new-patient rate were appropriate, and recommend recovery of overpayments
- Nationwide review of cardiac catheterization and heart biopsies
 - Determine if hospitals complied with Medicare billing requirements for right heart catheterizations and heart biopsies billed during the same operative session
- Indirect medical education payments
 - Determine whether IME payments were calculated properly and payments were made in accordance with Federal regulations and guidelines

OIG 2015 Work Plan (cont.)



Hospitals—Quality of Care and Safety

- Oversight of pharmaceutical compounding
 - Describe Medicare’s oversight of pharmaceutical compounding in Medicare-participating acute care hospitals, and describe how State agencies and hospital accreditors assess such pharmacy services in hospitals
- Oversight of hospital privileging
 - Determine how hospitals assess medical staff candidates prior to granting initial privileges, including verification of credentials and review of the National Practitioner Databank

OIG 2015 Work Plan (cont.)



OIG will continue to examine other Medicare Hospital Audit compliance risk areas that were the focus of earlier plans, which include:

- Reconciliations of Outlier Payments;
- Analysis of Salaries Included in Hospital Cost Reports;
- Medicare Oversight of Provider-Based Status;
- Critical Access Hospitals – Payment Policy for Swing-Bed Services;
- Inpatient Claims for Mechanical Ventilation;
- Review of Selected Inpatient and Outpatient Billing Requirements;
- Duplicate Graduate Medical Education Payments;
- Outpatient Dental Claims;
- Payments for Patients Diagnosed with Kwashiorkor;
- Bone Marrow or Stem Cell Transplants;
- Hospital Participation in Projects with Quality Improvement Organizations;
- Oversight of Pharmaceutical Compounding; and
- Inpatient Rehabilitation Facilities – Adverse Events in Post-Acute Care for Medicare Beneficiaries.

OIG 2015 Work Plan (cont.)



Medicare Providers and Suppliers

- These providers include skilled nursing facilities, hospices, ambulance suppliers, and individual practitioners
- One new focus area for these other providers include:
 - Selected Independent Clinical Laboratory Billing Requirements: Review Medicare payments to independent clinical laboratories to determine laboratories' compliance with selected billing requirements; results of reviews will be used to identify clinical laboratories that routinely submit improper claims

OIG 2015 Work Plan (cont.)



Other Provider and Supplier Compliance Risk Areas:

- Medicare Part A Billing by Skilled Nursing Facilities;
- Questionable Billing Patterns for Part B Services During Nursing Home Stays;
- Hospice in Assisted Living Facilities;
- Hospice General Inpatient Care;
- Home Health Prospective Payment System Requirements;
- End-Stage Renal Disease Facilities – Payment System for Renal Dialysis and Drugs;
- Ambulance Services – Questionable Billing, Medical Necessity and Level of Transport;
- Anesthesia Services – Payments for Personally Performed Services;
- Diagnostic Radiology – Medical Necessity of High-Cost Tests;
- Physicians – Place-of-Service Coding Errors;
- Physical Therapists – High Use of Outpatient Physical Therapy Services; and
- Sleep Disorder Clinics – High Use of Sleep-Testing Procedures.

What's to come in 2015...

- The Budget request includes \$400 million in discretionary and mandatory funding for the OIG, an increase of \$11 million above the FY 2014 level
- This increase will enable the OIG to:
 - Continue to focus on core risk areas associated with Health Insurance Marketplaces (i.e. payment accuracy, eligibility systems, contracting, and data security)
 - Expand its portfolio examining Medicaid, as the program expands to new populations
 - Address new and existing concerns regarding abuse in managed care, excessive payments to public providers, improper payments and eligibility for Medicaid programs

