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HCCA's Managed Care Compliance Conference

February 21 – 23, 2010

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(Ambitious) Agenda

- Health care reform? What health care reform?
- Re-emergence of the government's anti-fraud initiative
- Practical implications of CMS's shift in its approach to Plans' compliance programs
- Marketing (aka the Compliance Department Employment Security Initiative)
- Risk adjusters: the next "new frontier" for fraud?

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Health Care Reform?
What Health Care Reform?

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What Is Meant By Health Care Reform?

- Coverage/access
  - Expansion of Medicaid
  - Insurance coverage reforms
  - Sliding scale subsidies and small business tax credits
- Delivery system reform
  - Value-based purchasing, rewarding quality rather than volume
  - Hospital payments for post acute services
  - Expanding primary care workforce
- Prevention and wellness
  - Chronic disease prevention
  - Early detection
  - Promotion of healthier life styles
- Case management
  - Chronic diseases (*e.g.*, diabetes and congestive heart failure)
  - Dual-eligible population
- Comparative effectiveness
  - Clinical aspects to aid provider and patient decision-making
- Health information technology
  - Electronic health records
  - Avoiding preventable medical errors and duplicative tests
- Transparency
  - Costs associated with each service
  - Insurer, PBM expenses

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Health Care Reform – Phase One Initiatives Already Underway

- Children's Health Insurance Program Reauthorization Act of 2009
- Preventing increases in the number of uninsured
  - FMAP (Federal Matching Assistance Program under Medicaid)
  - COBRA (premium subsidies for COBRA continuation coverage for workers who lose their jobs)
- Laying the groundwork for quality and cost in ARRA
  - Health information technology ($19 billion)
  - Comparative effectiveness ($1 billion for research)
  - Prevention and wellness ($1 billion)
    - Evidence-based clinical programs
    - Community-based prevention and wellness strategies
  - Community health centers and primary care workforce ($2 billion)

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Health Care Reform – Phase Two Current Legislation

- Senate Bill - Patient Protection and Affordable Care Act
  - Passed on December 24, 2009 with 60-39 vote
  - Democratic filibuster-proof majority lost with Massachusetts election
- House Bill - Affordable Health Care for America Act
  - Passed November 2009 with some cushion
- House and Senate leaders thought to have reconciled the two bills prior to Massachusetts election
  - Passage of Senate bill by House?
  - "Fix" bill to follow on its heels?
  - Series of "mini" health reform legislation?
  - Obama proposal through budget reconciliation?

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Health Care Reform - Phase 3
Reading the Tea Leaves

- February 25, 2010 health reform summit
  - Obama Administration effort to shift tenor, create avenue for action
  - Potential opportunity notwithstanding Republican positioning
- Increasing pressure of other legislative priorities
- Other legislative, regulatory opportunities and initiatives remain in play

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CMS Moving Forward with
Regulatory Changes

- CY 2010 changes to MA Plan payments
  - National growth rate of .81% significantly lower than in prior years
  - Uniform coding intensity adjustment of -3.41%
    - Applies to all MA Plan members' risk scores
    - Reflects the effect of different growth rates in MA and traditional Medicare FFS on CY 2010 risk scores
  - Medicare Secondary Payer assumptions and documentation requirements
    - CMS will adjust for MA Plan members' MSP status using CMS's centralized Coordination of Benefits database

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CMS Is Moving Forward With Regulatory Changes (cont.)

- CMS Approval of CY 2010 Plans
  - "Meaningful" differences among MA and Part D Plan offerings
    - Type of plan (HMO v PPO)
    - Plan benefit package (*e.g.*, supplemental benefits)
    - Beneficiary premium and cost-sharing obligations
  - Elimination of MA and Part D Plans with low enrollment
  - Limitations on MA Plan cost-sharing for certain services
  - Preventive service incentive programs
  - Promotion of e-prescribing among Part D Plan Sponsors and network pharmacies
  - Data validation audits

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CMS Is Moving Forward With Regulatory Changes (cont.)

- CY 2011 Proposals
  - Estimate 1.38% increase in national per capita growth rate for MA Plans
  - Maintenance of -3.41% coding intensity adjustment
  - Routine release of MA and Part D data
    - Average PMPM by PBP
    - Average risk scores

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Re-Emergence of the
Government's Anti-Fraud Initiative

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Obama's Initiatives

- The U.S. Government Accountability Office has estimated that of the $1 trillion in governmental funds spent on health each year, 10%, or $100 billion is lost to fraud and abuse
- The Obama Administration has committed to stronger and more effective healthcare fraud enforcement
- Fiscal year 2010 budget proposal released in May 2009 included a $1.7 billion increase over five years to the Healthcare Fraud and Abuse Control Program, which is jointly operated by DOJ and HHS

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Obama's Initiatives (cont.)

