2009
HEALTH CARE REGULATORY UPDATE
January 13, 2009

Program Agenda

9:00 a.m.  Fraud and Abuse, Year in Review  
            T. Jeffrey Fitzgerald

9:25 a.m.  Hospital-Physician Relationships Under the Stark Law  
            Bruce A. Johnson

9:50 a.m.  Developments Involving Ambulatory Surgery Centers  
            Gerald A. Niederman

10:15 a.m. Break

10:30 a.m. Payment Trends and Medicare Reimbursement Update  
            Colleen M. Faddick

10:55 a.m. Health Facility Operational Issues  
            Ann C. McCullough and Steve Lokensgard

11:30 a.m. Employment Law Update  
            Dirk W. de Roos

11:55 p.m. Predictions for 2009 and Closing Comments  
            T. Jeffrey Fitzgerald

12:00 p.m. Close
Health Care Regulatory Update

January 13, 2009
Fraud and Abuse
Year in Review

Jeffrey Fitzgerald
Legislation

• Medicare Improvements for Patients and Providers Act of 2008
  – Physician Fee Schedule (PFS) rate reduction of 10.6% was retroactively replaced with the a 0.5% increase

• Michael Skolnik Medical Transparency Act (Colorado)
  – Doctors in Colorado must disclose certain information including malpractice settlements, professional disciplinary action, employment contracts, and ownership of health care businesses
  – This information will be posted on the Board of Medical Examiners web site
  – Disclosure required as part of licensure renewal, which is in 2009 for many physicians
Settlements

- DOJ announced that it recovered over $1.1 billion in FY 2008
  - 80% of recoveries were from whistleblower actions
  - Whistleblowers collectively received over $198 million
- Biggest payments were from pharmaceutical companies
  - Merck & Co. paid $650 million (pricing and marketing)
  - Cephalon Inc. paid $444 million (off-label marketing)
  - Bristol-Myers paid $389 million to 43 states (pricing and marketing)
  - Amerigroup Corp. paid $225 million (abusive enrollment practices)
  - Bayer HealthCare LLC paid $97.5 million (alleged kickbacks to diabetic supply companies)
Settlement Trends

• “Inflated” Medicare outlier settlements
  – Bayonne Medical Center paid $2.5 million
  – Cathedral Healthcare System paid $5.3 million
  – Cooper University Hospital paid $3.8 million
  – St. Vincent Health System Inc. paid $1.9 million
  – BlueCross BlueShield of Tennessee (intermediary) paid $2.1 million
  – Besler & Company Inc. (consultants) paid $2.9 million

• Lesson: there is neither an “advice of consultant” defense, nor an “everybody’s doing it” defense
Settlement Trends (cont.)

• Increase in hospital settlements
  – Staten Island University Hospital paid $89 million (alcohol and detox billing)
  – Milan General Hospital and Jackson Madison General Hospital paid $7.8 million (non-emergency ambulance transportation)
  – Yale-New Haven Hospital paid $3.7 million (billing for infusion therapy)
  – West Jefferson Medical Center paid $3.3 million (inpatient billing)
  – Ohio General Hospital paid $2.2 million (wound center visits billed as ED)
  – Saint Louis University paid $1 million (cost report treatment of faculty compensation)
  – Manchester Community Hospital paid $712,166 (chemotherapy billing)
Settlement Trends (cont.)

- Settlements based upon alleged Stark Law violations
  - Lester E. Cox Medical Centers paid $60 million
  - Condell Health Network in Illinois paid $36 million
  - Baptist Health South Florida, Inc. paid $7.7 million
  - Memorial Health, Inc. in Savannah, Ga. paid $5.08 million
    - Allegations included improper financial relationships with physicians, including below FMV rent, improper loans, and payment for services without a written agreement

- Quality of care / worthless services settlements continue
  - Centennial HealthCare Corp. paid $2 million
• **Allison Engine Co. v. U.S. ex rel. Sanders**, No. 07-214 (U.S.)
  - Held that government must prove that the “defendant intended the false record or statement to be material to the Government’s decision to pay or approve a false claim” under the False Claims Act (FCA)
  - Supreme Court rejected the DOJ’s argument that the FCA merely requires that the false statement resulted in a federal payment
  - Supreme Court rejected the DOJ’s argument that the FCA merely requires that government money was used to pay the false claim

• Implications of **Allison Engine** to health care could be significant
  - In **U.S. ex rel. Sterling v. Health Insurance Plan of Greater New York**, the court found no FCA violation because the allegedly false statements were made to secure accreditation from the National Committee for Quality Assurance, not to receive federal money

- The court rejected arguments that violations of Medicare conditions of participation create FCA liability under a false certification theory.
- The court noted that the government does not normally retroactively recover Medicare payments due to noncompliance with Medicare conditions of participation.
- The court held that use of the FCA to police noncompliance with Medicare conditions of participation would undermine the existing administrative mechanisms.

- **Zurich American Insurance Co. v. O’Hara Center for Rehabilitation**
  - FCA litigation not covered by a nursing home’s general liability policy.
Other Noteworthy Court Decisions

- Courts appear to be willing to scrutinize alleged violations of the Stark Law when included in a FCA case
  - In *U.S. v. Solinger*, the court concluded that the hospital met academic medical center exception by interpreting the exception using a goal and purpose oriented perspective rather than a hyper-technical one
- Medicare liabilities continue to transfer with the provider number
  - In *Triad at Jeffersonville I LLC v. Leavitt*, the court determined that the current owner of the nursing homes knowingly accepted assignment of the existing provider agreements from the previous nursing home operator and thus was responsible for a $2 million Medicare overpayment made to the prior owner of the facilities
• Individual liability under the FCA continues to be contingent upon personal involvement (or lack thereof) of owners and executives
  – In U.S. *ex rel.* Hebert v. Dizney, the hospital’s owner and executives were dismissed because complaint did not allege involvement in fraud
  – In U.S. *v.* Bourseau, the presidents of two hospital management companies were held liable for false statements in cost reports
  – In U.S. *ex rel.* Roberts v. Aging Care Home Health, the husband of the owner of a home health company was held liable because he signed cost reports
  – In U.S. *ex rel.* Baker v. Rehabilitation Specialists of Livingston County, a motion for summary judgment by the therapy company’s owner was denied because there were disputed issues of fact regarding whether the owner knowingly submitted false claims by signing two cost reports
Trends From Court Decisions (cont.)

• Whistleblower protections interpreted broadly
  – Employee can claim retaliation if she was acting on a suspicion that the defendant submitted a false claim, not a belief that the defendant actually submitted one. *Mendiondo v. Centinela Hospital Medical Center*
  – Hospital liable for terminating employees who disclosed medical record problems to the government even though allegedly falsified records were never submitted to the government. *Kuhn v. LaPorte County Comprehensive Mental Health Council*

• Employees protected from retaliation “while they are collecting information about possible fraud, before they have put all the pieces together,” as long as “investigatory conduct” is in good faith and is reasonable
Trends From Court Decisions (cont.)

• Mixed results on efforts to dismiss FCA cases under Rule 9(b)
  – U.S. *ex rel.* Serrano v. The Oaks Diagnostics Inc. (dismissed)
  – U.S. *ex rel.* Hopper v. Solvay Pharmaceuticals Inc. (dismissed)
  – U.S. *ex rel.* Foster v. Bristol-Myers Squibb Co. (dismissed)
  – U.S. *ex rel.* Pogue v. Diabetes Treatment Centers of America (not dismissed)
  – U.S. *ex rel.* Bane v. Breathe Easy Pulmonary Services Inc. (not dismissed)
  – U.S. *ex rel.* Thomas v. Bailey (dismissed only in part)

• Rule 9(b) continues to be an important tool for health care defendants
Other DOJ Developments

• DOJ continues to take an expansive interpretation of what could constitute “remuneration” under the Anti-kickback Statute (AKS)
  – In U.S. *ex rel.* Fry v. Health Alliance of Greater Cincinnati, the DOJ filed an intervention complaint alleging that a hospital’s process for allotting physicians’ time in its outpatient testing unit based upon each physician’s procedure volume for the previous year constituted a violation of the AKS

• Revised DOJ “Principles” for charging corporations
  – Waiver of the attorney-client privilege no longer considered in DOJ’s assessment of corporate cooperation
  – Advancement of legal fees for employees no longer considered in DOJ’s assessment of corporate cooperation
  – Employee discipline continues to be a factor considered by DOJ
OIG and CMS Developments

• HHS OIG issued 23 advisory opinions
  – 21 positive
  – 2 negative
• Apparent increase in OIG civil monetary penalty (CMP) settlements
  – CMP settlements related to provider employment of excluded individuals
• CMS demanding larger share of State recoveries
  – CMS position letter of 10/28/08 claims that CMS is entitled to the federal share of both overpayment recoveries and penalties
  – Alabama v. CMS — Alabama alleging that CMS position is an unlawful rulemaking (complaint filed 11/03/08)
Other Noteworthy Events

- Updated compliance codes from Pharma and Medical Device Industries
  - Revised PhRMA Code on Interactions with Healthcare Professionals issued in July 2008
  - Revised AdvaMed Code of Ethics on Interactions with Health Care Professionals issued in December 2008

- These industry codes are based upon those industries’ interpretation of the AKS
- Set industry norms that may apply beyond the pharma and medical device industries
Other Noteworthy Events (cont.)

- Continued emphasis on Voluntary Disclosures
  - OIG issued an Open Letter to providers
    - OIG indicated that settlements based upon a voluntary disclosure may not include a corporate integrity agreement
  - Trend may be for mandatory self-reporting
    - The government published an amendment to the Federal Acquisition Regulations (“FAR”) that requires mandatory disclosure of what would otherwise be voluntary disclosures of fraud-related matters
    - Regulations effective Dec. 12, 2008
Hospital-Physician Relationships Under the Stark Law

Bruce A. Johnson
Stark Law

- **No physician referrals** of “designated health service” (DHS)
- **To entity** with which the physician (or immediate family member) has a **financial relationship** (ownership, compensation or both)
- **Unless** an **exception** applies

- “Strict liability” statute
  - Prohibition on billing, reimbursement/payment, refunds required
  - Potential basis for FCA and/or AKS violations

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Looking Back at Stark (Raving Madness)

- 1989 enacted; 1995 amended and expanded
- 2001 Phase I Final Rule, 2004 Phase II Interim Final Rule
- July 2007 PFS proposals regarding “under arrangements,” “stand in the shoes,” per click, etc.
- Sept. 2007 Phase III Final Rule addressing “stand in the shoes,” then delayed
- July 2008 PFS proposed exception for shared savings programs
- July 2008 IPPS Final Rule governing “under arrangements,” “stand in the shoes,” per click and percentage based compensation
- November 2008 PFS Final Rule governing burden of proof, disclosure of financial relationships, etc.
Overall Themes

• Physician ownership is bad, with key distinctions based on whether physicians are or are not owners of a DHS entity

• Now that “bright line” rules are provided, compliance is required

• Certain arrangements involving hospital-physician integrated delivery systems still available, and potentially other relationships in the future
Physician Ownership and “Under Arrangements”

• “Under Arrangements” service delivery defined:
  – Hospital Inpatient Prospective Payment System (IPPS) or Outpatient Prospective Payment System (OPPS) billing for services furnished by entity “under arrangements”
  – Service delivered by entity other than hospital

• Example:
  – “Open” or “Mobile MRI” operated by separate MRI entity; MRI entity furnishes MRIs to hospital patients “under arrangements;” provides the space, equipment, and technicians required to perform MRI
  – Hospital IPPS or OPPS billing for services furnished to hospital patients; hospital pays MRI entity for its services

• More Current Example:
  – Physician-owned cardiac cath lab and JV ambulatory surgical center under arrangement entities
Issue: Inpatient and Outpatient Hospital services are DHS under Stark
– Before IPPS rule changes, Stark permitted physician ownership of “under arrangements” entity because that entity did not bill

CMS Solution: IPPS expanded Stark definition of DHS “entity” to include:
– Billing entity (the one that bills Medicare for the DHS), and
– Furnishing entity (i.e., entity that furnishes the service)
– Effective Oct. 1, 2009

Result:
– No exception to permit typical “under arrangements” ventures (except in rural area)
– Can’t use separate lease or services arrangements to get to same end
– Benefits where no physician ownership (e.g., integrated systems)
Physician Ownership and “Stand in the Shoes”

• Pre-Phase III Issue:
  – Physician organizations use rule governing “indirect” compensation relationships to avoid application of Stark and compliance with an exception

• Phase III Final Rule (Sept. 2007):
  – Physicians “stand in the shoes” of their physician organizations (defined as physician, physician practice or group practice)
  – Direct compensation relationship exists if physician organization is the only entity between physician and DHS entity; compliance with exception governing direct compensation arrangements required
  – Concern with “support payments,” so effective date delayed until Dec. 4, 2008 as applied to academic medical centers and integrated 501(c)(3) organizations
Physician Ownership and “Stand in the Shoes” (cont.)

- CMS IPPS Solution:
  - Only physicians who have an ownership or investment interest in a physician organization “stand in the shoes” of that physician organization
  - “Titular” owners (meaning physician does not receive any of the financial benefits of ownership) are not deemed to “stand in the shoes” of the organization in which they are a titular owner
    - Example: “Friendly” physician model
  - Effective Dec. 4, 2008
Physician Ownership and “Stand in the Shoes” (cont.)

• Result:
  – Compensation is measured at the physician organization to DHS entity level
  – Compensation relationship is direct and can be analyzed under any applicable direct compensation exception (i.e., personal services, leases, or FMV)
  – More arrangements must now meet an exception
  – Indirect compensation definition and exception still apply to arrangements with intervening entities that are not physician organizations or that have multiple intervening entities
  – Benefits where no physician ownership (e.g., integrated systems)
Physician Ownership and “Per Click” Arrangements

• Pre-IPPS Issues:
  – Certain Stark exceptions permitted “per click” (e.g., per unit of service, or per use) and percentage-based lease arrangements that CMS viewed to be abusive

• Example:
  – Physician-owned entity leases MRI to separate MRI entity for per use fee
  – Lease provides payment to physician leasing entity based on volume/value of referrals, even though physician owners can’t directly own and refer to the MRI entity
• CMS Solution:
  – Physician-owned entities cannot receive per click fees where referring
    physician is a physician owner
  – Effective Oct. 1, 2009

• Result:
  – Per click not prohibited, but benefits where no physician ownership
    (e.g., integrated systems)
• Pre-IPPS Issue:
  – Failure to meet Stark exception signature requirements

• IPPS Solution:
  – DHS entity can bill where financial relationship fully complies with Stark exception but for missing signature
  – Must obtain signature within 30 days after start of financial relationship
  – Only available once every three years with respect to same physician

• Result:
  – (Some) compliance flexibility
• Pre-IPPS Issue:
  – Who has the “burden of proof” to show compliance when denial of payment due to Stark?

