

Health Care Reform:
The New Program Integrity Provisions What's next
for physicians – audits on steroids?

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Introduction

- Patient's trust physician's medical choices for proper treatment
- Federal Gov. place trust in physicians for proper billing of Medicare/Medicaid claims
- Fraud and Abuse laws were put in place to combat the few physicians who might abuse this trust

Topics

- Fraud and Abuse Laws
 - False Claims Act (FCA)
 - Anti-Kickback Statute (AKS)
 - Physician Self Referral law (Stark)
 - Civil Monetary Penalties (CMP)
 - Exclusion Authorities
- More funding for Fraud and Abuse
- Mandatory Return of Overpayments Provision
- Amendments to Anti-Kickback Statute (AKS)
- New Penalties under the CMP Statute
- New Exclusions to Definition of “remuneration” under CMP Statute
- Health Care Reform (ACA) – MICs, MACs, RACs and ZPICs

False Claims Act (FCA) 31 U.S.C. 3729-3731

- As amended by the Fraud Enforcement and Recovery Act of 2009
- (FERA), liability under the False Claims Act occurs when a person or entity:
 - knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval (no specific intent to defraud required);
 - knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or
 - conspires to commit a violation of any of certain provisions of the False Claims Act (including the two listed above).
 - Violations are punished by penalties of not less than \$5,500 and not more than \$11,000 per claim, plus treble damages for the amount of damages the Government sustains.
 - Whistleblower (qui tam) suits are allowed.
 - Reverse false claims provision now may reach self-discovered overpayments.
- FCA actions can be based on Anti kickback Statute and/or Stark Law violation.

AKS

1. Anti-Kickback Statute (AKS) (Criminal Law)
 - a) Section 1128(b) of the SS Act, 42 USC 1320a-7b(b); regulations are at 42 CFR, Part 1001. The AKS prohibits:
 - b) Knowingly and willfully soliciting or receiving, or offering or paying, any remuneration, directly or indirectly, covertly or overtly, in cash or in kind, (illegal inducement) –
 - i. In return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under Medicare or a State health care program; or
 - ii. In return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under Medicare or a State health care program

AKS

- The AKS is a criminal statute, and government must provide beyond a reasonable doubt intent of an illegal inducement
 - Liability can attach to both sides of arrangement or just one side
- Case law holds that where even one intent of arrangement was for an illegal inducement, AKS is violated
- Statute prescribes exceptions, known as “safe harbors” and also allows OIG to issue additional safe harbors through regulations. Where all of the safe harbors are met, AKS will not apply, regardless of intent

AKS

- Volume/revenue-based performance measures implicate the AKS
 - Should not reward increase utilizations, revenue, or profits of service line
 - Should not reward change in case mix
 - Should not reward change in acuity
 - Should obtain independent appraisal of FMV to help negate inference of improper intent
- Non-Fair Market Value Compensation arrangements raise red flag
- Beneficiary Inducement Statute (42 USC 1320a-7a(a)(5)) – imposes CMP for offering Medicare/Medicaid beneficiaries remuneration to use physician's services

Physician Self Referral (Stark)

- Entity – is a person or entity that performs service billed as DHS or submits a claim for DHS
- Physician or immediate family member is defined broadly
- Financial relationship
 - May be ownership/investment interest or compensation arrangement
 - May be direct or indirect – definition of indirect is very technical
 - May exist between a physician and a DHS entity or between physician's immediate family and DHS entity

Physician Self Referral (Stark) Section 1877 of SS Act, 42 USC 1395nn

- Prohibits a physician from making referrals for certain “designated health services” (or DHS) payable by Medicare to an entity with which he or she (or an immediate family member) has a financial relationship, unless an exception applies
- Prohibits the entity from submitting a claim (or causing a claim to be submitted) to Medicare
- “Financial relationships” include both ownership and compensation relationships.
- Strict liability statute – no intent to violate necessary for claims to be denied, but enhanced penalties available for knowing violations (CMPs/assessments, exclusion, and False Claims liability)

Physician Self Referral (Stark) Section 1877 of SS Act, 42 USC 1395nn

- DHS includes:
 - Clinical Laboratory Services
 - Physical Therapy Services
 - Occupations Therapy Services
 - Radiology services, including MRI, CT, and ultrasound services (also includes nuclear medicine services effective 1/1/07)
 - Radiation therapy services and supplies
 - Durable medical equipment and supplies
 - Parenteral and enteral nutrients, equipment and supplies
 - Prosthetics, orthotics, and prosthetic devices and supplies
 - Home health services
 - Outpatient prescription drugs
 - Inpatient and outpatient hospital services