- Each of the healthcare reform bills proposed by Congress are consistent with the Obama Administration's expressed objectives of targeting healthcare fraud and waste
- The Obama Administration will provide increased funding and oversight to combat healthcare fraud and abuse:
  - Including a requirement that all providers and suppliers adopt compliance programs as a condition for participating in Medicare and Medicaid
  - Establishing new penalties for Medicare Advantage (MA) and Part D Plans that violate marketing regulations or submit false bids, rebate reports, or other submissions to the Centers for Medicare & Medicaid Services (CMS)

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HEAT

- On May 20, 2009, Attorney General Eric Holder and HHS Secretary Kathleen Sebelius announced the creation of the Healthcare Fraud Prevention and Enforcement Action Team (HEAT)
- HEAT will undertake a variety of anti-fraud efforts, including the following:
  - Creating and using "Strike Force" teams in major cities, including Miami, Los Angeles, Detroit, and Houston to investigate healthcare fraud;
  - Assisting state Medicaid officials with provider audits and other monitoring activities;
  - Analyzing electronic data to look for patterns and indicia of fraud and abuse;

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HEAT (cont.)

- Adopt increased site-visit fraud enforcement methods used in demonstration projects that focused on DME providers and suppliers, with an objective of preventing impostors from posing as legitimate providers;
- Increasing data and information sharing efforts to help HHS and law enforcement identify patterns of fraud equipment;
- Increasing plan and provider training on Medicare compliance;
- Strengthening monitoring activities for plans and providers under Medicare Parts C (MA) and D (prescription drug); and
- Improving citizen access to fraud hotlines and websites.

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The Fraud Enforcement Recovery Act (FERA)

- Amends the False Claims Act (FCA)
  - expands the risk of liability for knowingly retaining Medicaid or Medicare overpayments;
  - presenting false or fraudulent claims for payment or approval.
- Significant implications of the changes and expansions of the FCA for payors, plans, and managed care providers :
  - FERA removed the requirement that a false claim actually be "presented" to the government for payment.
  - Liability may attach to claims that are submitted to a "contractor, grantee, or other recipient" of federal funds, even when the false claims were not submitted to the government;
    - Upstream? Downstream? Midstream treading water?

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FERA (continued)

- FCA liability
  - knowingly makes a false claim to obtain money;
  - any part of which is provided by the Government without regard to whether the wrongdoer deals directly with the Federal Government, its agent acting on the Government's behalf, or a third-party contractor, grantee, or other recipient of such money or property.

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Expansion of Entities and Persons Liable Under the FCA

- FCA penalties will now apply to a person who:
  - Knowingly presents a false or fraudulent claim for payment or approval, if the money is used to "advance a Government program or interest, regardless of whether the government has title to the money requested and if it is requested directly from the government or from a recipient of federal fund"
  - Anyone know what that means?

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Expansion of Entities and Persons Liable under the FCA (cont.)

- The new definition substantially broadens the types of payments that fall within the FCA's scope:
  - May include payments to MA and Medicare Part D plans by the federal government
  - Payments to Medicaid managed care plans by state and local governmental programs that receive indirect federal government fund.
  - What else?

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Expansion of Entities and Persons Liable Under the FCA (cont.)

- FERA does not define "advanc[ing] a Government program or interest,"
  - Degree of connection
- **IMPORTANT: the government's interpretations may not be consistent with yours**
  - **No, that's not meant to be funny**
- Expect greater scrutiny of vendor relationships – whether as the provider or recipient of services.

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Proof of Intent to Defraud is Not Required Anymore

- FERA removes the FCA "intent" requirement and replaces it with a new "materiality" requirement that will not be hard to meet.
  - What is materiality?
- A false statement will be considered "material" to a false claim if the statement has "a natural tendency to influence, or be capable of influencing, the payment or receipt of money."
- You might violate the FCA if the record or statement is "material to" a false or fraudulent claim, regardless of whether intended to obtain payment from the government.
- Lessens the government's burden of proof in a FCA action
- This change will also permit the government and qui tam plaintiffs to more easily establish the required FCA elements for a healthcare fraud claim.