• CMS Solution:
  – The provider/billing entity (not the government or contractors)
  – Claims Adjustment Reason Code No. 213.

  • To be used by Medicare Contractors when a DHS entity’s claim is denied due to Stark
• Pre-IPPS Issue:
  
  – If prohibited financial and referral arrangement that doesn’t meet an exception, when are referrals and billing prohibited (e.g., the “period of disallowance”)?

• CMS Solution: Period of disallowance ends:
  
  • Compensation is not involved — ends when relationship meets all requirements
  
  • Compensation is involved — ends when excess compensation is returned
  
  • Vague in many other cases
• Pre-IPPS Issue:
  – Disclosure of financial relationships (DFFR) proposals, with associated concerns

• CMS Solution:
  – DFFR to be sent to 500 hospitals (general acute care and specialty) to:
    • Identify arrangements that may not comply
    • Assist with future rulemaking

• Overall Result of New Bright Lines:
  – Rules are clear, “bright lines” have been drawn; don’t expect leniency here!
Looking Ahead — Future Opportunities

- CMS Issues:
  - Medicare program expenditures
  - Changes to reimbursement and operation of health care delivery systems to promote quality and cost savings
  - Regulatory uncertainty with certain arrangements

- CMS Proposed Solution:
  - 2009 PFS *proposed* new Stark exceptions for:
    - “Shared savings” (e.g., “gain share programs”) and “incentive payment” programs (e.g., PQRI, P4P and other reimbursement systems)
    - No final rule, but expect in future
Looking Ahead — Future Opportunities (cont.)

• CMS Issues:
  – Changes to promote quality, save cost and rein in expenditures

• CMS Solutions:
  – Facilitate arrangements that promote quality and cost control goals

• Examples:
  – Electronic Health Record Stark exception and AKS safe harbor, relevant to “clinically integrated” networks and payment systems
  – Reimbursement demonstration programs
  – Other reimbursement changes driving additional hospital-physician alignment and integration strategies
Developments Involving Ambulatory Surgery Centers

Gerald A. Niederman
Developments Involving Ambulatory Surgery Centers

• Specialized Focus on ASCs

• Continued Growth of Ambulatory Care
  – McKinsey Global Institute Report: 41% of U.S. Healthcare Spending is for Outpatient Care ($850 Billion)

• Brief Review of Three Current Areas of ASC Regulation
  – New Federal Conditions for Coverage (“CfCs”)
  – New Federal Reimbursement Rule
  – Recent State Law Issues
ASC Conditions for Coverage

- First significant update of ASC CfCs since 1982
- Effective date = May 18, 2009
- Some changes reflect existing “Best Practices” for ASCs, but many new administrative and substantive requirements also added
- Existing Law = 10 Conditions and 16 Standards
- New Law = 13 Conditions and 35 Standards
- Review several key areas
• Definition of an ASC (I)
  
  – **Current**
    “any distinct entity that operates exclusively [to provide] surgical services to patients not requiring hospitalization.” (42 CFR § 416.2)
  
  – **Proposed**
    “any distinct entity that operates exclusively [to provide] surgical services to patients not requiring overnight care.”

  • “Overnight care” means patient requires “active medical monitoring” beyond 11:59 p.m.
  
  • Serious concerns regarding potentially constricted scope of operations
• New
  – “any distinct entity that operates exclusively [to provide] surgical services to patients not requiring hospitalization and in which the expected duration of services would not exceed 24 hours following an admission.” (42 CFR § 416.2)
  – Vindication of the “overnight care” model
  – Must still harmonize with state licensure laws
  • Colorado = 23 hours “combined operating and recovery and/or convalescent time.” (6 CCR 1011-1, VII.B.1)
ASC Conditions for Coverage (cont.)

• Definition of an ASC (II)
  – CfCs apply to all operations of a Medicare certified facility (i.e., all patients)
  – Medicare reimbursement rules apply only to Medicare patients
    • Certification does not necessarily equal payment
    • Most ASC-approved procedures don’t require overnight care
    • Surveyors may still object to overnight care for Medicare patients: procedures must still be approved by CMS
  – New CfCs should not affect private insurance arrangements
ASC Conditions for Coverage (cont.)

- Governing Board Responsibilities
  - Significant clarification of Board role (42 CFR § 416.41)
    - “Oversight and accountability for the quality assessment and performance improvement program”
    - “Ensures that facility policies and programs are administered so as to provide quality health care in a safe environment”
    - “Develops and maintains a disaster preparedness plan”
  - New requirements in addition to “conventional” fiduciary duty obligations of governing board
  - More education for board and documentation of board activities
ASC Conditions for Coverage (cont.)

• Quality Assessment and Performance Improvement (“QAPI”)
  – Expanded program requirements and procedures (42 CFR § 416.43)
    • “an ongoing comprehensive self-assessment of the quality of care provided,” including:
      – Medical necessity; and
      – Appropriateness of care
    • ASC policies must reflect an “ongoing, data-driven” QAPI program
      – Detailed quantitative and qualitative standards prescribed, using “adequate” allocation of staff and facility resources
      – May eventually overlap with CMS quality reporting measurements
ASC Conditions for Coverage (cont.)

• Patient Rights
  – Significant codification of facility duties
    • Verbal and written notice of rights plus posting at facility
    • Disclosure of physician financial interests
      – Distinct from AKS Safe Harbor requirement
    • Disclosure of policy on advance directives
  • Grievance Policy
    – Must complaints about bad coffee be documented?
    – “Substantiated” allegations reportable to state regulatory body
  • Timing of Disclosures
    – Prior to the date of procedure
    – Physician office disclosure should generally suffice, but ASC remains responsible
New Medicare ASC Reimbursement Rule

• Effective Jan. 1, 2009
• Second year of CMS rate phase-in (now at 50% of blend)
• Continuing inflation freeze and budget neutrality requirement heighten HOPD/ASC differentials
  – Estimated 59% of HOPD for ASCs in 2009, down from estimated 63% in 2008
• Great variation among surgical/procedural specialties
  – Pain/GI procedures are generally down
  – Orthopedics/General Surgery/ENT/Urology procedures are generally up
• Implications of the CMS Methodology
  – Is “Site of Service Neutrality” for outpatient surgery still a viable concept?
  – Does reimbursement disparity promote ASC sales and subsequent conversions to HOPD status?
    • Seemingly negative cost implications for payors and patients?
  – Will some (more) procedures migrate away from ASCs altogether?
    • Both to higher cost HOPD and, where possible, lower cost physician office settings (per PFS expense cap)?
    • Consequences for private insurance too?
Key State Law Issues

• **New Jersey Self-Referral Controversy**
  – Codey Law
  – Insurers use compliance argument to deny ASC reimbursement
  – Possible legislative fix — in process
    • Freeze on new non-joint venture facilities?

• **New York Out-of-Network Billing Audit**
  – Office of the State Comptroller; Report 208-S-130
  – Out-of-network discounts must be disclosed and reflected in facility billing to third-party payors
  – Significant penalties assessed against non-compliant ASCs
Key State Law Issues (cont.)

• California Licensure Issues
  – Physician-owned facilities are no longer licensed as ASCs
  – Physician-owned facilities must instead be accredited to satisfy state legal requirements for administration of outpatient anesthesia

• Georgia Expansion of Permitted Physician Ownership
  – ASC ownership by general and orthopedic surgeons is now permitted
  – Mandatory Medicaid participation and charity care requirements as conditions of ASC licensure
Key State Law Issues (cont.)

- **Colorado**
  - New deemed status law for ASC renewal licensure (CRS 25-3-102.1)
  - New peer review protection (discovery and liability) for ASCs (CRS 12-36.5-104(4))
  - Proposed amendment to CRS 25-3-601 for ASC infection control data reporting
    - ASC personnel on same footing as hospitals with ≤ 50 beds
  - Proposed administrative change to CDPHE “Exclusive Use” Policy for ASCs
    - Ongoing CDPHE dialogue
  - Report from the trenches: increased CDPHE survey activity overall: more to follow
Payment Trends and Medicare Reimbursement Update

Colleen M. Faddick
Agenda

- Anti-Markup Rule
- IDTF changes
- IPPS update
- OPPS update
Why the Target on Diagnostic Tests?

• Condo/pod pathology labs; remote locations used on a part-time basis
• Profiting from “marking-up” the professional component (PC) and technical component (TC) performed by and purchased from another supplier
  – Radiology and other imaging services; anatomical pathology services
• Use of personnel/infrastructure unrelated to the core patient care activities of the practice
• Financial incentives to furnish unnecessary tests/services
• Negative focus only on non-hospital diagnostic tests
  – Will new rules that reduce ability of physicians to perform diagnostic tests lower the volume of ordered tests enough to counter-balance higher cost of hospital tests?
A New Twist on the Anti-Markup Rule

- The Anti-Markup Statute (42 U.S.C. § 1395u(n))
  - A physician may not mark-up a diagnostic test that is not personally performed or supervised by the physician or another physician with whom the billing physician *shares a practice*
  - If applicable, payment for the PC and TC of diagnostic tests is the lesser of the billing supplier’s actual charge, the “net charge” or the Medicare fee schedule amount
A New Twist on the Anti-Markup Rule (cont.)

- PFS Regulations – if at first you don’t succeed…
  - Proposed PFS (July 12, 2007)
  - Final PFS (Nov. 27, 2007)
  - Revision to Final PFS Implementing Delay (Jan. 3, 2008)
  - Proposed PFS (July 7, 2008)
  - Final PFS (Nov. 19, 2009) (effective Jan. 1, 2009)
A New Twist on the Anti-Markup Rule (cont.)

- Out with the old and in with the new (sort of)
  - CMS’ current version of the Anti-Markup Rule combines some aspects of the 2008 delayed rule with an entirely new focus on relationships
    - Like the delayed rule, the current Anti-Markup Rule applies to both the PC and the TC of diagnostic tests
    - Shift in focus from tests “purchased” from “outside suppliers” to whether the billing physician (or other supplier) and the performing physician “share a practice” (the statutory language)
  - Does not apply to clinical lab tests
The billing physician or other supplier shares a practice with the physician performing the PC or TC of a diagnostic test if the arrangement meets either of two alternatives:

- Alternative 1 – performing physician furnishes “substantially all” professional services through the billing physician
- Alternative 2 – tests are performed in the “office of the billing physician or other supplier”

According to CMS, Alternative 1 should be considered before moving to Alternative 2.

But the Anti-Markup Rule does not apply if either alternative is met.

Analysis must be applied separately to the PC and the TC.
Anti-Markup Rule — Alternative 1

- Alternative 1 – “Substantially All” Test
  - Performing physician furnishes “substantially all” of his or her professional services through the billing physician or other supplier
    - Locum physician is the same as main physician
  - “Substantially all” = at least 75 percent
    - Reasonable belief at the time claim is submitted that either:
      - Test is met for the prior 12 months + the month test is performed; or
      - Test is expected to be met for the following 12 months
  - Does not require employment or an exclusive contract
  - Measured by time
Alternative 2 – The “Same Office” Test

- Performing physician *shares a practice* with the billing supplier if he or she is an owner, employee or contractor of the billing supplier and the test is performed in the office in which the ordering physician regularly provides patient care

- Includes space used for diagnostic testing located in the *same building* in which the ordering physician regularly furnishes patient care

- For physician organizations, office of the billing physician is space in which the ordering physician provides substantially the full range of patient care services he/she generally provides

- *Does not include* a “centralized building” (NO pod labs)

- Applies on a test-by-test basis
Anti-Markup Rule — Unfinished Business

- A hatchet or a scalpel?
  - No exception for non-profits
  - No centralized facility
  - What is the net charge?
  - Impossible to gauge impact
IDTF Changes

• New IDTF Rules
  – 2008 PFS Rule
    • Thou shalt not share
  – 2009 PFS Rule
    • IDTFs on the move
    • CMS declined to finalize proposals that would have applied the IDTF enrollment standards to diagnostic testing furnished physician practices and groups
IDTF 2008 Changes

- 2008 PFS Rule — Thou shalt not share
  - IDTFs (other than hospital-based or mobile) may not do any of the following with another Medicare-enrolled person or entity:
    - Share space (effective Jan. 1, 2009)
      - May share hallways, parking, waiting and common areas
    - Share equipment used in the initial testing
    - Lease or sublease its space or operations (IDTF → another)
      - IDTFs may lease space/equipment from another entity
    - But sharing personnel is okay
• Physician providing general supervision may oversee only 3 IDTF sites (fixed or mobile)
• IDTFs must be in appropriate sites (no PO boxes, hotel, motel)
• Supervising physician is NOT responsible for the overall operation and administration of the IDTF
• Effective date of billing privileges for new IDTFs (including new locations) is later of:
  – Filing date (signed application that contractor is able to process) of the enrollment application subsequently approved; or
  – The date the IDTF first started furnishing services
IDTF 2009 Changes

• 2009 PFS Rule – IDTFs on the move
  – CMS declined to finalize proposal to apply IDTF enrollment standards to diagnostic testing services furnished by physician practices and groups
  – But did finalize rules requiring all entities that furnish mobile diagnostic services to enroll and bill Medicare directly
    • Apply regardless of whether services are provided in a mobile facility (e.g., trailer) or fixed-based location (e.g., physician office)
    • Means mobile entities must comply with IDTF performance standards
  – Mobile entities that furnish services “under arrangements” must qualify and enroll as IDTFs, but need not bill directly
• Mobile IDTFs must meet enrollment standards (qualified physicians and non-physicians, supervising physician proficiency, no sharing diagnostic equipment)

• No IDTF enrollment if entity leases: (1) diagnostic testing equipment; (2) non-physician personnel described in 42 CFR § 410.33(c); or (3) diagnostic testing equipment and non-physician personnel described in 42 CFR § 410.33(c) to a Medicare-enrolled provider/supplier (e.g., physician group)
  – CMS continues to evaluate arrangements where both diagnostic testing equipment and non-physician personnel are contracted to a Medicare enrolled provider or supplier and where the Medicare enrolled provider or supplier is billing for the diagnostic service
  – Dec. 15, 2008 FAQ
IPPS

- Changes are variations on CMS’ well-established recent themes of:
  - Transparency in pricing
  - Reduction in reimbursement rates
    - Quality benchmarks
  - Forcing more services into bundled payments
IPPSS Highlights