OIG Compliance Reviews

OIG Compliance Reviews: Letter from AHA

- American Hospital Association (AHA) Letter to the Deputy Inspector General for Audit Services
 - OIG's use of extrapolation is “woefully inadequate” and “artificially inflates” overpayment amounts
 - Request that the OIG audits and issuance of reports immediately be halted
- Four Areas of Concern Addressed in the AHA Letter:
 1. The need for a physician order: the OIG invented the physician order requirement.
 - Prior to 10/1/13, CMS had never required a physician order for short-term, acute care inpatient admission as a condition of Medicare Part A payment.
 2. Treatment of canceled surgeries: the OIG has no basis for reviewing payments for cancelled surgeries under the two-midnight rule
 - Sub-regulatory guidance states that in cases in which a physician reasonably expected the beneficiary to require a hospital stay for two or more midnights at the time of the inpatient order and formal admission, but the surgery is cancelled after admission, the admission is generally appropriate for payment under Part A.
 3. Rebilling of Medicare Part A claims under Part B
 - Part A overpayment values should be offset by the amount of Part B payment the hospital is entitled to receive on the claim.
 4. Review of claims beyond the statute of limitation: the OIG should follow Medicare time limits
 - Medicare statute and regulations impose time limits on findings hospitals liable for overpayments or reopening and reviewing paid claims unless there is actual evidence of “fault.”

OIG Compliance Reviews: Response from the OIG Regarding the AHA Letter

- **OIG's Letter to the General Counsel and Senior VP of the AHA**
 - OIG's continued review of Medicare Part A payments (24% of all Medicare payments) ensures proper use of federal funds
 - 2014 Agency Financial Report estimated \$42.7 billion worth of improper payments in the Medicare fee-for-service program (11.8% improper payment rate)
- **OIG Response to the Four Areas of Concern Addressed:**
 1. **The need for a physician order**
 - OIG's application of a physician- order requirement is supported by legal authority. Prior to applying the requirement the OIG had "extensive" consultations with CMS. CMS regulation in effect during the audit periods stated that Medicare paid for inpatient hospital services only if a physician certified and recertified the reasons for continued hospitalization.
 2. **Treatment of canceled surgeries**
 - OIG found examples of canceled surgeries billed by hospitals to Medicare because of an overbooked surgery room or a preoperative exam with results that no longer qualified for a procedure, in which case these admissions were not reasonable and necessary for illness or injury treatment
 3. **Rebilling of Medicare Part A claims under Part B**
 - The OIG recognizes in a footnote that Medicare Part B rebilling may affect the final overpayment amount. However, it is the responsibility of CMS to process and pay claims. The OIG therefore cannot judge the value of Medicare Part B and providing a Part B value fall outside the scope of the OIG audit.
 4. **Review of claims beyond the statute of limitation**
 - CMS allows for reopening of claims at any time provided that there is reliable evidence that the initial determination was procured by fraud or similar audit. The OIG ultimately recognizes CMS as the cognizant Federal agency that has the authority to decide how to resolve any claims opened beyond the reopening period.

Physician Risk Areas and Recent Activity

Physician Financial Arrangements Overview

- Health care organizations must ensure professional services agreements with physicians, medical groups, physician-owned entities and other focused arrangements including laboratories, ambulance companies and research are in compliance with applicable laws
- These laws are broad in reach and complex in nature, requiring consistent policies and procedures to address risks
- Physician Financial Relationships set forth basic expectations for such organizations' policies and procedures
- Federal laws applying to physician financial arrangements include:
 - Ethics in Patient Referrals Act (Stark Law)
 - Anti-Kickback Statute (AKS)
 - Civil Monetary Penalties Law
 - False Claims Act (FCA)

Implications for Provider Arrangements with Healthcare Professionals (HCPs)

Stark Law

- States that an entity that collects payment for designated health services that were performed pursuant to a prohibited referral must refund all collected amounts on a timely basis

Anti-Kickback Statute (AKS)

- Courts generally accept AKS as predicate for FCA violation
- Government would not have paid claim had it known it was in violation of AKS
- Provider falsely certified compliance with Federal Laws

Potential Liability

- If a violation of Stark or AKS occurs, referrals are inappropriate and therefore should not have been billed (FCA violation)
- If the claims were billed and payment was made for them, then it falls under FCA related to overpayment

Implications for Provider Arrangements with Healthcare Professionals (HCPs)