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Retention of Overpayments in FERA-land

- "Obligation" includes "an established duty, whether or not fixed," arising from a variety of relationships, and specifically includes obligations "arising from statute or regulation, or from the retention of any overpayment."
- FERA amends "reverse false claims" provisions of the FCA :
  - knowingly and improperly avoiding or decreasing an obligation to pay or transmit money or property to the Government.

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Retention of Overpayments (cont.)

- An affirmative duty to refund overpayments and allow the government and whistleblowers to pursue violations:
  - false documents that are "material to an obligation to pay or to transmit money… to the Government";
  - regardless of whether a false claim has been submitted.
- Strict liability for retention of overpayment
  - require recipients to implement mechanisms to promptly detect whether they have received overpayments and repay.

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Increase in Retaliation Exposure

- Prior to FERA, the FCA prohibited employers from taking retaliatory action against employee whistleblowers.
  - Now protection for anyone employed or contracted with, which expands the non-retaliation provisions to independent contractors, agents, or other third parties.
  - Protected acts include those taken by the employee, contractor, or agent on behalf of the employee, contractor, agent, or "associated others" in furtherance of "efforts to stop one or more False Claims Act violations."
  - Potentially includes providers who subcontract with MA, Medicaid Managed care, and Medicare Part D Plans, and management companies, vendors, subcontracted physicians, and other independent contractors.

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New Government Enforcement Tools

- U.S. Attorney General's authority to issue civil investigative demands by permitting delegation of such authority to a third party
  - Broadens the government's authority to share documents obtained through subpoena with qui tam relators and others.
- Government can intervene in a qui tam case at any time and add new claims that will relate back to the date of the relator's filing.

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Effective Corporate Compliance Programs

- The best protection against FCA liability is an effective compliance program (this message brought to you by the Health Care Compliance Association).
- FERA's changes to the FCA, HEAT, and the new federal policy on healthcare fraud reiterates the importance of adopting and implementing effective corporate compliance programs using the seven elements outlined in the United States Sentencing Guidelines for Organizations.
  - The Seven Habits of Highly Compliant Organizations

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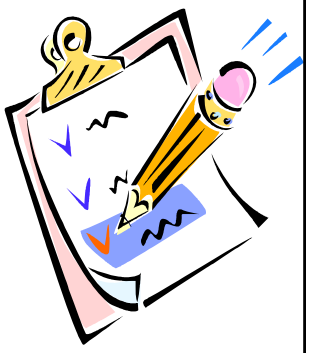
Seven Essential Elements of a Compliance Plan

- Standards and Procedures
- Oversight
- Education and Training
- Monitoring and Auditing
- Reporting
- Enforcement, Discipline and Incentives
- Response and Prevention



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What Does This Mean for Payors, Plans, and Managed Care Providers?

- Risk assessment of FERA's impact on your healthcare operations (including review and analysis of all contracts that involve government funding) and related vulnerabilities.
- Reassess and revise as needed billing and compliance policies and procedures, notice requirements, and record retention policies.
- Establish a mechanism to prevent, detect, and track potential overpayments.
  - Think through how this interrelates with downstream entities.
- Consider whether any compliance policies and contracts need to be revised given the new anti-retaliation provisions.

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What Does This Mean for Payors, Plans, and Managed Care Providers? (cont.)

- Conduct new education and training for their workforce that includes the implemented FERA changes.
- Implement an aggressive auditing and monitoring program. Consider using an outside independent entity to regularly audit and monitor operations.
- Revise anti-retaliation policies and procedures to make them applicable to non-employees such as subcontracted providers, vendors, management companies, and independent contractors.
- Treat allegations of fraud seriously by conducting internal investigations into all fraud allegations. Most whistleblower lawsuits can be prevented by assuring employees that all compliance issues are taken seriously and investigated.

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Practical Implications of CMS's Shift in Its Approach to Plan Sponsor Compliance Programs

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CMS's Evolving Approach to Plans' Compliance Programs

- 2005-08: CMS emphasized structure of compliance plans
  - Seven elements identified in the regulations
  - Chapter 9 of the Medicare Prescription Drug Benefit Manual
- April 2009: CMS officials announce shift towards outcomes
  - Is the compliance plan accomplishing its intended goals of preventing, detecting and correcting fraud, waste and abuse?
  - Monitoring, auditing, corrective action take on greater importance
- October 2009 proposed rule
  - Reiterates emphasis on effectiveness of MA Organizations' and Part D Plan Sponsors' (Plan Sponsors') compliance plans
  - Providing "clarification" as to what will constitute an "effective" compliance program

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Clarification of Compliance Program Elements

- Written policies and procedures reflect 7 characteristics
  - Articulate commitment to comply with all applicable standards
  - Provide employees with guidance on handling compliance issues
  - Describe how compliance issues are investigated and resolved
- Compliance officer and compliance committee
  - Compliance officer
    - Employee with direct reporting relationship with chief executive or other senior administrator
    - Tasked with day-to-day operations of compliance program
    - "Periodically reports" to the Plan Sponsor's governing body
  - Governing body
    - "Must be knowledgeable" about content and operation of the compliance program
    - Must "exercise reasonable oversight"

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Clarification of Compliance Program Elements (cont.)