• Changes implemented in the 2009 IPPS
  – Value-Based Purchasing
    • Expansion of Hospital-Acquired Conditions (HAC) policy
    • Quality measures
  – Charge compression cost centers
  – A note about DRG Relative Weights
    • 2009 is the final year of a three year phase-in to 100% cost based MS-DRG weights
• Value-Based Purchasing Program — HAC Policy
  – Expansion of policy to limit increased Medicare payments for certain reasonably preventable conditions
  – Continuation of Congress’ 2005 efforts to combat medical mistakes

• CMS perceives that HACs generate higher Medicare payment when:
  – the costs of hospital stays increase to trigger an outlier payment; and
  – the condition is a complicating condition (CC) or major complicating condition (MCC) under the MS-DRG and qualifies for increased payment

– Part of an “array” of Medicare value-based purchasing tools that CMS is using to promote quality of care
• Hospital-acquired conditions
  – 2009 IPPS adds 3 new conditions to HAC list:
    • Certain manifestations of poor blood sugar levels
    • Surgical site infections for certain orthopedic procedures and bariatric surgery for obesity
    • Deep vein thrombosis or pulmonary embolism following total knee and hip replacement procedures
  – A case with one of the 11 HACs will group to a lower MS-DRG and Medicare will no longer pay the additional costs of hospitalization if:
    • The HAC was not present on admission and is acquired during the hospital stay and the HAC is the only complication/comorbidity
    • NCDs could affect payments to hospitals (as with the HACs) and also affect payments to physicians
• Value-Based Purchasing — Quality Measures
  – Originated in the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU)
  – 13 new quality measures; one existing measure — pneumonia/oxygenation assessment — retired
  – A measure to track re-admissions for heart failure is among the new measures
  – 2 point reduction in market basket payment (general 3.6% increase in 2009 reduced to 1.6% if quality measures not reported)
  – Purpose: to “reward quality of care and deliver higher value to Medicare beneficiaries” and make quality data available to hospitals and consumers
CMS has long-standing concern with “charge compression”

- Hospitals reporting higher percentage mark-ups on lower cost items and lower percentage mark-ups on higher cost items
- Understates the cost of more expensive items; overstates cost of less expensive items
• Splitting cost centers used to combat “charge compression” and update cost reporting
  – Medical device and implants selected because CMS believes modification could have the largest impact
    • Medical devices split into two cost centers (implementation now Spring 2009)
      – Medical Supplies Charged to Patients
      – Implantable Devices Charged to Patients
        » Does not require the device remain in the patient after discharge
• More variations on a theme
  – Quality measures
  – Bundling and packaging – new APCs
  – Outpatient observation
  – “Clarification” of supervision required for incident to therapeutic services
• Market basket increase will be reduced by 2% for hospitals that fail to report quality data.

• Hospitals must report 11 quality measures (5 ED — MI measures, 2 perioperative measures) + 4 new imaging efficiency measures (based on claims)
  – MRI lumbar spine for low back pain
  – Mammography follow-up rates
  – Abdomen CT — use of contrast
  – Thorax CT — use of contrast

• Look for cancer, more ED, diabetes, falls, depression, stroke & rehab, osteoporosis, respiratory and medication reconciliation for 2011…
OPPS — Bundling and Packaging

- More imaging efficiency issues
- 5 new APCs that bundle into a single APC payment two or more imaging procedures using the same imaging modality are furnished on a single day:
  - Ultrasound
  - Computed tomography (CT) and computed tomographic angiography (CTA) without contrast
  - CT and CTA with contrast
  - MRI and magnetic resonance angiography (MRA) without contrast
  - MRI and MRA with contrast
- Separately billable drugs paid at ASP + 4%
• History of Medicare observation reimbursement
  – Before Aug. 1, 2000: reimbursed on a reasonable cost basis
  – Aug. 1, 2000 – April 1, 2002: no separate payment; all observation treated as a packaged service
  – April 1, 2002 – Dec. 31, 2007: separate payment for observation services only for patients with diagnoses of chest pain, asthma, or congestive heart failure
  – Jan. 1, 2003: procedure codes added to allow separate payment for observation for a patient referred by community physician for observation (“direct admission”)
  – Jan. 1, 2008: elimination of diagnoses codes limitations and implementation of “bundled” APC composite payments for observation services furnished for patients with any diagnosis
As of Jan. 1, 2008, Medicare pays for observation services that are:

- Provided as part of a high level clinic visit (Level 5), a high level emergency dept. visit (Levels 4 or 5), critical care services, or a direct admission as an integral part of a patient’s extended encounter
- Provided for a stay of more than 8 hours
- Not reported in association with a surgical procedure

Payment no longer limited to particular diagnosis codes

Observation services provided as an integral part of a patient’s extended care encounter are paid under two new composite APCs (APC 8002 and 8003)
OPPS — Physician Supervision

• Medicare covers outpatient hospital therapeutic services furnished incident to a physician’s service (e.g., lithotripsy) in the hospital and in off-campus facilities
  – SSA § 1861(s)(2)(B); 42 CFR § 410.27

• 2000 OPPS: Outpatient therapeutic services furnished in an off-campus provider-based facility “incident to” physicians’ services require “direct” physician supervision; direct supervision is “assumed” when services are furnished in an on-campus department of the hospital

• Unclear why CMS adopted this supervision standard
  – What if a mobile lithotripter pulls up to the hospital’s loading dock?
• 2009 OPPS: CMS “clarified” that “direct” physician supervision is required for all outpatient therapeutic services whether furnished in the hospital or in any provider-based departments of the hospital, specifically both on-campus and off-campus departments of the hospital
  – This is a radical change (or, according to CMS, a “clarification”) from the “presumption” of general physician supervision in the hospital setting that has long-existed
• Even as “clarified,” direct supervision requirements do not apply to all hospital outpatient services furnished by an off-campus provider-based facility “incident to” a physician service

• Example: physical therapy and other outpatient therapy services
  – Physical therapy services covered under a unique category separate from incident to outpatient therapeutic services (SSA § 1861 (s)(2)(D); 42 CFR § 410.60)
  – CMS has suggested that services, like physical therapy, that have their own coverage category are not provided “incident to” a physician service and need not comply with the direct supervision requirements (65 Fed. Reg. 18,525 (Apr. 7, 2000))
  – CMS’ “clarification” does not appear to affect this earlier guidance
The Not-So-Crystal Ball

- Keep looking for APC bundling
- Reductions in payment amounts
- Methods for addressing charge compression
- Cost report reform
Health Facility Operational Issues

Ann C. McCullough
Poliner v. Texas Health System

• Hospital temporarily suspended Dr. Poliner’s heart catheterization privileges to investigate quality concerns

• Dr. Poliner sued for defamation, mental anguish, etc.; Jury awarded $350 million; later reduced to $33 million

• Fifth Circuit Court of Appeals
  – Applied the Health Care Quality Improvement Act immunity standards
  – Hospital had legitimate quality concerns, suspension was objectively reasonable
  – Hospital’s judgments about the quality concerns were ultimately proved to be wrong; this fact did not defeat immunity
  – Court overturned the award
• Effective Jan. 1, 2009, JC standard (LD.03.01.01) addresses disruptive and inappropriate behaviors in two of its elements of performance:
  – EP 4: The hospital/organization has a code of conduct that defines acceptable and disruptive and inappropriate behaviors
  – EP 5: Leaders create and implement a process for managing disruptive and inappropriate behaviors
• What kind of behavior is “disruptive”?

“I know it when I see it* ...”. Justice Potter Stewart

Jacobellis v. Ohio, United States Supreme Court, 1964

*Justice Stewart’s “it” was a different kind of prohibited conduct

• American Medical Association 2000 Code of Medical Ethics, E-9.045
  – Prohibited conduct should include “personal conduct, whether verbal or physical, that affects or that potentially may affect patient care negatively...”
Disruptive Behavior and Joint Commission (cont.)

• JC Sentinel Event Alert July 9, 2008
• “Intimidating and disruptive behaviors” include:
  – verbal outbursts and physical threats … passive activities such as refusing to perform assigned tasks or quietly exhibiting uncooperative attitudes during routine activities. ... reluctance or refusal to answer questions, return phone calls or pages; condescending language or voice intonation; and impatience with questions
• American Medical Association House of Delegates (Dec. 2008)
  – Expressed concerns regarding arbitrary and capricious enforcement; Requested one year postponement
  – JC has not agreed
How does a health facility and its Medical Staff define and manage “disruptive” behavior?

- Definitions and examples

- Measured, progressive response in proportion to the behavior (document, document, document in the physician’s credentials file)

  - Minor infractions — informal intervention, counseling, letter
  
  - Intermediate — conditional reappointment, anger management
  
  - Extreme — suspension or restriction of privileges, if necessary

- Structure policies and processes to promote immunity under Health Care Quality Improvement Act and Colorado Professional Review Act
“Never Events” or Hospital Acquired Conditions

• Private payors following CMS lead in limiting payment
• “Never Events” or HACs as basis for alleged violations of Conditions of Participation (“CoPs”)?
  – Example: CMS allegation that pressure ulcers were evidence a hospital failed to meet nursing service CoPs and immediate jeopardy
• Operational issues for Hospitals and Medical Staff for “Never Events”
  – Physicians still receive payment for necessary treatment for HACs
  – Medical Staff education, peer review and enforcement mechanisms
    • Automatic review of “Never Events” and HACs (quality management program and Medical Staff peer review)
    • Assess physician contribution to “Never Events” or HACs
    • Are “Never Events” or HACs 100% preventable?
• **Emergency Medical Treatment and Labor Act ("EMTALA")** (42 USC §1395dd)
  
  – If an individual **comes to the emergency department**:
    
    • the hospital must provide a **medical screening exam** to determine whether the individual has an **emergency medical condition**
  
  – If the individual has an **emergency medical condition**:
    
    • the hospital must provide **stabilizing medical treatment** within its capability and capacity (including on-call medical staff), and the hospital may **transfer** the patient only as specified by EMTALA
  
• Hospitals must “maintain a **list of physicians who are on call** for duty after the initial examination to provide treatment necessary to stabilize an individual with an emergency medical condition.”
• FY 2009 IPPS relocated the on-call requirement to 42 CFR § 489.20(r), effective Oct. 1, 2008:
  – Eliminates the requirement that the list be maintained in a manner to meet the “best needs of the hospital’s patients”
  – Hospitals must maintain on-call list “in accordance with the resources available to the hospital”

• Per CMS: “physicians should not perceive the change in the text of the regulation as confirmation that they should limit their on-call availability”
• Hospitals may meet on-call physician requirement by participating in a formalized Community Call Plan among two or more hospitals

• Key elements of a Community Call Plan include:
  – Clear delineation of on-call coverage responsibilities (e.g., by specialty, dates)
  – Definition of the specific geographic area
  – Signatures from each hospital’s representatives
  – Local and regional EMS protocol must formally include information on community on-call arrangements
  – Hospital must comply with EMTALA regarding appropriate transfers
EMTALA Update (cont.)

• Community Call Plan (cont.):
  – Community Call Plan reassessed annually
  – Even if the hospital is not designated as the on-call hospital, it must perform medical screening examinations on patients who present to the hospital and arrange for “appropriate transfers”
  – Written policies and procedures when on-call physician is unable to respond because of situations beyond his or her control
  – 42 CFR § 498.24(j)(2)

• Antitrust risks regarding Community Call Plans (e.g., market allocation)
EMTALA Update (cont.)

• EMTALA — Complaint-driven enforcement mechanism
• 2009 OIG Work Plan
  – Earlier OIG review raised concerns about CMS’ EMTALA oversight
  – OIG to review CMS’ oversight of hospitals’ compliance with EMTALA
New Health Facility

- Initial Surveys for New Medicare Providers — Nov. 5, 2007, S&C 08-03
  
  – CMS and State Surveyors
    
    • constrained resources; priorities are complaint investigations and resurveys
  
    – Four priority “tiers” (Tier 1 — high priority: existing nursing homes and home health agencies. Tier 4 — low priority: hospitals, ASCs, hospices, etc.)
  
- Providers that have the option of attaining accreditation (e.g., through JC, AOA, AAAHC, AAASF) that conveys “deemed” status should do so
New Health Facility (cont.)

- Accreditation is not sufficient for special requirements (e.g., rehabilitation hospitals, psychiatric hospitals, IPPS-excluded units)
- No approved accreditation organization (e.g., DME)
- Deemed status through accreditation not available (e.g., dialysis)

• Updates
  - Feb. 2008 — CMS: AOA can accredit CAH distinct part units
  - Mar. 2008 — CMS: Rural health clinics, SNFs (moved from Tier 4 to Tier 3) and dialysis facilities (a “priority” within Tier 3)
Select Medicare Conditions and Guidance

- CMS revised the End Stage Renal Disease ("ESRD") CfCs, effective Oct. 14, 2008 (Relocated to 42 CFR § 494)

- The new ESRD Conditions include:
  - Incorporation of the Centers for Disease Control infection control guidelines
  - Isolation room for Hepatitis B+ patients*
  - National Fire Protection Association 2000 Life Safety Codes*
  - Emphasis on the role of the interdisciplinary team in patient care
  - Certification of patient care dialysis technicians*
  - Mandatory electronic submission of clinical performance measures*
  - Patient grievance policy — 30 day notice to involuntarily terminate patient

- CMS announced phase-in dates*, waivers for certain requirements on Nov. 21, 2008
Select Medicare Conditions and Guidance (cont.)

• CMS revised Hospice CoPs, effective Dec. 2, 2008 (42 CFR §§ 418.2 and 418.52-116)
  – Patient rights
  – Initial assessment within 48 hours of admission; Comprehensive assessment within 5 days
  – Full drug profile for patients, pharmacist (or other qualified personnel) as part of team
  – Hospice may contract for services (e.g., counseling, nursing) with another hospice under non-routine circumstances
  – For respite care, < 24 hour staffing by registered nurse

• Advance copy of Interpretative Guidelines posted Jan. 2, 2009
Select Medicare Conditions and Guidance (cont.)

• CMS Hospital CoPs (42 CFR § 482)
  Interpretative Guidelines Oct. 17, 2008, including:
  • Histories and physicals (up to 30 days before admission; update within 24 hours of admission, but always before surgeries)
  • Orders (Verbal orders – infrequent, authentication within 48 hours; Standing orders – authentication; Preprinted orders – medical staff approval, authentication)
  • Anesthesia (Pre-anesthesia assessments — 48 hours; Post anesthesia assessments — within 48 hours; CRNA supervision unless State opts out)
  • Informed consent and disclosures (e.g., physician-owned hospitals, no physician on-site 24 hours per day)
  • Patient restraints and seclusion (40+ pages)
  • Physician supervision of emergency services
• Critical Access Hospitals ("CAHs") Provider-Based (42 CFR § 483.610(e))

• Jan. 1, 2008 — Co-location prohibition and location requirements (35 miles; 15 miles if mountainous or secondary roads), with grandfathering provisions.