Civil Monetary Payments Act

- The OIG may seek payments, assessments and in some cases exclusion from participation in Medicare or Medicaid programs
- Conduct resulting in CMPs includes violations of AKS and Stark and arranging with individuals or entities that should be excluded from participation in a Federal Healthcare program

False Claims Act

- Federal law and civil statute prohibiting anyone from knowingly submitting claims to, or making a false record or statement in order to seek payment by the federal government

Potential Liability

- If an individual or entity presents or causes to be presented a claim to a Federal Healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent, they are liable and subject to a CMP
- False claims submitted with actual knowledge, taken in deliberate ignorance of or in reckless disregard of the truth or falsity of information provided

Compliance Risk Areas for Physician Financial Arrangements

Policies and Procedures

- Lack of formalized written policies and procedures
- Policies not current, updated, or comprehensive

Database

- No means to track and monitor physician arrangements
- Incomplete, inaccurate database
- Missing supportive documentation

Contracts

- Not fully signed or executed
- Not reviewed or updated for regulatory changes
- No documentation of review and approval according to hospital policy

Payments

- Payment is made for a service that is not properly described or included in the agreement
- Payment is made to a party other than the actual party to the agreement
- Payment is not reviewed and approved, or is made without a written agreement
- Payment is made after contract has expired

Other

- Lack of auditing and monitoring
- Non-monetary compensation not tracked
- Identified potential issues not resolved

Physician Arrangements in the Headlines

“Kidney Care Company to Pay \$389M to settle an anti-kickback Probe”

- *Department of Justice, October 22, 2014*

- The kidney care company identified physicians who had a significant number of patients with renal disease and offered to compensate the physicians for illegally referring their patients to the company’s dialysis centers.
- The settlement resolves allegations regarding the company’s arrangement with physicians and physician groups from March 2005 to last February and allegations originally brought in a whistleblower lawsuit.
- As a part of the settlement, the company has agreed to have an independent monitor review its arrangements with physicians.
- The payment will include \$350 million for the settlement and a civil forfeiture of \$39 million for two specific joint ventures the company entered into with physicians.

Physician Arrangements in the Headlines (cont.)

“Medical Device Companies to pay over \$6M to Resolve Whistleblower Claims that They Paid Kickbacks to Doctors”

- Two medical device companies have agreed to pay the United States \$6.07 million to resolve allegations that they used kickbacks to induces physicians to purchase the companies' bone growth stimulators.
- The settlement comes from a whistleblower complaint filed by a former employee, pursuant to the qui tam provisions of the False Claims Act.
- The defendant claimed that the companies caused false claims to be submitted to Medicare and Medicaid by using illegal kickbacks, which included remuneration to staff in doctor's offices.
- The U.S Concluded that the payments violated the Anti-Kickback Act.

Physician Arrangements in the Headlines (cont.)

Cardiologists Agree to Pay \$380,000 to Settle False Claims Act Allegations Based on Illegal Referrals

- Two cardiologists have agreed to pay \$380,000 to resolve allegations that they violated the False Claims Act.
- Alleged that they entered into sham management agreements with a nearby hospital, in exchange for the referral of cardiology procedures and other healthcare services.
- The two doctors entered into an exclusive agreement with the hospital to refer their clinic patients to the hospital for cardiology and other services, directly violating the Stark Law and the Anti-Kickback Statute.
- The settlement stems from a complaint filed by three cardiologists pursuant to the whistleblower provisions of the False Claims Act.

Physician Arrangements in the Headlines (cont.)

Health System and Clinics to Pay \$24.5 Million to Settle Alleged Diagnostic Imaging Scheme

- A health system and its clinics agreed to pay the United States Department of Justice \$24.5 million to settle a qui tam action alleging improper payments to physicians in violation of the federal Stark Law and Anti-Kickback Statute.
- Two of the clinics within the health system paid it a percentage of collections, including collections from services referred by the health system's physicians that were performed and billed by the clinics to Medicare.
- The health system also allegedly compensated individual physicians based on their referrals of diagnostic tests to these clinics.
- The health system had already been advised by outside counsel in 2010 that the payments likely violated the Stark Law, but the defendants continued to make the payments.
- A formerly employed cardiologist employed by DPG brought the whistleblower qui tam action.