Physician Self Referral (Stark)

- Penalties:
 - For knowing or unknowing violations:
 - Denial of payment
 - Refund amounts collected from beneficiary as a result of improper billing (never enforced)
 - For knowing violations, potentially:
 - CMP of \$15,000 per item or service plus 2X the amount claimed
 - CMP of \$100,000 for “circumvention schemes”
 - Exclusion
 - Caselaw:
 - Potential False Claims Act (FCA) Liability for knowing violation (Boot strap of FCA liability to Stark violation)

Civil Monetary Penalty (CMP) Statute

- CMP Statute – Section 1128A of the SS Act, 42 USC 1320a-7a
- Statute gives Secretary the authority to issue CMPs and “assessments” for, among (many) other things:
 - Illegal kickbacks
 - A hospital paying a physician to reduce or limit care (anti-gainsharing provision)
 - Presenting False Claim – could also trigger FCA
 - Violating AKS
- “Knows or should know” standard for liability
- OIG delegated authority to administer
- CMP statute also authorizes exclusion from Federal and State healthcare programs
- Penalties include:
 - \$10,000 - \$50,000 per violation plus 3x amount of the remuneration (violation of AKS)

Exclusion Statute 42 USC 1320a-7

- OIG is required to exclude individuals and entities from participating in Federal health care programs who are convicted of the following:
 - Medicare or Medicaid Fraud
 - Patient Abuse/Neglect
 - Felony Convictions for healthcare related fraud, theft or other misconduct
 - Felony Convictions for unlawful manufacture, distribution, prescription, or dispensing of controlled substances
- OIG discretion to exclude on other grounds
 - Mandatory Exclusion – imposed based on basis of certain criminal conviction
 - Permissive Exclusion – based on sanctions from other agencies – Board issues etc.
- Excluded physicians cant bill Medicare/Medicaid – even through entity (Group); cant prescribe meds that are paid by a federal health care program as well.

The Health Care Reform Statutes

1. The Patient Protection and Affordable Care Act (PPACA)
 - a) Enacted March 23, 2010
 - b) CBO – estimate of \$940 million cost during first 10 years
 - i. Paid for, in part, by eliminating fraud, abuse and waste in Federal health care programs
2. The Health Care and Education Reconciliation Act of 2010 (Reconciliation Act)
 - a) Enacted March 30, 2010
 - b) Makes changes to PPACA

The Health Care Reform Statutes

1. Funding:

- a) Omnibus Appropriations Act of 2009 – provided a one time additional \$198 million
- b) 2010 Budget invests \$311 million in 2 year funding (50% increase over 2009)
- c) 2011 Budget seeks \$250 million to expand HEAT
- d) Section 6402 of PPACA increases health care fraud and abuse control (HCFAC) for FY2011-2020 by \$10 million each year
- e) Section 1303 of the Reconciliation Act adds \$250 million over 6 years
 - i. \$95 million for FY 2011
 - ii. \$55 million for FY 2012
 - iii. \$30 million for FY 2013 and 2014
 - iv. \$20 million for FY 2015 and 2016

The Health Care Reform Statutes

- Most important provision of PPACA
 - a) Section 6402 adds section 1128J to the SS Act (Medicare and Medicaid Program Integrity Provisions)
 - i. Amongst those – Reporting and Returning Overpayments
 - ii. The provision provides that a person or entity receiving an “overpayment” is required to
 - a. Report and return it to the Secretary or the State Medicaid Agency or the appropriate contractor, and (or could have reverse false claim)
 - b. Notify the agency or contractor of the reason for the overpayment
 - iii. Overpayment must be reported and returned within 60 days of the date on which it was identified (By who?), or the date any corresponding cost report is due (if applicable), whichever is later

The Health Care Reform Statutes

- Overpayment is defined as – any funds a person receives or retains under Medicare or Medicaid to which the person, “after applicable reconciliation,” is not entitled
- Any overpayment retained past the deadline is an “obligation” (as defined in, and ofr purposes of, the reverse false claims provision of the False Claims Act.