• Nov. 21, 2008 Advance Copy of Guidelines, effective immediately
  • CAH provider-based facilities created or acquired on or after Jan. 1, 2008 must comply with location requirements (except rural health clinics) and co-location prohibition
  • Grandfathering necessary for provider CAHs with agreements before Jan. 1, 2008 from co-location prohibition
  • Violation of co-location prohibition or location requirements will result in termination of the CAH’s Medicare participation
Provider-Based Update (cont.)

• 2009 OIG Work Plan
  – OIG will:
    • Review potential impact on Medicare program and beneficiaries of hospitals improperly claiming provider-based status
    • Review appropriateness of reimbursement to hospital-owned physician practices that have provider-based designation
    • Determine the extent to which hospital-owned physician practices without provider-based designation improperly received reimbursement under OPPS
    • Review physician coding for place of service
Patient Safety Organization Update

- Patient Safety and Quality Improvement Act of 2005 ("PSQIA")
- Final Rule effective Jan. 19, 2009
  - Health care providers may voluntarily report patient safety data—such as errors, near misses, and quality-related data—to Patient Safety Organizations ("PSOs")
  - The patient safety data submitted to PSOs and the analyses provided by PSOs are subject to federal statutory legal privilege and confidentiality, which begin at time of collection, not upon reporting
  - Patient safety work product includes patient, provider, and reporter identifying information that is collected, created, or used for patient safety activities
Certification and listing of PSOs — Agency for Healthcare Research and Quality ("AHRQ").

- Certain entities prohibited from being PSOs (although may be parent organization)
- 30 PSOs listed as of Jan. 1, 2009 under interim guidance (including 4 hospital association affiliates and 2 entities that include hospital associations as members)
- Common formats for reporting have been developed for hospital inpatients; ambulatory care standards may take additional 2 years

Compliance with the confidentiality provisions — Office for Civil Rights ("OCR")

- CMPs up to $10,000 may be imposed for knowing or reckless impermissible disclosures of patient safety work product
Antitrust and Payor Contracting

- Boulder Valley Independent Practice Association (“BVIPA”)
- Federal Trade Commission (“FTC”) alleged that BVIPA and its approx. 365 otherwise competing physician members:
  - Engaged in illegal price fixing for health care payor contracts
  - Engaged in illegal collective bargaining with payors
  - Encouraged its physician members not to negotiate with payors except through BVIPA
  - Did not engage in efficiency-enhancing integration
• Consent Order announced by FTC on Dec. 24, 2008
  – For the next 20 years:
    • BVIPA may not: facilitate agreements among physicians to collectively negotiate with payors, collectively refuse to deal with payors, exchange information on pricing or other terms of payor agreements, etc.
    • BVIPA must: terminate certain “illegal” agreements, notify the FTC in advance if it will act as agent or “messenger” for physicians, distribute the Consent Order to physicians, payors, etc., publish the Consent Order in its newsletter, report to the FTC
    • BVIPA may: enter into certain “qualified arrangements,” provided the physicians may still negotiate with payors apart from BVIPA
Antitrust and Payor Contracting (cont.)

• What does this mean for IPAs and Physician Hospital Organizations (“PHOs”)? Not much new:
  – Antitrust laws prohibit price fixing among competitors
  – Certain “qualified arrangements” that promote efficiency are not prohibited by antitrust laws (and are permitted by BVIPA’s Consent Order)
    • “Qualified [financial] risk-sharing joint arrangements”
    • “Qualified clinically-integrated joint arrangements”
  – True “messenger models” can avoid price fixing (but are cumbersome to administer)
• Review contracting processes for physicians who are not employees
Internal Revenue Service (‘‘IRS’’) Update

• Intermediate Sanctions — Section 4958 of the Internal Revenue Code.

• The Basics:
  – IRS can impose excise taxes on "disqualified persons" who engage in excess benefit transactions with 501(c)(3) public charities and 501(c)(4) social welfare organizations
  – IRS can also impose excise taxes on managers who approve excess benefit transactions
  – But intermediate sanctions do not preclude revocation of exempt status
• IRS regulations Mar. 23, 2008 — Factors for determining whether to recognize tax exemption for organizations that engaged in excess benefit transaction:
  – The size and scope of activities that advance exempt purposes
  – The size of the excess benefit transaction compared to exempt activities
  – Did the organization enter into multiple excess benefit transactions
  – Were reasonable safeguards implemented by the organization
  – Good-faith efforts to seek correction from the disqualified person
• Best if the organization discovers the excess benefit transaction and takes action before the IRS discovers
• Correction after the IRS discovers the excess benefit transaction, by itself, is not a sufficient basis for continuing to recognize exemption
Internal Revenue Service ("IRS") Update (cont.)

- IRS Form 990 2008, to be filed 2009
  - Final version issued Dec. 23, 2008 for filing 2009
  - Governance, policies and practices
  - Public document
  - Still time to adopt policy changes

- New IRS compliance initiative, focus on corporate governance Dec. 2008
  - Focus is potential for behavioral changes in exempt organizations prompted by financial turmoil (e.g., transactions, fundraising, non-cash donations)
  - IRS will “be vigilant to make sure the tax exempt sector keeps walking away from deals that just don’t feel and smell right”
Medicare Recovery Audit Contractor Program

Steve Lokensgard
RAC Demonstration

• $992.7 million in overpayments
• $187 million contingency fee
• 85% of overpayments from inpatient hospitals
• 4% from outpatient hospitals
• 40% were for medically unnecessary services
• 35% were for coding errors

“Because the Claim RACs were paid on a contingency fee basis, they establish their claim review strategies to focus on high-dollar improper payments, like inpatient hospital claims, which gave them the highest return with regard to the expense of reviewing the claim and/or medical record. CMS anticipates the permanent RACs will adopt a similar strategy at first.”
Permanent RAC Program

- Connolly Consulting coming to Region C:
  - Colorado
  - Florida
  - South Carolina
  - New Mexico
- On hold pending bid protest
- Florida will be subject to a RAC blackout period during transition to MAC
Connolly Consulting by the Numbers

- 35% of complex reviews resulted in an overpayment
- $12,157 = average value of overpayment
- 9.1% = percent of overpayments appealed
  - 22.5% for all RACs
- 54.1% = percent of appealed claims overturned
  - 34% for all RACs
- 4.9% = overall percent of overpayment determinations overturned on appeal
- 9% = their contingency fee in Colorado!
Demonstration Ramp Up

Figure 4. Overpayments Collected by Quarter: Claim RACs Only

Million Dollars

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Source: RAC invoice files and RAC Data Warehouse.
RAC Appeals Process

- **1st level** to fiscal intermediary (FI) within 120 days
  - 30 days to avoid recoupment
- **2nd level** to QIC within 180 days
  - 60 days to avoid recoupment
  - Last opportunity to submit documents
- **3rd level** to ALJ within 60 days
- **4th level** to Departmental Appeals Board
- **5th level** to federal district court
Disability Discrimination, Reasonable Accommodation, and The ADA Amendments Act Of 2008

Dirk W. de Roos
Definition of Disability Discrimination

• The ADA prohibits discrimination against a qualified individual with a disability because of the individual’s disability

• A qualified individual with a disability is a person who can perform the essential functions of the job he or she holds or desires, with or without reasonable accommodation
Legal Elements of Disability Discrimination Claims

• Disability Discrimination in General
  – To establish a claim for disability discrimination under the ADA, an employee must show that he or she:
    • has a disability as defined by federal law;
    • is qualified to perform the essential functions of the job with or without accommodation; and
    • suffered an adverse employment action because of the disability

• Failure to Accommodate
Definition of Disability

• Original ADA
  – An individual has a “disability” under the original ADA if he or she:
    • Has an actual disability;
    • Has a record of a disability; or
    • Is regarded as having a disability
  – An actual disability is defined as an impairment that substantially limits one or more major life activity
• Major Life Activities

• Major Bodily Functions

• Mitigating measures must be disregarded

• “Regarded as disabled” — more broadly defined
Reasonable Accommodation & The Interactive Process

• Definition

• Interactive process: What can you do?

• Responding to requests for reasonable accommodation
  - Employees
  - Job Applicants
Compliance with the ADA Amendments Act of 2008

• ADAAA of 2008

• What does it really mean?
  - Assume
  - Disability
  - Always
  - Attempt
  - Accommodation
Predictions for 2009 and Closing Comments
This presentation is for educational purposes only. Nothing in this presentation should be construed as legal advice, and the specific advice of legal counsel is recommended before acting on any matter discussed herein.
I. LEGISLATION

A. FEDERAL

07/15/08 Medicare Improvements for Patients and Providers Act of 2008. The 2008 Medicare Physician Fee Schedule, which included a rate reduction of 10.6 percent, was retroactively replaced with a schedule which reflected a 0.5 percent increase from 2007 rates. The law also reinstated the therapy cap exceptions process.

10/08/08 Health Care Safety Net Act. President Bush signed legislation (H.R. 1343) that reauthorizes the community health centers program and will provide for $13 billion in funding during the next five years. The Act also reauthorizes the National Health Services Corps. and the Rural Health grants program.

10/15/08 Ryan Haight Online Pharmacy Consumer Protection Act of 2008. The law amends the Controlled Substances Act to counter the growing sale of controlled substances over the internet without adequate medical oversight. Specifically, it bars the sale or distribution of all controlled substances via the internet without a valid prescription, increases the penalties for illegal distributions of Schedule III, IV or V substances, and creates a new cause of action that would allow a state attorney general to shut down a rogue site selling controlled substances in any state.

B. COLORADO

01/01/08 Michael Skolnik Medical Transparency Act. The law requires doctors in Colorado to disclose certain information, including malpractice settlements, professional disciplinary action and ownership of health care businesses. This information will be made public, via a Web site, by the Board of Medical Examiners. This law took effect January 1, 2008.

06/06/08 Increased Transparency To Consumers. The law directs the creation of an "apples-to-apples" consumer shopping guide for health insurance and requires insurance brokers to tell customers how much commission they make on each policy they sell. This law took effect January 1, 2009.
SB 160 expanded eligibility for Child Health Plan Plus, the state's version of SCHIP, to include children in families with incomes up to 225% of the federal poverty level. The act also will expand mental health benefits for children enrolled in the program. A companion bill (SB 161) will remove some administrative barriers to applying for Medicaid and Child's Health Plan Plus.

II. FRAUD AND ABUSE SETTLEMENTS

01/09/08 Dey LP and Takeda Pharmaceuticals North America Inc. agreed to pay Alabama $4.75 million and $2 million, respectively, to settle allegations that they and 71 other pharmaceutical companies fraudulently inflated the prices of their drugs, causing the Alabama Medicaid to overpay for the drugs.

02/04/08 Bayonne Medical Center in New Jersey agreed to pay $2.5 million to resolve allegations that it improperly increased charges to Medicare patients to obtain enhanced Medicare outlier payments.

02/07/08 Merck & Co. agreed to pay more than $650 million to the federal government and states to resolve allegations in two separate lawsuits that the pharmaceutical manufacturer failed to pay proper rebates to Medicaid and other government health care programs. The settlement agreements also resolved allegations that Merck paid illegal remuneration to health care providers to induce them to prescribe the company’s products.

02/14/08 CVS Caremark Corp. agreed to pay 28 states and the District of Columbia $41 million to settle civil charges it encouraged physicians to switch patients to different brand-name prescription drugs.

03/04/08 Cathedral Healthcare System of New Jersey agreed to pay $5.3 million, plus interest, to settle allegations that the Newark-based hospital system improperly increased the charges to Medicare patients in order to receive enhanced outlier reimbursement from the federal program.

03/05/08 Besler & Company Inc., a health care consulting company in North Brunswick, N.J., agreed to pay the United States almost $2.9 million to settle charges that the company improperly counseled hospital clients to increase charges to Medicare patients to obtain enhanced outlier payments from Medicare.

03/07/08 Yale-New Haven Hospital agreed to pay the federal government $3.7 million to settle charges that it violated the False Claims Act. The settlement resolved allegations of improper billing for infusion therapy, chemotherapy administration and blood transfusion services.

03/07/08 Eleven drug companies agreed to pay $125 million to consumers and insurance companies to settle a class action lawsuit charging that the drugmakers inflated average wholesale prices for certain products, resulting in overcharges to patients and payers.

03/12/08 The Federal Government agreed to pay 650 hospitals across the country treating low-income patients $666 million to settle a dispute over Medicare disproportionate share hospital payments.
03/27/08  **Bristol-Myers Squibb Co.** agreed to pay $4 million to resolve allegations it violated the False Claims Act by engaging in off-label marketing of the antipsychotic drug Ability.

03/28/08  **HealthEssentials Solutions**, a nationwide in-home nursing service based in Louisville, KY, agreed to pay the government $3.1 million in criminal restitution for submitting false claims to Medicare.

04/09/08  **Medicaid Dental Center** (MDC), a privately owned chain of dental clinics in North Carolina, agreed to pay more than $10 million to resolve allegations it violated the False Claims Act through improper Medicaid billing.

04/14/08  **Fred Steinberg and his University MRI-related entities**, which provide radiology services in Palm Beach County, Fla., agreed to pay $7 million to resolve a False Claims Act *qui tam* action which alleged that the doctor billed Medicare and other federal health care programs for computed tomography (CT) scans that were never performed.

04/17/08  **Touro Infirmary**, New Orleans, agreed to pay $1.75 million to resolve False Claims Act allegations that it disguised kickbacks to a physician in the form of consultant and medical directorship contracts.

04/24/08  **Memorial Health, Inc.**, the parent company of a hospital in Savannah, Ga., agreed to pay $5.08 million to resolve allegations the hospital defrauded Medicare by violating the Stark Law.

05/13/08  **Baptist Health South Florida Inc.** agreed to pay more than $7.7 million to settle claims that it overpaid an oncology group that was a source of patient referrals to two of its hospitals.

05/22/08  **Kyphon, Inc.**, now known as Medtronic Spine LLC, agreed to pay the United States $75 million to resolve allegations that the spinal device manufacturer caused the submission of false claims for its kyphoplasty procedure to Medicare.

05/27/08  **Express Scripts Inc.**, a St. Louis-based pharmacy benefits manager, agreed to pay $9.5 million to settle the state’s claims that it improperly encouraged physicians to switch patients to different brand-name prescription drugs.

06/04/08  **Walgreen Co.** agreed to pay $35 million to resolve allegations that it improperly switched patients to different versions of three prescription drugs to receive more money from Medicaid.

06/18/08  **North East Medical Services**, a federally-qualified health clinic, agreed to pay almost $5 million to resolve allegations it submitted false claims to California Medicaid.