Meaningful Use and EHRs

Meaningful Use Industry Update

CMS recently released key statistics that resulted from the adoption of EHRs through MU requirements. ***As of the end of October 2014:***

Over ***\$16.7 billion*** has been issued in Medicare and Medicaid incentive payments

92 percent of hospitals have registered for the EHR Incentive Program and approximately ***88 percent of hospitals have been paid***

Approximately 82 percent of EPs have registered for the EHR Incentive Programs and ***62 percent have received an EHR incentive payment***



Meaningful Use



Sources: Philip Peisch, CMS Releases EHR (Electronic Health Records) Incentive Program Data, *The National Law Review*, 15 Jan. 2015, <http://www.natlawreview.com/article/cms-releases-ehr-electronic-health-records-incentive-program-data>; HIT Policy Committee, 4 Feb 2014. http://www.cms.gov/Regulations-and-Guidance/Legislation/EHRIncentivePrograms/Downloads/HITPC_January2015_Full_Deck.pdf

Meaningful Use Attestation

Prior to 'pushing the button', your Attesting Officer will need to agree to the following statement:

*"I certify that the foregoing information is **true, accurate, and complete**. I understand that the Medicare EHR Incentive Program payment I requested will be paid from Federal funds, that by filing this attestation I am submitting a claim for Federal funds, and that the use of any false claims, statements, or documents, or the concealment of a material fact used to obtain a Medicare EHR Incentive Program payment, may be prosecuted under applicable Federal or State criminal laws and may also be subject to civil penalties."*

- CMS Attestation Site

Meaningful Use Audit Landscape

- **CMS is targeting approximately 10% of all providers for audit in a given year.** All aspects of the attestation are subject to audit, as Meaningful Use is an “all-or-nothing” program.
- CMS began pre-payment audits in January 2013 after pressure from GAO and OIG. OIG has added elements of Meaningful Use to their work plan for fiscal year 2014.
- CMS audits require supporting documentation to be provided to the auditor to validate the submitted attestation data.
- During a presentation on MU Audits given Tuesday February 25, 2014 at HIMSS, Rob Anthony, deputy director at the CMS Office of E-Health Standards and Service had this to say:
*“You absolutely have to document how you got to those numbers,” Anthony said. “I’m shocked by the number of people who do not retain any documentation. **This is the No. 1 area that people experience problems with audits – the No. 1 area where people fail with audits, and it’s with audit documentation related to their attestation figures.**”*
- His advice regarding the three ways to dispel the uncertainty that comes with audits:
“Document, document, document.”

Meaningful Use Audits — Case Study

- In the headlines ***“HMA to Repay \$31M in Improper Meaningful Use Payments”***
- HMA filed a report with the SEC in October 2013 after an internal review revealed an error occurred when certifying its EHR technology.
- Although HMA’s discovery of improper payments was internal, Modern Healthcare reported that hospitals nationally will be taking a closer look at their eligibility for receiving federal incentive payments for EHRs as Meaningful Use audits are being performed.

Meaningful Use Audits — What Will Be Audited?

Upon receipt of an audit letter, EHs and EPs are required to submit supporting documentation for the following:

- Ownership of Certified EHR
- Reporting method used (All ED Visits or Observation Services)
- Core and Menu Measure Meaningful Use Reports used to enter attestation data
- Documentation for Yes/No attestation measures

It is expected that CMS and the states will utilize the supporting documentation to perform a desk review. Depending on the results of the desk review, an onsite review could follow. Audit procedures may take the form of, but are not limited to the following:

- Reconcile Meaningful Use Reports to attestation data
- Observe required functionality within certified EHR
- Contact public health agencies to validate partnership with providers and hospitals
- Request and review of audit logs from the certified EHR

Meaningful Use Audits — How Can You Prepare?

Be Prepared

- Don't wait until the audit letter has arrived to begin compiling the supporting documentation. Have it ready to go before, or as soon as possible after, the attestation.
- Archive Meaningful Use reports at the end of the reporting period. Do not rely on the EHR to regenerate reports with exactly the same numerators and denominators months later.