The Health Care Reform Statutes

- Intent Standard – PPACA amends criminal statutes under AKS to provide “with respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section”
 - Removes intent based
 - Resolves a split in the circuit courts and makes it easier for Government to gain convictions or extract settlements in the 9th Cir.
- Also PPACA makes the same amendment to the criminal Health Care Fraud Statute

The Health Care Reform Statutes

- AKS violation now per se false claim under PPACA
 - “In addition to the penalties provided for in this section or section 1128A, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claims for purposes of the FCA”
 - Amendment applies to AKS and all other criminal statutes in section 1128B of SS Act

The Health Care Reform Statutes

- Section 1128A of the SS Act contains a long list of prohibited activities that subject the actor to CMP, assessments and exclusion from Federal and State Health Care Programs
 - Depending on the act, the max CMP is \$10k, 15k, or 50k, and the maximum assessment is 3X the amount claimed for each such item or service
 - Many but not all of the prohibited acts also subject the actor to exclusion

So what happens if you have a problem?

- If you are engaged in a relationship that could be problematic or have some potential billing issues you realize are wrong:
 - Immediately cease filing problematic bills
 - Seek knowledgeable legal counsel
 - Determine what money you collected in error from patients and Federal healthcare programs – report and return overpayments
 - Unwind problem investments
 - Remove yourself from suspicious relationships
 - Consider either OIG or CMS (Stark) self disclosure protocols

Strategies

How to address issues

1. Before a criminal investigation (Preventative Measures)
2. During a criminal investigation (what to do and not to do)
3. After a criminal investigation (charges brought by prosecutor – federal or state)



Strategies

How to address issues

1. After you become aware of a criminal investigation
 - a) Retain experienced criminal defense counsel immediately
 - b) Do not destroy any records – files, email messages, etc.
 - c) Do not speak with law enforcement officers without counsel present
 - d) Do not speak to anyone on the phone/in person about investigation

Strategies

How to address issues

1. After the criminal investigation – charges filed
 - a) Rely on the advice of your defense attorney

CMS Audit Update

What's in store for you?

- Current CMS audit trail:
 - Recovery Audit Contractors (RACs)
 - Medicare Administrative Contractors (MACs)
 - Medicare Integrity Contractors (MICs)
 - Program Safeguard Contractors (PSCs)
 - Zone Integrity Contractors (ZPICs)

CMS Audit Update

RACs

- Background
 - RAC Demonstration Project began in 2005 in California, Florida and New York (all had highest Medicare Expenditures)
 - RAC was expanded in 2007 to add Massachusetts, South Carolina, and Arizona
 - Demonstration Project – very successful (savings of \$693.6 million to Medicare Trust Fund)
 - Section 302 of Tax Relief and Health Care Act 2006 – makes RAC permanent program
 - RAC expands to all 50 states effective January 1, 2010

CMS Audit Update

RACs

- Who are RACs?
 - 4 Regions – A-D
 - Region C: Connolly Consulting, Inc.
 - Working in Al, Ar, Co, Fl, Ga, La, Ms, NC, NM, OK, SC, Tn, Tx, Va and Wv
 - www.connollyhealthcare.com/RAC
 - Strategy
 - Automated review
 - DRG Validation – Complex review
 - DME Medical Necessity Reviews – Complex Review
 - Medical Necessity Reviews – Complex Review
 - Offsets (unless check/valid appeal/payment plan) based on review – using same rules as Carriers, FI, MACs – NCDs, LCDs and CMS.
 - Appeal timeframes –
www.cms.gov/MLNproducts/downloads/MedicareappealsProcess.pdf

CMS Audit Update

MACs

- What is a MAC
 - Pursuant to Medicare Prescription Drug, Improvement and Modernization Act of 2003, CMS is transitioning and consolidating the roles of intermediaries and carriers into MACs
 - MACs are assuming all functions of the current intermediaries and carriers
 - Provider services will be simplified by having a single MAC process for both Part A and B claims
 - Trailblazer Health Enterprises – LA/MS - MAC

CMS Audit Update

PSCs and ZPICs

- CMS is in the process of transitioning the functions of PSCs to ZPICs
- PSCs and ZPICs main function is to identify fraud
 - Different from the medical review program which is concerned with error identification and prevention
 - PSCs and ZPICs request medical records and conduct medical review to evaluate identified potential fraud
 - PSCs and ZPICs may also refer to OIG/DOJ for further investigation/follow up