07/08/08  **Saint Louis University** agreed to pay $1 million to settle charges that its School of Public Health committed fraud in charging the federal government for supplemental pay for faculty members.
07/08/08 Ohio General Hospital agreed to pay $2.2 million to settle allegations involving the alleged fraudulent billing for wound ointment, double-billing for patients treatments and billing for emergency room visits for patients who were actually treated at the hospital’s wound center, which carried a lower rate of payment.

07/22/08 Amerigroup Corp. agreed to pay $225 million (plus $9 million in attorney fees) to resolve qui tam litigation against it relating to certain marketing practices of the company’s former Illinois health plan. The settlement resolves allegations that it violated the False Claims Act by not enrolling pregnant women or sick people to keep costs down.

07/22/08 Lester E. Cox Medical Centers, Springfield, MO, agreed to pay the United States $60 million to resolve allegations it violated the False Claims Act, Stark Law and the Anti-Kickback Statute by entering into financial arrangements with a physician group and inducing physicians to refer patients to the hospital.

08/05/08 St. Elizabeths Hospital agreed to pay $11.3 million to resolve allegations it received reimbursement for inadequately documented or non-covered services the hospital claimed under the Medicare Part B program. CMS suspended payments on St. Elizabeths’ Part B outpatient claims amounting to more than $10.3 million, which CMS will retain as payment, the settlement agreement said. St. Elizabeths’ also agreed to forego $998,095 in Part A claims for inpatient services that CMS withheld.

08/11/08 BlueCross BlueShield of Tennessee, d/b/a Riverbend Government Benefit Administrators, agreed to pay $2.1 million to settle allegations of violating the False Claims Act that resulted in excessive outlier payments by Medicare to many New Jersey hospitals.

08/15/08 Caritas Carney Medical Group agreed to pay $347,456 to the federal government to settle allegations under the False Claims Act that it improperly billed federal government programs for services over a period of nearly seven years. The group submitted claims using physician provider numbers for services provided at nursing homes when the services were actually provided by nurse practitioners.

08/26/08 Rotech Healthcare, Inc., a durable medical equipment supplier, agreed to pay $2 million to the United States to resolve allegations it submitted false claims to Medicare.

09/08/08 Abbott Laboratories Inc. agreed to pay $28 million to settle an enforcement action alleging it falsely reported drug prices to the Texas Medicaid program because it failed to obtain Certificates of Medicaid Need.

09/15/08 Staten Island University Hospital agreed to pay $89 million to settle claims that it defrauded federal and state health care programs, through alcohol and detox billing. The hospital agreed to pay just over $74 million to the United States and $14.9 million to New York.

09/16/08 Carlson Therapy Network agreed to pay $1.88 million to settle allegations that it violated the False Claims Act. The government alleged the company billed government health programs for direct one-on-one therapy when the therapist was providing therapy services to multiple patients at one time.
09/24/08 **Bristol-Myers** agreed to pay 43 states a total of $389 million dollars to Medicaid fraud allegations. The settlement is based on 9 whistleblower lawsuits filed in federal courts across the country.

09/24/08 **Cooper University Hospital** agreed to pay the United States $3.8 million plus interest to resolve allegations that it defrauded the Medicare program by inflating charges to qualify for higher outlier reimbursements. The civil settlement resolved allegations against the hospital violated the False Claims Act by improperly increasing its charges for inpatient and outpatient care to Medicare patients between January 2001 and August 2003.

09/29/08 **Cephalon Inc.** agreed to pay $444 million to resolve claims of marketing three of its drugs for uses that were not approved by the FDA. The government alleged that as a result of the off-label marketing campaign by Cephalon, false claims for reimbursement were submitted to Medicare, Medicaid and other government insurance programs.

09/30/08 **Walgreen Co.** agreed to pay the United States $9.9 million to settle allegations that its pharmacies in four states falsely billed the Medicaid Program. According to the lawsuit, the Medicaid programs reimbursed Walgreens in an amount equal to the difference between what the third-party insurance paid when the claims were submitted and what the participating states' Medicaid programs would have paid in the absence of third-party insurance.

10/21/08 **St. Joseph Healthcare System** agreed to pay $1.75 million to the federal government to resolve a False Claims Act *qui tam* lawsuit alleging Medicare fraud by improperly inflating its Medicare reimbursement claims. The whistleblower alleged that St. Joseph excessively billed for “outlier” payments.

10/21/08 **West Jefferson Medical Center** agreed to pay $3.3 million to the federal government and the state of Louisiana to resolve a False Claims Act *qui tam* suit alleging the hospital overcharged the Medicaid program. The lawsuit alleged that the hospital falsely billed Medicaid the median per diem reimbursement rate for services provided in a Level I facility, but the hospital did not meet the service requirements of a Level I facility.

10/31/08 **Schering-Plough** agreed to pay the state of Missouri $31 million to settle charges that it defrauded the state Medicaid program by manipulating the price-reporting mechanism used by Medicaid to establish reimbursement rates.

11/07/08 **Harris County Hospital District** agreed to pay an additional $2.2 million dollars to the Medicare and Medicaid programs after a compliance audit found the agency had allegedly improperly filed claims for the treatment of motor vehicle accident victims without proper checks for other payment sources. This amount is an addition to the $15.4 million dollars that the agency has to pay pursuant to a settlement agreement it entered into in June, 2007.

11/24/08 **St. Vincent Health System Inc.** agreed to pay the United States $1.9 million to settle a whistleblower’s allegations that it defrauded the Medicare program by inflating charges to qualify for higher outlier reimbursement.
11/24/08 Centennial HealthCare Corp. agreed to pay $2 million to resolve allegations of fraudulent Medicare and Medicaid billing. The government alleged that Centennial violated the False Claims Act by seeking reimbursement for skilled nursing services and other services that were not provided or were so inadequate that they amounted to worthless services.

11/25/08 Bayer HealthCare LLC agreed to pay $97.5 million, plus interest, to settle allegations it paid illegal kickbacks to 11 diabetic supply companies between 1998 and 2007. The settlement resolves allegations that Bayer's actions caused the suppliers to submit false claims to the federal government for Medicare-covered diabetic supplies manufactured by Bayer and settles allegations that Bayer paid the medical supply companies more than $3 million in a so-called cash-for-patient scheme in which the suppliers received payment incentives to switch patients to Bayer products from competing products.

11/25/08 Manchester Community Hospital agreed to pay $712,166 to settle allegations that it improperly billed Medicare for chemotherapy and infusion therapy services.

12/01/08 MedQuist, Inc. agreed to pay $6.6 million to the federal government to resolve allegations that it knowingly overbilled several government agencies. According to the government, MedQuist overbilled the Veterans Administration, Department of Defense and the Public Health Service for medical transcription services by allegedly inflating the number of lines transcribed.

12/01/08 Condell Health Network agreed to pay $36 million after voluntarily disclosing that it received improper Medicare and Medicaid payments. The federal government will receive $33 million and Illinois will receive $2.8 million. The settlement resolves allegations of improper financial relationships with physicians, including below-FMV rent, improper loans and payment for services without a written agreement.

12/01/08 Milan General Hospital and Jackson Madison General Hospital agreed to pay a total amount of $7.8 million to settle allegations related to inpatient services at Milan General Hospital and claims for non-emergency ambulance transportation to Jackson Madison General Hospital.

12/24/08 Boulder Valley IPA agreed to enter into a consent order with the Federal Trade Commission, to settle charges the physician group engaged in unlawful agreements to raise fees it received from health plans in violation of the Federal Trade Commission Act. The complaint alleged that the IPA, acting as a combination of its competing physician members and in conspiracy with its members, acted to restrain competition in fee-for-service contracts by, among other things, entering agreements to fix prices at which its physician members would contract with payers, threatening to terminate contracts with payers who refused to deal with the IPA and having its members refrain from negotiating individually with payers.
III. COURT DECISIONS

02/08/08 United States ex rel. Digovanni v. St. Joseph’s/Chandler Health System Inc., No. CV 404-190 (S.D. Ga.). While the court declined to dismiss the complaint for failure to plead fraud with particularity, the court found that the alleged fraudulent activities were immaterial to the government’s payment of any claims. According to the court, even if the relator proved that Saint Joseph’s had improperly charged for reusable equipment in inpatient claims submitted to Medicare, such submissions would not impact the hospital’s Medicare inpatient PPS reimbursement.

02/25/08 United States v. Prabhu, No. 2:04-CV-00589 (D. Nev.). A federal district court held that the government must pay a physician $542,495 to cover his attorneys’ fees and costs after he prevailed in a False Claims Act case charging him with Medicare fraud. The district court found that the government failed to demonstrate that special circumstances would make the award unjust.

03/31/08 Atlantic Urological Associates PA v. Leavitt, No. 1:08-CV-00141 (D.D.C.). A federal district judge blocked CMS temporarily from enforcing a provision in a November 2007 rule that would have made substantial changes to the way physicians bill for anatomic pathology diagnostic testing services. A preliminary injunction enjoined the enforcement of a provision in the anti-markup rule that applied to anatomic pathology diagnostic testing services provided in a centralized building, as defined in physician self-referral regulations.

04/01/08 Mendiondo v. Centinela Hospital Medical Center, No. 06-55981 (9th Cir.). A nurse who claimed that a California Hospital fired her for protesting “civil and criminal violations” in reference to a possible Medicare fraud, was entitled to proceed with her lawsuit under the False Claims Act, even though her complaint was vague and “inartfully drafted.” The Ninth Circuit found that the nurse’s complaint was adequate under federal court rules, and the trial court erred in dismissing her claims under the False Claims Act, California False Claims Act and California Safety Code. The Ninth Circuit concluded that an employee claiming retaliation under the False Claims Act need only claim a suspicion that a defendant submitted a false claim—“not that the defendant actually submitted one.”

04/01/08 United States ex rel. Fry v. Health Alliance of Greater Cincinnati, No. C-1-03-167 (S.D. Ohio). DOJ intervened in a qui tam action alleging that a hospital’s scheduling of physicians at its outpatient testing unit based on the physician’s procedure volume for the previous year constituted a violation of the Anti-Kickback Statute.

04/08/08 United States v. Solinger, No. 3:03-CV-519 (W.D. Ky.). A qui tam realtor pursuing a False Claims Act lawsuit against an academic medical center failed to show that the defendants did not qualify for the academic medical center exception under the Stark Law. The district court interpreted the academic medical exception using a goal and purpose oriented perspective rather than a hyper-technical one. The court noted that such an approach reflected the recognition of the important relationships between physicians, hospitals and medical instruction.
04/21/08  **Triad at Jeffersonville I LLC v. Leavitt**, No. 08-329 (D.D.C.). The District Court determined that the current owner of certain nursing homes knowingly accepted assignment of the existing provider agreements from the previous nursing home operator and thus was responsible for a $2 million overpayment made to the prior owner of the facilities.

05/16/08  **Fresenius Medical Care v. United States**, No. 07-2299 (8th Cir.). A federal appeals court held that Fresenius Medical Care was not immune from further investigation of its administration of a drug because of an earlier settlement agreement of allegations that the company submitted false claims to Medicare for the same drug.

05/23/08  **Alameda County Medical Center v. Leavitt**, No. 1:08-CV-00422 (D.D.C.). The U.S. District Court for the District of Columbia vacated regulations issued by the Department of Health and Human Services related to Medicaid reimbursement because HHS acted improperly and the rule was contrary to Congress’s plain intent to prohibit the reimbursement change.

06/09/08  **Allison Engine Co. v. United States ex rel. Sanders**, No. 07-214 (U.S.). In a unanimous decision, the U.S. Supreme Court held that, while presentment is not required for liability under two provisions of the False Claims Act, it must be proved that the false statement was made with the intent of getting a false claim paid or approved by the government.

06/18/08  **Zurich American Insurance Co. v. O’Hara Regional Center for Rehabilitation**, No. 06-1357 (10th Cir.). The Tenth Circuit held that a nursing home’s general and professional liability policies did not cover potential False Claims Act liability that was based upon quality of care allegations against the nursing home.

07/14/08  **United States v. Bourseau**, No. 06-56741 (9th Cir.). The presidents of two hospital management companies must pay the government almost $15.7 million for submitting false statements in three annual Medicare cost reports. The Ninth Circuit held that none of the disputed costs in the 1997, 1998 and 1999 cost reports for Bayview Hospital, owned by California Psychiatric Management Services (CPMS), were allowable. The court found that the government sustained actual damages of more than $5.2 million and was entitled to treble damages of $15.7 million and $31,000 in civil penalties under the False Claims Act.

07/24/08  **Di Carlo et al. v. St. Mary Hospital et al.**, No. 06-3579 (3d Cir.). The court dismissed a class-action lawsuit against a local hospital for allegedly charging uninsured patients higher rates than patients who are insured or covered by publicly funded health care programs.

07/25/08  **United States ex rel. Serrano v. The Oaks Diagnostics Inc.**, No. CV 03-2131 (C.D. Cal.). The court dismissed a False Claims Act qui tam action alleging a diagnostic clinic defrauded Medicare, after finding the intervening complaint failed to allege the charges with sufficient particularity, but the court granted to leave to amend the complaint.
07/25/08 United States ex rel. Roberts v. Aging Care Home Health Inc., No. 3:02-cv-02199 (W.D. La.). A federal district court in Louisiana held that the husband of the owner of a home health agency was responsible for paying almost $4.7 million in damages and fines after finding he knowingly violated the False Claims Act by signing false cost certifications. The Court found that the owners had sufficient knowledge or reckless disregard of the truth to warrant his liability under the FCA. The Court found that the defendants had signed four of the five cost certifications submitted to Medicare that were false and material to the Medicare program's decision to pay.

08/01/08 United States ex rel. Hopper v. Solvay Pharmaceuticals Inc, No. 8:04-CV-2356 (M.D. Fla.). A magistrate judge recommended dismissal of a False Claims Act action because the whistleblowers failed to provide specific allegations that a pharmaceutical company's marketing scheme for unapproved uses of a drug caused submission of false claims to any government health program.

08/13/08 United States ex rel. Baker v. Rehabilitation Specialists of Livingston County Inc., No. 2:00-CV-74410 (E.D. Mich.). A federal district held that a jury, not the court, should decide whether a physical therapist and his company knowingly submitted false claims to Medicare by signing two cost reports that relied on an employee's fraudulent information.