Be Organized

- Have an “Executive Summary” which describes the most important information related to your Meaningful Use program. Explain any system affiliations or other unique scenarios which pertain to only your EHs and EPs.
- Create measure by measure documentation to direct an auditor's attention to the pertinent facts.
- Have the documentation available online via SharePoint or an equivalent for easy access remotely.
- Put only the information which evidences you met the measure. Don't give an auditor more than they need.

Be Aware

- Educate EPs and designees of the EHs who may need to respond in the event of an audit. Designate an individual who will coordinate documentation requests.

Meaningful Use Update – Incentives and Penalties

From January 2011 to November 2014, over \$26 billion in Electronic Health Record (EHR) Incentive Program payments have been made to over 425,000 Eligible Professionals (EPs) and 4,700 Eligible Hospitals (EHs).

- For EPs and EHs who have not started Meaningful Use, the incentive payment opportunity has past or been significantly reduced from the maximum
- For EPs and EHs who have met Meaningful Use, the majority of the available incentives have been exhausted and the focus of Meaningful Use compliance has shifted to penalty avoidance

| Reduction In IPPS* Payment Rate for EHs | |
|-----------------------------------------|----------------|
| Penalty Year | Penalty Factor |
| 2015 | 0.25% |
| 2016 | 0.50% |
| 2017+ | 0.75% |

*Inpatient Prospective Payment Schedule

| Reduction In Medicare Part B Payment Rate for EPs | |
|---------------------------------------------------|----------------|
| Penalty Year | Penalty Factor |
| 2015 | 1.0% |
| 2016 | 2.0% |
| 2017+ | 3.0%* |

*Subject to change based on number of total EPs who have met MU

Penalties began in 2015 for EPs and EHs who have not attested for Stage 1 Meaningful Use prior to October 1, 2014 and July 1, 2014 respectively. The opportunity to receive penalties remains indefinitely. EPs and EHs who do not attest to Meaningful Use in a given year are subject to a penalty two years from the missed attestation. Example Timeline:



Meaningful Use Update – Regulatory Environment Update

10/1/2013

Starting in federal fiscal (for EHRs) and calendar year (for EPs) 2014, EHRs and EPs must utilize 2014 Certified EHR Technology (CEHRT) in order to meet Meaningful Use, regardless of Stage. For many providers, 2014 is their first year of Stage 2 compliance, meaning they will be required to meet new, more complex measures while trying to implement upgraded or new technology

1/1/2014

9/4/2014

CMS releases the Flexibility Rule, designed to allow providers to meet Meaningful Use despite being unable to implement 2014 CEHRT due to vendor delays. The Flexibility Rule comes after months of industry chatter about the challenges in implementing 2014 CEHRT. Providers now have the opportunity to attest to Stage 1 or Stage 2 using either 2011 or 2014 CEHRT, depending on their situation

1/29/2015

CMS announces their intent to make changes to the Meaningful Use program for the 2015 reporting year. The proposed changes include moving EHRs to a calendar year reporting year and shortening the 2015 reporting period to 90 days from 365 days. A timeline for the proposed rule to be released was not provided.

March 2015

The Stage 3 proposed rule is expected to be released. This is a separate rule making from the one described above. Stage 3 compliance is required beginning in 2017 for providers who began meeting Meaningful Use prior to or beginning in 2013

Meaningful Use – Updated Timeline

| First Payment Year | Stage of Meaningful Use | | | | | | | | | | |
|--------------------|-------------------------|------|------|--------|------|------|------|------|------|------|------|
| | 2011 | 2012 | 2013 | 2014 | 2015 | 2016 | 2017 | 2018 | 2019 | 2020 | 2021 |
| 2011 | 1 | 1 | 1 | 1 or 2 | 2 | 2 | 3 | 3 | TBD | TBD | TBD |
| 2012 | | 1 | 1 | 1 or 2 | 2 | 2 | 3 | 3 | TBD | TBD | TBD |
| 2013 | | | 1 | 1 | 2 | 2 | 3 | 3 | TBD | TBD | TBD |
| 2014 | | | | 1 | 1 | 2 | 2 | 3 | 3 | TBD | TBD |
| 2015 | | | | | 1 | 1 | 2 | 2 | 3 | 3 | TBD |
| 2016 | | | | | | 1 | 1 | 2 | 2 | 3 | 3 |
| 2017 | | | | | | | 1 | 1 | 2 | 2 | 3 |