- Training and education
  - More expansive scope
    - CEO, senior managers, governing body members, employees
    - First tier, downstream and related entities
  - Must occur at least annually
  - Must be part of orientation for new CEO, senior managers, governing body members, employees
  - Debate about certification continues
- Effective lines of communication
  - Must include a mechanism for anonymous and confidential good-faith reporting

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Clarification of Compliance Program Elements (cont.)

- Well-publicized disciplinary standards
  - Articulate employee expectations and obligations
    - Reporting issues and supporting resolution
    - Identifying non-compliance or unethical behavior
- Monitoring and auditing
  - Internal and external audits
    - Evaluate compliance with CMS requirements
    - Evaluate overall effectiveness of the compliance program
- Response to compliance issues
  - Established process and procedures for prompt response, investigation of potential issues

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Corrective Action Plans (CAPs)

- CMS shifting priorities
  - Away from process for identifying issues
  - Towards demonstrable achievement of resolution
- Proposed modifications of CAP role in context of notice of intent to terminate/not renew contract
  - Prior to issuing notice of intent to terminate or not renew, CMS will provide notice of deficiencies and opportunity to develop CAP
  - Plan Sponsor "solely responsible" for identification, development and implementation of CAP and demonstration of deficiency corrections
  - Single 30-day period to develop and implement CAP

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Intermediate Sanctions

- December 2007 final rule streamlined CMS's ability to impose sanctions
  - Eliminated "informal resolution" steps
  - 10 days notice period of agency intent to impose sanctions
  - Request for hearing does not delay imposition of sanctions
- Proposed rule modifies basis for lifting sanctions
  - Engagement of an independent auditor to determine correction of deficiencies and likelihood of recurrence
    - One proposal calls for analysis provided directly to CMS
    - Alternate proposal for Plan Sponsor to provide results to CMS, who considers review in determination of lifting sanctions
  - "Test period" for lifting of marketing or enrollment sanctions to enable CMS to evaluate whether deficiencies are corrected

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…And This Affects Me How?

- Consider CMS's modified approach to compliance programs and compliance activities
  - Mere existence of a compliance program no longer is sufficient
  - New emphasis on active monitoring, auditing, and corrective action
- Plan Sponsors must be able to demonstrate pro-active approach to compliance activities
  - Work plan for monitoring and auditing activities
  - Demonstration (including documentation) of corrective action
    - Development of corrective action plan, implementation steps
    - Monitoring and auditing issues to confirm corrections, no further issues

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Marketing

(aka the Compliance Department Employment Security Initiative)

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Common Issues and Questions

- Individual marketing appointments
  - Scope of appointment forms
  - Selling Medicare, health (non-Medicare) and non-health
- Compensation
  - Agents/brokers
  - Other entities (*e.g.*, FMOs)
  - Referral fees
- Use of Medicare beneficiary data

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Marketing-Related Proposals in Health Care Reform Legislation

- House bill would authorize the Secretary to impose intermediate sanctions for various marketing violations
  - Failure to comply with marketing restrictions
  - Employment of, or contracting with, any individual or entity that engages in prohibited marketing conduct
- Senate bill would authorize enhanced penalties for "misrepresentation or submission of falsified information" as well as other marketing violations

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Medicare Advantage Risk Adjustment:
The Next "New Frontier" for Fraud?

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What Are Risk Adjusters?