CMS Audit Update

Medicaid Integrity Contractor (MICs)

- Section 6034(e)(3) of the Deficit Reduction Act of 2005 mandated the creation of the Medicaid Integrity Program (MIP)
- Under MIP, CMS intends to hire contractors to review Medicaid provider activities, audit claims, identify overpayments, and educate providers on Medicaid program integrity issues
 - As such, Medicaid Integrity Group (MIG) was created to help manage MIP
- Three types of MIC Contracts:
 - Review MICs
 - Audit MICs
 - Education MICs

CMS Audit Forecast – the future!

Overpayments

- Recent ZPIC Post-Payment Review Results Letter:
 - The ZPIC has determined that it is likely you have been overpaid for the services provided from the end of the audit period through the current date based on the documentation submitted for medical review. Section 1833(e) of the SSA places the burden on the provider to furnish information necessary to determine the amount due to the provider.
 - The ZPIC is requesting that the provider conduct an internal audit of its claims to determine the accuracy of the claims billed. If research determines the claim/payment is incorrect, please process claims adjustments and arrange repayment with claims processing contractor. Please provide ZPIC with the results of this audit within 90 days.

CMS Audit Forecast – the future!

Overpayments

- Section 6402(d)(1) of ACA:
 - Requires providers, suppliers and health plans to “report and return [an] overpayment to the Secretary, the State, an intermediary, a carrier or a contractor, as appropriate, at the correct address; and
 - Notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for overpayment.”
- ACA – Deadline:
 - Overpayment must be reported and returned within 60 days of the date on which it was identified (by who? – issue); or
 - the date any corresponding cost report is due (if applicable)

CMS Audit Forecast – the future!

Overpayments

- Section 6402(d)(3) of ACA:
 - Enforcement
 - Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in 31 USC 3729(b)(3)).
 - Obligation – means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of an overpayment.

CMS Audit Forecast – the future!

Overpayments

- Fraud Enforcement and Recovery Act (FERA) of 2009 – targets retention of overpayments from a federal health care program, as opposed to false claims submitted (triggering FCA)
 - Pre-FERA – “Any person who...knowingly makes, uses, or causes to be made or used, a **false record or statement** to conceal, avoid, or decrease any **obligation** to pay or transmit property to the Government...”
 - Post – FERA – “Any person who...knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the Government or knowingly conceals or knowingly or improperly avoids or decreases an obligation to pay or transmit money or property to the Government...”

CMS Audit Forecast – the future!

Overpayments

- Liability for Overpayment retention
 - FERA - Expands liability to include knowing failure to repay
 - “...knowingly or improperly avoids or decreases an obligation to pay or transmit money or property to the Government...”
 - Eliminates requirement pre-FERA of an affirmative act of concealment
 - Knowing is defined to include – “deliberate ignorance” and “reckless disregard” – 31 USC 3729(a)(1)(G)

CMS Audit Forecast – the future!

Overpayments

- Post ACA and FERA:
 - ACA makes reporting and returning an “Obligation” under False Claims Act (FCA)
 - Failure to report/return overpayment within time frame may result in FCA liability
 - Could also implicate CMP penalties as well
 - Exclusion???

CMS Audit Forecast – the future!

RACs

- Once approved, new issues are posted online on www.cms.gov/rac prior to start of any reviews
- The approved issues lists are updated regularly
- 3 year look back
- Currently has RAC presentation on recoupment
- Recent RAC developments:
 - Medical Necessity Reviews for all 4 Regions
 - Approved medical necessity reviews implicate inpatient hospital short-stay issue

CMS Audit Forecast – the future!

RACs

- ACA – expands RACs to:
 - Medicaid
 - Part C & D
 - Anti-Fraud plans
 - Examine Claims for reinsurance payments
 - Review estimates for enrollment of high cost beneficiaries
- Statistical Sampling?

CMS Audit Forecast – the future!