Key Takeaways:

- No matter which year you begin Meaningful Use, the provider will start with a 90 day reporting period for Stage 1
- In 2014, all providers may utilize a 3-month quarter reporting period, regardless of Stage
 - Providers can also choose to attest to Stage 1 or Stage 2 under the Flexibility Rule, should they be eligible
- CMS intends to propose a 90 day reporting period for 2015
- Stage 3 compliance begins no earlier than 2017

Meaningful Use Audits: The Request

Currently, CMS audits are initialized by an email sent to address on file with the EH or EP's registration. The initial email includes a documentation request list, a link to the secure web portal where required documentation will be submitted, a username and password, and a request to confirm receiving the email.

In our experience, the majority of the audits request the following documentation:

| Request | Examples of Common Audit Evidence |
|-------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Proof of EHR Ownership | An invoice, licensing agreement or letter from your vendor which provides evidence that an EH or EP has access to a EHR certified to the criteria needed to meet the in scope Stage of Meaningful Use. |
| Core and Menu Measure Reports | The reports generated from your EHR or other reporting solution which provided the numerators and denominators used to complete the attestation. This may also include an explanation of the report creation process. |
| Security Risk Analysis | Documentation which evidences the completion of a Security Risk Analysis by the end of the reporting period and development of an implementation plan based on the results of the analysis. |
| "Yes/No" Measure Supporting Documentation | For select measures that require a "Yes" attestation, provide documentation which evidences you have met that measure during the reporting period. This may include letters from a public health agency or screenshots from the EHR with accompanying narratives. |

It is expected that future audits will request documentation which supports the use of the Flexibility Rule. This documentation must provide evidence that the failure to fully implement 2014 CEHRT was due to vendor delays.

Outpatient & Physician Coding Highlights

Modifier 59 and Related Updates

Modifier 59 / X(ESPU) Modifiers

- Effective January 1, 2015
- In facility outpatient payments, projected \$11 Billion was billed on lines with a modifier 59 and projected error of \$450 million
- Can still utilize 59, however if more specific use the following modifiers:
 - XE: Separate encounter, a service that is distinct because it occurred during a separate encounter
 - XS: Separate structure, a service that is distinct because it was performed on a separate organ / structure
 - XP: Separate practitioner, a service that is distinct because it was performed by a different practitioner
 - XU: Unusual non-overlapping service, the use of a service that is distinct because it does not overlap usual components of the main service

Modifier 59 and Related Updates (cont.)

Other OPPS changes to watch for

- New modifier “PO” – services, procedures and/or surgeries provided at off campus provider-based outpatient departments
- Deactivated the “procedure-to-device” and “device-to-procedure” edits
 - Now have device dependent codes, but not editing to make sure correct device
- Comprehensive APCs – all inclusive payment for specific procedures
- G codes:
 - New CPT and HCPCS codes / changes are not always available when the proposed OPPS rule is published for comment. Creating G codes for old codes and will not use new codes January 1, 2015. Hoping AMA can release new codes earlier to include in proposed OPPS rule.
 - Voluntary January 1, 2015, but will be mandatory to use G codes in 2016
 - As an example: 80152 (Assay of Amitriptyline) was deleted on December 31, 2014. The new codes are 80335, 80336, 80337. CMS created G6030 for Assay of Amitriptyline.

Other physician coding enforcement

Overbilling for in-office urine drug testing

- A Georgia physician entered into a settlement for \$305,168.54. The OIG contends the physician submitted claims to Medicare for urine drug tests that exceeded the number of units allowed by Medicare by using an inappropriate code to bypass coding edits.

Overbilling for CPT code 93042

- OIG alleged that a cardiology group billed Medicare for CPT code 93042 (Rhythm ECG, 1-2 leads; interpretation and report only) in excess of one per patient per day where there was no documented change in the patient's condition to warrant an additional service.