09/04/08 Kuhn v. LaPorte County Comprehensive Mental Health Council, No. 3:06-CV-317 (N.D. Ind.). The federal trial court refused to dismiss a lawsuit brought by two employees of a medical center who allegedly were fired for disclosing medical record problems to government officials. The court rejected the contention that the False Claims Act protections did not apply because the altered documents were never submitted to the government in support of a request for payment. The court held that the False Claims Act protects employees from retaliation "while they are collecting information about possible fraud, before they have put all the pieces together." The court held that the whistleblowers are not required to show that the entity was subsequently liable for its actions in order to have been engaged in protected activity, instead, the whistleblowers are only required to show sufficient evidence to establish that their 'investigatory conduct' was motivated by a good faith belief, consistent with that of a reasonable person in the same or similar circumstances.

09/19/08 United States ex rel. Pogue v. Diabetes Treatment Centers of America, No. 1:99-CV-03298 (D.D.C.). The court held it will not reconsider a July decision that refused to dismiss a False Claims Act lawsuit brought against Diabetes Treatment Centers of America because the court found that the company provided no new evidence or justification for the court to retreat from its prior determination that proof of false claims could be based on circumstantial evidence. The court also held that evidence of claim submission as to a subset of physicians can create a genuine issue of material fact as to a related subset of physicians.

09/24/08 U.S. ex rel. Foster v. Bristol-Myers Squibb Co, 9:05-CV-00084 (E.D. Tex.). The court determined that even under a relaxed pleading standard, the whistleblower failed to set forth the factual basis for his "information and belief" that Bristol-Myers Squibb Co. submitted false claims in a kickback scheme. The whistleblower provided no facts to support his belief that physicians at an HMO prescribed Bristol-Myers drugs instead of its competitor's drugs and, therefore, failed to satisfy a relaxed Federal Rule of Civil Procedure 9(b) pleading standard.
09/30/08 United States ex. rel. Sterling v. Health Insurance Plan of Greater New York Inc., No. 06 civ. 1141 (S.D.N.Y.). Claims brought by a woman who alleged a health insurer she worked for defrauded the United States in violation of the False Claims Act were dismissed because the allegedly false statements were not made with the intent of securing a government payment. The court held that the qui tam relator could not pursue her False Claims Act allegations against the insurer because the allegedly false statements were made to secure accreditation from the National Committee for Quality Assurance and were not made to receive federal money.

10/02/08 United States ex rel. Conner v. Salina Regional Health Center Inc., No. 07-3033 (10th Cir.). A federal appeals court dismissed a lawsuit after finding no basis in either law or logic to adopt an express false certification theory that turns every violation of a Medicare regulation into the subject of a False Claims Act qui tam action. The court upheld a district court's decision finding that the whistleblower cited no regulations or case law indicating that the government normally seeks retroactive recovery of Medicare payments for services actually performed on the basis that the noncompliance rendered them fraudulent. The court held that the government has established a detailed administrative mechanism for managing Medicare participation and that although the government considers substantial compliance a condition of ongoing Medicare participation, it does not require perfect compliance as an absolute condition to receiving Medicare payments for services rendered.

10/07/08 United States ex rel. Bane v. Breathe Easy Pulmonary Services Inc., No. 8:06-CV-00040 (M.D. Fla.). A federal district court denied dismissal of a False Claims Act qui tam action alleging a durable medical equipment company conspired with independent diagnostic testing facilities to submit fraudulent claims to Medicare. The court overruled the defendant's objections because it found that none of the litigation documents from an unrelated case constituted a "public disclosure of allegations or transactions" that the defendant engaged in a scheme to defraud Medicare.

10/10/09 United States ex rel. Hebert v. Dizney, No. 07-31053 (5th Cir.). A federal court upheld the dismissal of a False Claims Act qui tam action against a hospital, its owner and the owner's executives, saying that the complaint failed to adequately allege the nature of the underlying fraud. The court held that the whistleblowers failed to point with specificity to the what, when, or where of any individual false claim in their complaint against the hospital and its executives. The court stated that the whistleblowers "do not make, even on information and belief, particularized allegations of any false claim having been submitted and pleading on information and belief does not otherwise relieve a qui tam plaintiff from the requirements of Rule 9(b)."

11/03/08 Alabama v. CMS, M.D. Ala., (No. 2:08-CV-00881). Alabama filed an action in the U.S. District Court for the Middle District of Alabama seeking to prevent CMS from implementing a policy related to the federal share of state Medicaid recoveries. The complaint requests that the court set aside CMS's Oct. 28 letter and permanently enjoin CMS from implementing its requirements.
United States ex rel. Thomas v. Bailey, No. 4:06-CV-00465 (E.D. Ark.). The court held that an amended False Claims Act qui tam complaint failed to state a claim that a company selling spinal surgery devices and its salesman knowingly caused hospitals to present false or fraudulent claims for payment to Medicare, Medicaid and TRICARE. The court, however, found the amended complaint, filed by the whistleblower did state a claim upon which relief could be granted under the False Claims Act, insofar as it alleged that the defendants caused a physician to submit false claims to the government for payment. The court determined that the whistleblower could file the amended complaint, so long as it was limited to the claim that defendants violated the False Claims Act by knowingly causing the physician to present to the government false claims for payment or approval.

United States ex rel. Ben Bane v. Life Care Diagnostics, No. 8:06-CV-00467 (M.D. Fla.). A federal judge dismissed a False Claims Act qui tam complaint alleging a diagnostic testing laboratory caused Medicare to pay for medically unnecessary and redundant services because the allegations in the complaint were nearly identical to an earlier False Claims complaint by the same relator. The court dismissed the complaint against Life Care Diagnostics for lack of jurisdiction under the False Claims Act "first-to-file" bar.

United States ex rel. Kennedy v. Aventis Pharmaceuticals Inc., No. No. 1:03-CV-02750 (N.D. Ill.). A federal district court dismissed for lack of particularity a False Claims Act qui tam action filed by two former sales representatives in which they alleged a pharmaceutical manufacturer marketed a drug for off-label use, thereby inducing hospitals to submit fraudulent claims to Medicare. The court found that the relators/whistleblowers failed to identify any particular cost report submitted to CMS that contained a claim for an off-label use of the drug as a covered expense. Because the relators did not tie the cost reports to particular claims, they failed to allege an individual hospital's cost reports were material to the payment of any given claim, the court found.

IV. CENTERS FOR MEDICARE & MEDICAID SERVICES PRONOUNCEMENTS

A. Advisory Opinions

Advisory Opinion 08-01. CMS concluded that a hospital system’s proposal to pay for development of customized software that allows the hospital’s electronic health records system to communicate with similar systems owned by staff physicians does not constitute a compensation arrangement under physician self-referral laws. As such, the hospital would not have to meet a so-called Stark Law exception in order to pay for the development of the custom "interfaces."

Advisory Opinion 08-02. Physician owners of a diagnostic center can refer patients to the facility without running afoul of physician self-referral laws because the center meets the criteria for a rural provider.

B. Other

CMS announced it is making publicly available the names of all 136 nursing homes targeted in its Special Focus Facilities (SFF) program for underperforming nursing homes. This list expands upon the list of 54 poor-performing nursing homes announced in November 2007.
04/23/08 CMS informed North Carolina it would withhold about $175 million in Medicaid reimbursement claims. CMS wrote state regulators that approximately $175 million in reimbursement for community support services the state sought for the fourth quarter of 2007 may not be allowable. The matter stems from certain community-based mental health services that audits found to be not medically or clinically necessary. A series of state audits over the past year found inconsistencies in the quality of care provided and a misunderstanding of the service by some providers and recipients.

05/08 CMS published a report stating that Medical Integrity Group has developed algorithms that will allow its contractors to complete far more audits than possible with traditional audit methods. MIG has already developed 50 algorithms, and more will be completed in the next six to nine months. The algorithms allow auditors to zero in on potential billing errors quickly and efficiently.

06/27/08 CMS published a final rule that modifies how the agency will determine extended payment schedules for providers that were overpaid by the Medicare program. The final rule makes no changes to the proposed rule that CMS published in November 2006. 73 Fed. Reg. 36443.

06/27/08 Medicare providers and suppliers as of August 26, 2008, will have expanded abilities to appeal the denial of their rights to bill the federal health program. CMS finalized the regulations that entitle providers and suppliers to a hearing before an administrative law judge and the right to appeal ALJ decisions to the Departmental Appeals Board. 73 Fed. Reg. 36448.

09/29/08 CMS issued several clarifications on payments of routine costs in clinical trials in the September 29, 2008, edition of Medicare Learning Network Matters. CMS stated that a research sponsor could create a fraud and abuse problem, if it pays for the co-payments of Medicare beneficiaries enrolled in clinical trials. CMS also clarified that if a research sponsor agrees in writing to pay for routine costs for which an insurance company—including Medicare—will not provide reimbursement, then the sponsor must absorb those charges.

10/28/08 CMS issued a letter regarding its policy regarding the refunding of the federal share of Medicaid overpayments, damages, fines, penalties and any other component of a legal judgment or settlement when a state recovers pursuant to a legal action under the state’s false claims act. CMS asserted that the amounts recovered by a state through the state false claim action are to refunded at the Federal Medical Assistance Percentage (“FMAP”) rate and also demands that a state return not only the federal amount originally paid attributable to fraud or abuse, but also the FMAP-rate proportionate share of any penalties recovered. CMS asserted that neither a whistleblower’s share nor legal expenses paid by the state, may be deducted from the federal portion of the litigation’s proceeds.

V. INSPECTOR GENERAL PRONOUNCEMENTS

A. Advisory Opinions

01/03/08 Advisory Opinion 07-18 (concerning the management by a health care industry consultancy of a charitable organization’s arrangements to subsidize patient cost-sharing and premium obligations).
01/03/08 Advisory Opinion 07-19 (concerning an arrangement whereby a radiology group practice prepares written reports of its interpretations of radiology tests for a critical access hospital without charge to the hospital).

01/03/08 Advisory Opinion 07-20 (concerning an investment by a physician in an imaging center in a medically underserved area devastated by Hurricane Katrina).

01/14/08 Advisory Opinion 07-21 (concerning an arrangement in which a hospital has agreed to share with a group of cardiac surgeons a percentage of the hospital’s cost savings arising from the surgeons’ implementation of a number of cost reduction measures in certain surgical procedures).

01/14/08 Advisory Opinion 07-22 (concerning an arrangement in which a hospital has agreed to share with a group of anesthesiologists a percentage of the hospital’s cost savings arising from the anesthesiologists’ implementation of a number of cost reduction measures related to anesthesia services provided during cardiac surgical procedures).

02/01/08 Advisory Opinion 08-01 (concerning a non-profit corporation's program that arranges for pharmaceutical manufacturer patient assistance programs to provide donated drugs to free clinics and Federally qualified health centers (FQHCs) for use by financially-needy patients who do not have any form of outpatient prescription drug insurance coverage).

02/05/08 Advisory Opinion 08-02 (concerning a non-profit corporation's program that arranges for pharmaceutical manufacturer patient assistance programs to provide donated drugs to free clinics and Federally qualified health centers (FQHCs) for use by financially-needy patients who do not have any form of outpatient prescription drug insurance coverage).

02/08/08 Advisory Opinion 08-03 (concerning a proposed arrangement by which a health care system would provide prompt pay discounts to Federal health care program beneficiaries and other insured patients in connection with both inpatient and outpatient care).

02/12/08 Advisory Opinion 08-04 (concerning a proposal to offer a free trial prescription program to hemophilia A patients who are Federal health care program beneficiaries).

02/22/08 Advisory Opinion 08-05 (concerning a pharmaceutical company's proposal to place in certain physicians' offices electronic kiosks that offer patients free disease state screening questionnaires).

05/09/08 Advisory Opinion 08-06 (concerning a laboratory's proposal to provide services consisting of the labeling of test tubes and specimen collection containers at no cost to dialysis facilities).

07/07/08 Advisory Opinion 08-07 (concerning a proposal for a health care system to provide $10 gift cards to patients whose service expectations were not met).

07/25/08 Advisory Opinion 08-08 (concerning an investment in an ambulatory surgery center by a group of surgeons and a health care corporation that owns hospitals).
08/07/08  **Advisory Opinion 08-09** (concerning an arrangement under which a medical center has agreed to share with groups of orthopedic surgeons and a group of neurosurgeons a percentage of the medical center’s cost savings arising from the surgeons’ implementation of a number of cost reduction measures in spine fusion surgical procedures).

08/26/08  **Advisory Opinion 08-10** (concerning a proposal for a physician practice group to provide space, equipment and personnel to other physician practice groups through block leases).

09/04/08  **Modification of OIG Advisory Opinion No. 04-15** (concerning Advisory Opinion No. 04-15, which was issued on 11/05/04, regarding proposed modifications to the nonprofit, charitable organization’s existing program to provide grants to financially-needy patients suffering from specific chronic or life-threatening diseases to defray the costs of prescription drug therapies).

09/24/08  **Advisory Opinion 08-11** (concerning the waiving of cost-sharing obligations for protocol-required clinical services and oxygen therapy provided to Medicare beneficiaries who participate in the Long-term Oxygen Treatment Trial sponsored by the National Heart, Lung and Blood Institute and the Centers for Medicare and Medicaid Services).

09/26/08  **Advisory Opinion 08-12** (concerning a proposed arrangement under which a newly formed legal entity would provide purely administrative insurance preauthorization processing and submission services for various radiology and imaging centers).

10/02/08  **Advisory Opinion 08-13** (concerning the use of a “preferred hospital” network as part of a Medicare Supplemental Health Insurance (“Medigap”) policy).

10/02/08  **Advisory Opinion 08-14** (concerning a substance abuse treatment center’s use of motivational incentives to reward a patient’s achievement of certain treatment-related goals).

10/14/08  **Advisory Opinion 08-15** (concerning an existing multiple-year arrangement in which a hospital shares with groups of cardiologists a percentage of the hospital’s cost savings arising from the cardiologists’ implementation of a number of cost reduction measures in certain procedures).

10/14/08  **Advisory Opinion 08-16** (concerning a proposed arrangement by which a hospital would share with a physician-owned entity certain performance-based compensation available to the hospital under a quality and efficiency agreement with a private insurer).

10/21/08  **Advisory Opinion 08-17** (concerning a nonprofit, tax-exempt, charitable organization’s proposed arrangement to provide financial assistance to cover cost-sharing obligations associated with outpatient drug treatment owed by financially needy Medicare or Medicaid patients with a certain disease).

10/28/08  **Advisory Opinion 08-18** (concerning a proposal whereby a medical center providing emergency medical services transportation in a county would not bill bona fide county residents for applicable cost-sharing amounts, but would instead be paid such amounts by the county from a fund consisting of tax revenue).
11/05/08 Advisory Opinion 08-19 (concerning an Internet advertiser’s proposal to extend its "pay per call” or “pay per lead” advertising business to the chiropractic industry).