- Section 1853(a) of the Social Security Act instructs CMS to adjust MA Plan payment amounts "for such risk factors" as
  - Age
  - Disability status
  - Gender
  - Institutional status
  - "Such other factors as the Secretary determines to be appropriate, including health status"
- Section 1853(a)(3) requires MA Organizations (MAOs) to submit data on inpatient hospital services as well as "data regarding other services" the Secretary deems necessary (*i.e.*, ambulatory setting data)

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Risk Adjustment Data Requirements

- 42 C.F.R. § 422.310
  - Includes all data that are used in the development and application of a risk adjustment payment model
  - Risk adjustment data sources, according to the regulation, are the providers, suppliers, physicians or other practitioners that furnished the item or service
  - Risk adjustment "sub-regulatory" guidance further limits to hospital inpatient, hospital outpatient, and physician data
  - Prescription records, ASCs, lab tests and other sources are not valid risk adjustment data sources
- Under § 422.310(c), MAOs and their providers are required to submit a sample of medical records for the validation of risk adjustment data

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Risk Adjustment Data Validation (RADV) Audits

- CY 2007 pilot audit initiated in Summer 2008
- Sample of medical records provided to CMS subcontractor through a statistical sampling approach
  - MAOs required to obtain and provide "single best medical record" supporting each Hierarchical Condition Categories (HCCs) upon which risk adjustment payment modification is premised
  - Process created for attestations of medical records that did not meet medical record documentation requirements
- Reference is made to an appeal process that appears to focus on disputes related to medical record documentation (only)

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CMS October 2009 Proposed Rule on RADV Audits

- Key proposed definitions
  - Attestation process means a CMS-developed RADV audit-related dispute process that enables MAOs to submit CMS-generated and physician practitioner signed attestations **for medical records with missing or illegible signatures or credentials**
  - Documentation dispute process means a dispute process that enables the MAO to dispute **medical record discrepancies** that pertain to incorrect ICD-9-CM coding by allowing affected MAOs to submit formal written disputes regarding discrepancy findings for the initial medical record that the MAO submitted for HCC validation
  - RADV payment error calculation appeal process means an administrative process that enables MAOs to appeal the CMS **calculation** of an MAO's RADV payment error

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CMS October 2009 Proposed Rule on RADV Audits (cont.)

- Proposed audit dispute and appeal process
  - RADV Audit Report provided to MAO post-medical record review
  - Report will contain the following:
    - Detailed enrollee-level information relating to confirmed HCC discrepancies
    - A contract–level RADV payment adjustment amount
    - An approximate timeframe for the payment adjustment
    - An enrollee-level description of HCC-level discrepancies that will be eligible for dispute
    - A description of the MAO's audit appeal rights

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CMS October 2009 Proposed Rule on RADV Audits (cont.)

- Proposed attestation process
  - CMS will only accept an attestation to support a physician or outpatient medical records with missing or illegible signature or missing or illegible credentials or both
    - Only CMS-generated attestations accepted
    - Attestations must be submitted simultaneous with medical records
    - Attestations must address medical records that document face-to-face encounters between beneficiaries and RADV-eligible physicians/practitioners

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CMS October 2009 Proposed Rule on RADV Audits (cont.)

- Proposed documentation dispute process
  - Applies only to the operational processing of those medical records selected for the RADV audit
    - "Operational processing" mean errors that arise from the collection and processing of medical records for RADV audit.
    - Example is an MAO that submits a two-page medical record that inadvertently becomes separated into "two" medical records upon receipt by the contractor.
    - This process is to deal with non-signature or credential-types of RADV-related medical record diagnosis coding
  - The MAO has 30 days from the date of issuance of the RADV audit report to request a documentation dispute

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CMS October 2009 Proposed Rule on RADV Audits (cont.)

- CMS review and notification
  - CMS reviews the MAO's documentation to determine whether it supports overturning errors in the audit report
  - CMS provides notice of aggregate determinations regarding overturning errors in the audit report and recalculating the RADV payment error
  - CMS documentation dispute determination is final and binding and is not eligible for further administrative appeal
    - Rationale for abbreviated process for documentation dispute and attestation review is the opportunity for the MAO to submit the one best medical record and the two rounds of medical review by CMS independent contractors

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CMS October 2009 Proposed Rule on RADV Audits (cont.)

- Appeal of Payment Error Calculations
  - Errors identified in RADV payment error calculation subject to appeal
  - MAOs may not
    - Introduce new HCCs
    - Appeal RADV medical record review-related errors
    - Appeal physician/practitioner signature or credential-related medical record review errors
    - Appeal RADV errors that result from an MAO's failure to submit a medical record
    - Appeal CMS's RADV payment error calculation methodology
- Right of Reconsideration
- Right of Hearing

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How Prepared Are You?

- Responding to an audit request
  - Medical record collection
  - Selection of "one best" medical record
- Do you know what your error rate might be?
  - Absence of physician signatures and credentials
  - Verification of diagnoses within medical records
- Data verification efforts and implications
- Provider contracts

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Questions and Comments

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