Improper E&M charges

- OIG alleged that a pulmonary group submitted E&M services at higher CPT codes than supported by documentation. Group to pay settlement amount of \$79,792.33.

RAC Updates

News and updates: Medicare RAC

Medicare RAC contracts

- Regions 1-4 - expected to not be solidified with vendors until late summer 2015
- Region 5 - awarded to Connolly, and immediately protested by Performant

Medicare RAC activities through December 2015

- Limited reviews continue, such as automated reviews and specific inpatient DRGs
- Medical necessity of inpatient care (two-midnight rule) continue to be off limits

Medicare RAC new terms include

- Sliding scale number of records that can be requested, based on percentage of findings
- No ability to review two-midnight rule records from October 2013 through October 2015

Medicare RAC Region 5 (DME & HH/H) anticipated methodology

- Automated and complex reviews
- Focus on prior vulnerabilities uncovered by MAC, OIG, ZPIC and CERT reviews

News and updates: Medicare RAC

Appeals backlog

- Comments from Chief Administrative Law Judge Nancy J. Griswold, November 5, 2014:
 - Current stats for the the Office of Medicare Hearings and Appeals (OMHA):
 - Appeals are taking 514 days to be processed
 - The level of appeals remain high at 14,000 per week
 - Two issues identified:
 - Handling the large number of appeals already pending at OMHA
 - Positioning OMHA for the future so that it can handle its workload of incoming receipts in a timely manner
 - Recent progress:
 - New field office in Kansas City: Opened in August 2014 and by next spring the Kansas City office will be expanded to accommodate 18 ALJ teams and 18,0000 appeals a year
 - Electronic Case Adjudication and Processing Environment (ECAPE): development contract to be awarded January 2015, with the first release scheduled for fall of 2015.
 - Scanning contract to be awarded by the end of the calendar year

Clinical Trial Billing Compliance

Clinical Trial Billing Compliance

Reporting of the 8-digit National Clinical Trial (NCT) Registry Number:

- Beginning January 1, 2015, the actual NCT number will be required to be reported.
 - A use of the actual clinical trial registry number **OR** generic number of 99999999 can only be reported through December 31, 2014.
- Medicare Part B clinical trial/registry/study claims with dates of service on and after January 1, 2014, not containing NCT number will be returned as unprocessable to the provider for inclusion of the trial number. The following coding requirements will assist Medicare identify such claims:
 - ICD-9-CM diagnosis code V70.7 / ICD-10 diagnosis code Z00.6
 - Condition code 30
 - Modifiers Q0 / Q1
 - Investigational Device Exemption (IDE) Number for the Category B investigational device claims
- **Why is this a challenge?** – **There is a direct reimbursement impact!** This requirement is requiring organization to re-evaluate their processes and enhance communications across departments to validate accuracy and completeness of the claims before it is submitted to the payor.
- The NCT number requirement is the **'icing on the cake'**, requiring and encouraging compliance with billing guidelines for the government payors!

Sources: CMS Q&A on the Mandatory Reporting of National Clinical Trial (NCT) Identifier Numbers on Medicare Claims: <http://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Downloads/Mandatory-Clinical-Trial-Identifier-Number-QsAs.pdf>; CMS NCT number reporting requirements: <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-LN/MLNMattersArticles/downloads/MM8401.pdf>; <http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-LN/MLNMattersArticles/downloads/SE1344.pdf>

Clinical Trial Billing Compliance

Leading practices

- Establish communication channels to support administrative infrastructure for clinical trial revenue cycle processes
- Perform periodic review of policies & procedures
- Maintain clear delineation of roles and responsibilities
- Implement an on-going education plan for all stakeholders
- Develop and implement an auditing and monitoring plan

Some key auditing and monitoring areas

- Billing of Research Sponsored (RS) and Standard of Care (SOC) services
- Coding of in-patient vs. outpatient claims
- Coding and billing of investigational devices
- Complete and accurate medical documentation to support billing
- Denied claims by government and non-government payors

Contact Information

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