11/26/08 Advisory Opinion 08-20 (concerning a proposal whereby two suppliers of durable medical equipment, prosthetics, orthotics and supplies will (i) place inventory in consignment closets on-site at certain hospitals and (ii) have licensed personnel on-call or on-site at the hospitals to train and educate patients who have been prescribed respiratory equipment and have selected one of the companies as their supplier upon discharge to their homes).

12/08/08 Advisory Opinion 08-21 (concerning a multiple-year arrangement in which a hospital has agreed to share, with cardiology groups and a radiology group, a percentage of the hospital’s cost savings arising from the physicians’ implementation of cost reduction measures in certain cardiac catheterization procedures).

12/15/08 Advisory Opinion 08-22 (concerning certain part-time physician employment arrangements).

12/19/08 Advisory Opinion 08-23 (concerning a proposal for a county, which provides emergency medical services (EMS) transportation through its fire department, to treat revenue received from taxes as payment of otherwise applicable cost-sharing amounts owed by bona fide county residents for EMS transportation to hospitals).

B. Civil Monetary Penalties Actions

01/04/08 After it self-disclosed conduct to the OIG, Shands at Alachua General Hospital (Shands), Florida, agreed to pay $119,838 and to enter into a 3-year certification of compliance agreement for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Shands employed an individual that Shands knew or should have known had been excluded from participation in Federal health care programs.

02/01/08 Newton Memorial Hospital (NMH), New Jersey, agreed to pay $89,279.70 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that NMH employed an individual that NMH knew or should have known was excluded from participation in Federal health care programs.

04/03/08 After it self-disclosed conduct to the OIG, Caritas Christi, Massachusetts, agreed to pay $250,060 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Caritas Christi employed or contracted with five individuals that Caritas Christi knew or should have known were excluded from participation in Federal health care programs.

04/15/08 After it self-disclosed conduct to the OIG, Biotronic West LLC, NeuralWatch LLC and Regents of the University of California, for its University of California Davis Medical Center (collectively, Respondents), agreed to pay $41,488.24 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that the Respondents employed an individual that the Respondents knew or should have known had been excluded from participation in Federal health care programs.
05/09/08 After it self-disclosed conduct to the OIG, Sabine County Hospital District, Texas, agreed to pay $82,341 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Sabine fraudulently included a physician recruiting fee on its cost report as a reimbursable expense.

06/16/08 After it self-disclosed conduct to the OIG, Sparks Health System, Sparks Medical Foundation and Sparks Regional Medical Center (collectively, Respondents), Arkansas, agreed to pay $1,142,973 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that the Respondents billed Medicare for medically unnecessary hospital services.

07/02/08 Southern Illinois Healthcare Foundation (SIHF), Illinois, agreed to pay $562,021 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that SIHF employed an individual that SIHF knew or should have known was excluded from participation in Federal health care programs.

07/16/08 St. Barnabas Hospital, New York, agreed to pay $132,000 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that the hospital employed three individuals that the hospital knew or should have known were excluded from participation in Federal health care programs.

07/24/08 Whole Health Pharmacy (WHP), Colorado, agreed to pay $100,000 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that WHP employed an individual that WHP knew or should have known was excluded from participation in Federal health care programs.

07/26/08 After it self-disclosed conduct to the OIG, FutureCare Irvington, LLC (FutureCare), Maryland, agreed to pay $36,290.79 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that FutureCare employed an individual that FutureCare knew or should have known was excluded from participation in Federal health care programs.

09/18/08 After it self-disclosed conduct to the OIG, Courtyard Manor of Farmington Hills (Courtyard Manor), Michigan, agreed to pay $1.7 million for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Courtyard Manor received federal health care program funds while the entity was excluded. Courtyard Manor also agreed to be excluded from Medicare, Medicaid and all other federal health care programs for two years in addition to its original 10-year period of exclusion.

09/30/08 After it self-disclosed conduct to the OIG, Briarcliff Nursing and Rehabilitation Center LP (Briarcliff), Texas, agreed to pay $1,833 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Briarcliff and its management company, Skilled Healthcare LLC, employed an individual that Briarcliff knew or should have known was excluded from participation in Federal health care programs.

09/30/08 After it self-disclosed conduct to the OIG, Pacific Healthcare and Rehabilitation Center, LLC (Pacific), California, agreed to pay $4,657.50 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Pacific and its management company, Skilled Healthcare LLC, employed an individual that Pacific knew or should have known was excluded from participation in Federal health care programs.
After it self-disclosed conduct to the OIG, Rossville Healthcare and Rehabilitation Center, LLC (Rossville), Kansas, agreed to pay $46,216.50 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Rossville and its management company, Skilled Healthcare LLC, employed an individual that Rossville knew or should have known was excluded from participation in Federal health care programs.

After it self-disclosed conduct to the OIG, Town & Country Manor LP, Texas (Town & Country), Texas, agreed to pay $4,383 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Town & Country and its management company, Skilled Healthcare LLC, employed an individual that Town & Country knew or should have known was excluded from participation in Federal health care programs.

After it self-disclosed conduct to the OIG, St. Elizabeth Healthcare and Rehabilitation, California, agreed to pay $6,223 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that St. Elizabeth and its management company, Skilled Healthcare LLC, employed an individual that St. Elizabeth knew or should have known was excluded from participation in Federal health care programs.

After it self-disclosed conduct to the OIG, Hallmark Rehabilitation, California, agreed to pay $68,055 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Hallmark employed an individual that Hallmark knew or should have known was excluded from participation in Federal health care programs.

After it self-disclosed conduct to the OIG, Royalwood Care Center, California, agreed to pay $1,054.50 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Royalwood employed an individual that Royalwood knew or should have known was excluded from participation in Federal health care programs.

After they self-disclosed conduct to the OIG, Eureka Healthcare and Rehabilitation Center, LLC (Eureka) and Grenada Healthcare and Rehabilitation Center, LLC (Grenada), California, agreed to pay $58,323 for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that Eureka and Grenada and their management company, Skilled Healthcare LLC, employed an individual that Eureka and Grenada knew or should have known was excluded from participation in Federal health care programs.

After it self-disclosed conduct to the OIG, City of Chicago, Illinois, agreed to pay $6.9 million for allegedly violating the Civil Monetary Penalties Law. The OIG alleged that the City of Chicago submitted claims to Medicare for ambulance services that were not medically necessary, billed at the wrong level of service, and submitted claims without the patient's or other appropriate person's signature as required by CMS regulations.

C. Other.

Revision to the OIG Advisory Opinion Process. The OIG revised the terms and process for obtaining an advisory opinion. Requesters still are required to pay a fee equal to the cost of preparing an advisory opinion, but the OIG no longer will require an initial payment at the time of the request.
04/15/08  **Open Letter to Providers.** According to the OIG, providers that resolve fraud matters using the OIG’s Provider Self-Disclosure Protocol generally will no longer be required to enter into corporate integrity agreements. An open letter to providers said that accurate and complete disclosures, timely responses to OIG requests for additional information, and accurate audits by disclosing providers all indicate “effective compliance measures,” ruling out the need for corporate integrity agreements or certification of compliance agreements in most cases.

07/08  **OIG Policy Statement on Retroactive Medicare Rate Increase.** The OIG issued a policy statement assuring providers, practitioners and suppliers affected by retroactive increases in Medicare payment rate increases under the Medicare Improvements for Patients and Providers Act of 2008 will not be subject to OIG administrative sanctions if they waive Retroactive Beneficiary Liability.

**VI. OTHER NOTEWORTHY DEVELOPMENTS**

05/23/08  The Department of Health and Human Services announced the beginning of Sentinel Initiative, a program which would allow the FDA to use information on Medicare claims to assess the risks of drugs already on the market. FDA officials will be able to monitor almost immediately how drugs affect health.

07/10/08  The Pharmaceutical Research and Manufacturers of America (PhRMA) issued a revised version of the PhRMA Code on Interactions with Healthcare Professionals (the “PhRMA Code”). The PhRMA Code sets industry standards for pharmaceutical marketing practices.

08/28/08  The U.S. Department of Justice revised its *Principles of Federal Prosecution of Business Organizations*, published in the United States Attorneys’ Manual. The Principles specifies the DOJ policy concerning how it will measure a corporation’s cooperativeness in a criminal investigation and how the DOJ determines whether an entity should be charged with a crime.

09/15/08  **New Marking Rules for Medicare Advantage Plans and Part D Plans.** New marketing and sales agent compensation rules for Medicare Advantage and Part D prescription drug plans were finalized to protect beneficiaries from high-pressure sales tactics by insurance agents. Plans will be prohibited from providing meals at sales and marketing events for beneficiaries, from conducting unsolicited telemarketing and door-to-door sales campaigns, from cross-selling of non-health care related products, from conducting sales activities in health care provider locations and at pharmacy counters and from conducting sales activities at educational events. 73 Fed. Reg. 54208; 73 Fed. Reg. 54226.

11/04/08  CMS was required to impose an automatic stay in the contract work of the Recovery Audit Contractors (“RAC”) program. The automatic stay will stop work for all four RAC regional awards. The action is the result of protests filed by two unsuccessful bidders for the RAC program.
11/12/08 Amendment to Federal Acquisition Regulations ("FAR"). The government published an amendment to FAR to require mandatory disclosure of what would otherwise be voluntary disclosures of fraud related matters. The new rule expands the scope of contractors who are required to have a code of business ethics and conduct and an internal control system. The rule also mandates disclosure to the government of certain violations of criminal law, violations of the civil False Claims Act and significant overpayments.

12/18/08 AdvaMed issued a major update of its Code of Ethics on Interactions with Health Care Professionals (the “AdvaMed Code”). The revised AdvaMed Code clarifies and distinguishes between appropriate and inappropriate activity between health care professionals and medical device manufacturers.
The Pharmaceutical Research and Manufacturers of America (PhRMA), an association representing leading pharmaceutical and biotechnology companies, released on July 10 its revised Code on Interactions with Healthcare Professionals. The new code, which becomes effective Jan. 1, 2009, includes more stringent limitations on relationships between pharmaceutical manufacturers and the health care providers who use their products.

New Provisions

The revised code replaces a version released by PhRMA in 2002. Its provisions include new restrictions on meals and gifts, as well as additional requirements related to training, continuing medical education and speaker compensation.

- **Prohibition against the provision of restaurant meals by manufacturer sales representatives to health care professionals.** The code will still permit manufacturer representatives who make informational presentations at a hospital or physician office to provide occasional modest meals in that setting in connection with the presentation. In addition to barring restaurant meals, the code prohibits company representatives from providing entertainment or recreation, such as tickets to theater or sporting events, sporting equipment or leisure travel.

- **Ban against the provision of non-educational gifts, even if they are practice related.** Historically, the provision of practice-related items of nominal value, such as pens, note pads, clipboards and mugs, was considered acceptable. The new code states that providing such items may foster misperceptions about the manufacturer’s relationship with the health care professionals, and therefore, bans providing the items. Manufacturers may still provide educational materials for patients with a value of $100 or less. Examples of acceptable items include anatomical models, informational brochures, and patient self-assessment and tracking tools. The code affirms that non-practice-related items, such as golf balls and sports bags, should not be provided, whether branded with the manufacturer’s logo or not.

- **New training requirements for manufacturer representatives.** The code requires companies to ensure their sales and other representatives (whether employed or independent contractors) receive training about the code and laws that regulate their interactions with health care professionals. Companies must also ensure their representatives have sufficient knowledge of general science and product-specific information to provide accurate
information, consistent with FDA requirements.

- **More independence in supporting CME.** Manufacturers who provide funding for continuing medical education (CME) should separate their CME grantmaking function from their sales function to help ensure the educational program promotes a full range of treatment options rather than promoting a particular medicine. Further, manufacturers should not provide meals at CME events under the new code.

- **More stringent requirements for speakers and consultants.** The new code requires that companies cap the total annual compensation paid to each company speaker, and develop policies concerning the use of speakers and consultants. In addition, manufacturers are expected to require speakers and consultants who are members of committees that set formularies or develop clinical guidelines to disclose their work for the manufacturer to the appropriate committee to avoid actual or apparent impropriety.

**Certification**

The code has always been and remains voluntary for PhRMA members. As of Jan. 1, however, new public disclosure and certification provisions will apply for companies that follow the code. The CEO and chief compliance officer of each manufacturer will be asked to certify their company's compliance with the code and to announce their commitment to complying with the code. To encourage manufacturers to participate in the certification and public disclosure process, PhRMA will list on a public Web site the names of all manufacturers making the certification.

**The Code in Context**

The changes to the code reflect a general trend in the pharmaceutical and medical device industries toward increased transparency and efforts to ensure manufacturers do not inappropriately attempt to induce referrals and purchases through their relationships with health care providers. Further, it seems likely the expectations for drug and device manufacturers will continue to increase. Pending federal legislation known as the Physician Payments Sunshine Act is intended to require enhanced reporting of payments made by drug and device manufacturers to health care providers. A number of states have already enacted or are considering similar disclosure laws.

Although the AdvaMed Code of Ethics on Interaction with Health Care Professionals, the voluntary ethics code that applies to medical device manufacturers, is currently less strict in some ways than the new PhRMA code, AdvaMed may revisit its standards in light of PhRMA's changes. Drug and device manufacturers would be well-advised to review their compliance programs and ensure sufficient resources are devoted to monitoring and navigating the changing regulatory landscape.
Stark Rules Change—Again

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How could the government possibly make matters worse for hospitals and physicians doing their best to avoid Stark violations in their everyday business transactions? Simple: just take one of the most complicated sets of regulations ever imposed and change it up three times in the course of a year!

Hospital administrators' and physicians' heads are surely spinning, and their lawyers are struggling mightily to come to grips with the nearly 2,000 pages of regulatory text containing additional Stark rule changes in the 2009 Inpatient Prospective Payment System final rule (hereafter referred to as the “2009 IPPS final rule”), issued by the Centers for Medicare and Medicaid Services (CMS) on July 31, 2008. However, come to grips with it they must, because the final rule contains many important changes to the so-called Stark II, Phase III final rules issued in September 2007 (the “Phase III final rule”), and finalizes several of the more controversial aspects of the 2008 Physician Fee Schedule proposed rule (the “2008 PFS proposed rule”) issued in July 2007.

Deals will be killed; contracts will need to be re-written. More fundamentally, avenues will be narrowed for hospital-physician collaboration in the provision of ancillary and other services. Except as noted below, these rules take effect October 1, 2008. So as painful as it may be given the frequency and complexity of the changes to the Stark rules, providers should read on.

Six Feet “Under Arrangements”

A year after expressing serious reservations with “under arrangements” contracts, CMS adopted changes to clarify the definition of “entity” in a manner that will prevent many “under arrangements” models involving physician-owned entities in most settings.