Medicare Part C and D

- RACs – Part C & D
 - ACA expands RACs to:
 - Part C – Medicare Advantage (MA) Plans
 - Part D – Medicare Prescription Drug Benefit program
 - ACA – under 6114(b) amended 1893(h) to provide general authority for CMS to contract with RACs to identify overpayments and underpayments and recoup overpayments in Medicare Part C and D, as well as:
 - Ensure each MA plan and Part D plan has anti-fraud plan in place
 - Review effectiveness of anti-fraud plan
 - Examine claims for reinsurance payments to determine if Part D plan submitting such claims incurred costs in excess of allowable reinsurance costs
 - Review estimates of enrollment of high cost beneficiaries and compare estimates with number of beneficiaries actually enrolled in plans

CMS Audit Forecast – the future!

Medicare Part C and D

- December 27, 2010: Solicitation of comments on RAC program for Parts C and D.
 - 75 Fed Reg 81278
 - Input on implementation of RAC to Parts C & D
 - Part C appeals process

CMS Audit Forecast – the future!

Medicare Part C and D

- New Issues:
 - OIG work plan part II – FY 2011
 - Medicare Part C and D planned reviews
 - Part D Sponsor – internal monitoring and audit procedures
 - Targeted program audits

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Medicaid RACs

- Recent proposed rule – Nov 10, 2010
 - States must establish Medicaid RAC programs by December 31, 2010
 - States must fully implement Medicaid RAC by April 1, 2011 (absent an exception)
 - Louisiana has filed an extension – in process for organizing RAC program
 - Paid on a contingency fee basis
 - CMS sets rate (Max rate)
 - States have flexibility to determine how and when to pay fee

CMS Audit Forecast – the future!

Medicaid RACs

- States are required to refund federal share regardless of whether state is actually able to recover overpayments from the provider
- States must have an adequate appeal process but are permitted to use an existing administrative appeals process for Medicaid RACs
- RACs are in addition to, not in place of MICs and other state Medicaid integrity initiatives

CMS Audit Forecast – the future!

Data Mining

- Use of data mining by all major Medicare and Medicaid recovery program
 - RACs, MICs and ZPICs
- Data mining – use of techniques and technology to derive or predict patterns of data
- Moving away from claims focused reviews
- Providers – use of data mining internally, incorporating results/techniques used by government auditors

CMS Audit Forecast – the future!

Medicare Appeals Process

- Rebuttal
- Discussion period (only available for RACs)
- Redetermination
- Reconsideration
- ALJ
- Medicare Appeals Council (MAC)
- Federal District Court

CMS Audit Forecast – the future!

Medicare Appeals Process

- Medicare Appeals Council (MAC)
 - A provider dissatisfied with ALJ ruling has 60 days to file an appeal to the MAC
 - Key Issues
 - Criteria for review – inpatient medical necessity determination
 - Impact of MAC decisions; federal and state court decisions will decide impact as providers challenge MAC decisions

CMS Audit Forecast – the future!

Medicare Administrative Contractors

- Post payment audits
 - Limitation on recoupment
 - Serial submission of evidence
 - Substantive work up at early levels of appeal process
 - Arguing merits
 - Statistic challenges
 - Use of experts

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Medicare Administrative Contractors

- Pre-payment reviews
 - Challenging basis of pre-payment reviews
 - 10% threshold
 - Appeals; consolidation of claims
- Challenges to Statistics
 - Section 935 of Medicare Modernization Act
 - Limitations on use of extrapolation – A Medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise, unless the Secretary determines that
 - There is a sustained or high level of payment error; or
 - Documented educational intervention has failed to correct the problem
 - Can not challenge the substance of the finding of “sustained or high rate of error” but can challenge whether or not a finding was made

CMS Audit Forecast – the future!

Medicare Administrative Contractors

- Challenges to Statistics
 - Guidelines for extrapolations – MPIM (CMS Pub 100-08, Chapter 3, 3.10.1 through 3.10.11.2)

CMS Audit Forecast – the future!

MICs

- Audit MICs
 - Audit report process
 - Provider given 2 weeks notice – usually desk audit – might be field audit
 - Audit MIC prepares draft report
 - Draft report shared with State Medicaid Agency to ensure policies were followed
 - Draft report is shared with provider – provider given 30 days to comment and submit additional information
 - CMS prepares second draft report – taking comments into consideration
 - Draft report again shared with State for comment
 - After receiving response from State – MIC will submit final report to State for collection

CMS Audit Forecast – the future!

MICs

- New Policy Changes
 - 5 year look back
 - Expanded time for responding to audit MIC requests for records
 - From 10 days to 30 days
 - Option for 15 business day extension

Questions or Comments Please contact:

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