“Under arrangements” models involve one entity furnishing services to hospital patients, coupled with the hospital's billing and reimbursement for those services under the hospital outpatient fee schedule. Historically, these arrangements have involved hospitals, large physician groups or other non-physician entities. More recently, however, physician-owned joint venture entities, including those in the specialties of cardiology, radiology and urology, began to use “under arrangements” models, thereby triggering concerns that the arrangements created the potential for overutilization of services through a loophole permitting self-referrals that would otherwise be prohibited by the Stark law.
Making good on its warnings in the 2008 PFS proposed rule, CMS redefined “entity” in the 2009 IPPS final rule in such a way as to encompass most physician-owned joint ventures providing services “under arrangements” with a hospital. Until the new rule, “entity” for purposes of the Stark law includes the person or entity that bills and is paid for designated health services (DHS), as well as the person or entity that actually performs the service. Under the revised definition, an entity performing services “under arrangements” will qualify as a DHS entity. And where a physician has an ownership interest in the under arrangements entity, the physician may not make referrals to that entity absent compliance with one of the ownership exceptions to the Stark law—the exception for rural providers being the only viable exception available.

CMS’ decision to expand the definition of “entity” will significantly curtail “under arrangements” joint ventures between hospitals and physician-owned organization groups. Given its breadth and recognizing that the new definition will require many hospitals and physicians to significantly restructure existing “under arrangements” contracts, CMS delayed implementation of this change until October 1, 2009.

Some Percentage Pay, Per-Clicks Go Clunk

In various exceptions—including those governing rental of office space, equipment, fair market value and indirect compensation arrangements—the Stark rules mandate that the manner of payment not take into account the volume or value of any referrals or other business generated between the parties. In all but the latter of those exceptions, the payment must also be set in advance.

Nevertheless, citing congressional intent to permit certain per-use or per-unit of service leases (referred to as “per-click” arrangements), CMS had previously allowed for per-click payments in prior phases of the rules—even for services provided to patients referred by a physician lessor. CMS had also allowed percentage-based payments, provided that the percentage-based formula was fixed (“set in advance”) for the term of the agreement.

Now CMS has changed its mind on both scores, at least in part. With respect to per-click arrangements, the 2009 IPPS final rule changes the space, equipment, fair market value, and indirect compensation exceptions to prohibit rental of space or equipment using a formula based on per-unit of service rental charges, to the extent that such charges reflect services provided to patients referred between the parties. Similarly, the same exceptions now prohibit percentage-based pay in space or equipment rentals, whether the percentage is based on revenues, billings, collections, or is otherwise attributable to the services performed or business generated using the space or equipment.

CMS made these changes because of heightened concerns that certain per-click and percentage-based compensation arrangements provide an incentive for increasing DHS referrals in order to increase the rental payment under the lease. CMS is also concerned that fluctuating rental payments using these methodologies may not result in fair market value payments, and that physician lessors may refer patients to the lessee of his/her equipment rather than to entities that may employ a different and/or more appropriate
treatment modality. The changes are effective October 1, 2009. Existing arrangements will not be grandfathered.

Note that the new per-click limitation does not prohibit physicians from accepting per-click payment from entities for services rendered to patients that were referred by others. Thus, a physician could lease equipment or space to an entity and refer patients for DHS to that entity, and structure the arrangement so that the physician would receive per-use fees for services rendered to patients referred by others, but receive compensation calculated on another basis for services rendered to patients referred by the lessor physician.

Note also that CMS did not ban percentage-based payment formulae in non-rental arrangements. Indeed, it expressly approved percentage-based pay for personally performed physician services. However, CMS warned that it will continue to monitor arrangements for non-professional services (e.g., management or billing services) that are based on a percentage of revenue raised, earned, billed, collected, or otherwise attributable to a physician's or physician organization's professional services. Further restrictions on percentage-based formulae may appear in future rulemaking.

Finally, CMS states that block-time leases, if properly structured, may meet the requirements for space and lease rental. However, it notes that it will continue to monitor such arrangements and may propose rulemaking in the future. CMS specifically notes that parties entering into such arrangements should structure them carefully, particularly taking the anti-kickback statute into consideration.

**Tough Shoes to Fill**

Recall that the Stark law and regulations prohibit a physician from referring a Medicare, Medicaid or other government beneficiary to an entity for any of eleven DHS if the physician has a financial relationship with the entity—unless one of numerous exceptions applies. Stark also prohibits the entity (which will typically be a hospital or physician practice) from submitting a claim to Medicare/Medicaid. The eleven DHS include clinical laboratory, physical/occupational therapy, radiology, durable medical equipment, and inpatient and outpatient hospital services, to name a few. Violations of Stark can lead to recoupment of payments, civil money penalties, False Claims Act liability (including whistleblower claims, treble damages, $11,000 per-claim fines and attorneys fees), and possible exclusion from participation in governmental programs.

Under the Phase III final rule, referring physicians were considered to "stand in the shoes" of their physician organizations—meaning that the referring physician was treated as having the same compensation arrangements with the entity billing or performing the DHS as did his or her physician organization.

The Phase III stand in the shoes rule had a dramatic impact by requiring many previously compliant indirect compensation arrangements to fit within one of the exceptions available for direct compensation arrangements. It also called into question the permissibility of certain mission support payments among
components of hospitals, integrated delivery systems, and academic medical centers (AMCs). The widespread outcry over this change prompted CMS to delay the application of the stand in the shoes rule as it applied to AMCs and nonprofit integrated health systems until December 4, 2008.

Under the 2009 IPPS final rule, with one exception, a physician who has an ownership or investment interest in a physician organization is deemed to stand in the shoes of that physician organization. The exception is in the case of physicians with only “titular” ownership interests in the physician organization (i.e., the physician does not receive any of the financial benefits of ownership through the distribution of profits, dividends, proceeds of sale, or similar returns). Such titular physician owners and non-owner physicians are not required to stand in the shoes of their physician organizations—although they may choose to treat themselves, if they desire, as standing in the shoes of their physician organizations. This option is designed, in part, to ease compliance for those providers who already modified compensation arrangements to comply with Phase III, but the option will continue to be available in the future. Under the 2009 IPPS final rule, the stand in the shoes analysis also does not apply to arrangements that meet the Stark law’s exception for AMCs.

The IPPS final rule provides the flexibility to continue using the indirect compensation exception for non-owner physician employees (including titular owners) of physician organizations. And by excepting titular owners from the stand in the shoes analysis, CMS accommodates the “friendly PC” structure used in states where physician groups may not be employed by hospitals or other than physician-owned entities due to so-called corporate practice doctrines.

(For)Got Signature?

In the 2008 PFS proposed rule, CMS proposed to give providers some leeway when they inadvertently fail to comply with the procedural requirements of a Stark exception. The 2009 IPPS final rule creates a new section § 411.353(g) which allows, under certain circumstances, an entity to bill for DHS when the financial relationship between the entity and the referring physician fully complies with a Stark exception but for the signature requirement. Where signatures are missing inadvertently, providers may avoid Stark law penalties if they obtain the missing signature within 90 days after the start of the financial relationship. Where missing signatures are not inadvertent, providers have a 30-day grace period within which to obtain the needed signatures.

In order to take advantage of these grace periods, the financial relationship must, from the beginning, meet all the requirements of the applicable exception except for the signature requirement, and entities may only use the grace periods once every three years with respect to the same physician.

CMS promulgated this final rule in order to relieve providers from severe punishment for technical violations of the Stark law. In order to encourage providers to utilize this new rule, CMS chose not to mandate self-reporting as a prerequisite to the alternative method of compliance. The alternative method of compliance does not forgo the need for signatures, as the period of disallowance will be triggered if the necessary signatures are not obtained within the specified timeframes.
Is it Fixed Yet?

Under the Stark rules, the “period of disallowance” refers to the period of time for which a physician cannot refer DHS to an entity, and the entity cannot bill Medicare, because a financial relationship between the referring physician and the entity failed to satisfy all of the requirements of an exception to the Stark self-referral prohibition. There has long been confusion over when the period of disallowance ends—if ever—if parties discover a noncompliant relationship.

In the 2009 IPPS final rule, CMS creates an outside limit on the period of disallowance. The final rule provides that where the non-compliance is not related to the payment of compensation, the period of disallowance will end no later than the date that the financial relationship satisfies all of the requirements of an applicable exception. Where the noncompliance is related to the payment of compensation, then the period of non-compliance will end no later than the date on which all excess compensation is returned to the party that paid it (or to which it is owed) and the financial relationship satisfies all of the requirements of an applicable exception.

CMS is attempting to create a bright line rule so that providers can be assured that referrals made after a certain date will not run afoul of the statute. CMS also emphasizes that the final rule does not preclude providers from arguing that the period of disallowance may be in fact shorter than the outer limit set in the rule.

OB Insurance Subsidies

In the 2009 IPPS final rule, CMS retains the current exception allowing obstetrical malpractice insurance subsidies but broadens the exception’s potential application. The prior exception only allowed a “hospital or other entity” to provide obstetrics malpractice subsidies to physicians practicing in a primary care Health Care Professional Shortage Area (HPSA). The expanded exception now allows hospitals, federally qualified health centers, and rural health clinics to provide obstetrics malpractice insurance subsidies when a physician’s practice is: (1) located in a primary care HPSA, rural area, or an area with a demonstrated need, as determined by the Secretary of Health and Human Services in an advisory opinion; or (2) comprised of patients at least 75 percent of whom reside in a medically underserved area or are part of a medically underserved population.

CMS declined requests to expand the exception to physicians practicing other medical specialties, although it kept the door open to considering data indicating that, without an expansion of the exception, beneficiary access to other (or all) medical specialties is hindered.

Closing the Retirement Investment Loophole

The current Stark rules exempt any interest in a retirement plan from the definition of “ownership and investment interests.” In prior proposed rulemaking, CMS expressed a concern that some physicians may be using retirement plans to purchase or invest in other entities to which they refer
patients as an end-run around the Stark rules.

In the 2009 IPPS final rule, CMS modifies the retirement plan exemption to specify that the only interest in a retirement plan that is exempted from the definition of "ownership and investment interests" is an "interest in an entity that arises from a retirement plan offered by that entity to the physician (or a member of his or her immediate family) through the physician's (or immediate family member's) employment with that entity." CMS indicates that this is not a change, but rather a clarification better reflecting its original intent.

Disclosure of Financial Relationships

The Stark regulations have contained reporting requirements since their initial adoption in 1991, but to-date CMS has not implemented this aspect of the regulations, nor has it engaged in any comprehensive reporting initiative to examine financial relationships between hospitals and physicians.

In prior proposed rulemaking, CMS created a collection instrument called the Disclosure of Financial Relationships Report (DFRR) to collect information concerning the ownership and investment interests and compensation arrangements between hospitals and physicians. In the 2009 IPPS final rule, CMS announces that the DFRR will be sent to 500 hospitals, both general acute care hospitals and specialty hospitals. CMS' goal is to identify arrangements that potentially may not be in compliance with Stark, as well as practices that may assist CMS in any future rulemaking. CMS may decide to decrease, but not increase, the number of hospitals receiving the DFRR based on further review and comments its receives. CMS indicates the DFRR will be used as a one-time collection effort. However, it may propose future rulemaking to use the DFRR or some other instrument as a periodic or regular collection instrument.

CMS cautions that to the extent it does not find a Stark violation in a hospital's DFRR, the hospital should not interpret that finding as an affirmative statement that its financial relationships are in compliance. The government might still determine that a violation exists based on further review of information collected as part of the DFRR or from other sources.

CMS estimates that it will take each hospital approximately 100 hours to complete the DFRR at a cost of $4,080 per hospital. While this estimate is up from 31 hours and $1,550 per hospital in the IPPS proposed rule, many hospitals will still find that CMS revised estimates still substantially understate hospitals' actual experience.

Hospitals will have a 60-day limit during which to complete and return the DFRR. Failure to timely submit the requested information may result in civil monetary penalties of up to $10,000 for each day beyond the deadline; however, CMS stated it will work with entities to comply with the reporting requirements before seeking to invoke its authority to impose civil monetary penalties.

Who Says You Didn't?

CMS has long contended that the burden of proof was on the provider when Medicare denies payment on a claim due to a Stark violation, but to-date the
regulations have not expressly addressed the burden. CMS fills that gap in the 2009 IPPS final rule.

Under the new rules, when payment for DHS is denied on the basis of a purported Stark violation, and the denial is appealed, the ultimate burden of proof at each level of administrative appeal will be on the entity submitting the claim to establish that the service was not furnished pursuant to a prohibited referral (and not on CMS or its contractors to establish that the service was furnished pursuant to a prohibited referral). The rules do allow for the burden of production to shift to the government “depending on the evidence presented by the claimant,” but the threshold showing necessary for this burden-shifting to take place is nowhere explained.

Note that this new provision does not impact the evidentiary rules in False Claims Act cases or in other types of court cases, as CMS readily acknowledges. Federal court rules and jury instructions in civil cases clearly place the burden on the government and plaintiff whistleblowers in all court proceedings.

CMS believes that, in most instances, the question of whether a provider or supplier meets a Stark exception will be a factual one, and that the provider or supplier, and not CMS or its contractors, will possess documentation containing the particulars of the financial relationship at issue. However, because many of the exceptions to the physician self-referral prohibition require compliance with the anti-kickback statute, providers may have a difficult time “proving a negative” under an intent-based criminal statute. In a court proceeding, the government has the burden to prove intent under the anti-kickback statute.

CMS to Contractors: Just Say "213"

Anyone who reached the bottom of this article will be acutely aware of just how complicated the Stark rules can be. Nevertheless, as if to prove the point that a label is easier to grasp than a concept, on August 15, 2008, CMS announced the implementation of a new “Claims Adjustment Reason Code”—No. 213—which it wants its fiscal intermediaries and carriers to use when they get a claim from a DHS entity that should be denied because of “Stark.”

CMS' Transmittal and accompanying MedLearn piece instructs contractors:

*Please note that the statute enumerates various exceptions, including exceptions for physician ownership or investment interest in hospitals and rural providers. You can read these exceptions in Section 1877 of the Social Security Act Sec. 1877 which you can find [on CMS' website] and in 42 C.F.R. Part 411, Subpart J.*

The confidence CMS demonstrates in its contractors' ability to understand and correctly implement Stark's regulatory morass is nothing short of breathtaking.

But then again, even if they get it wrong, the burden of proof will be on providers.
Three New Laws Aim to "Rein in Health Insurance"

The Colorado General Assembly recently passed three new laws aimed to increase the accountability of Colorado health insurance companies.

Insurance companies, as well as employers, plan sponsors, plan administrator, third-party administrators and others dealing with health and disability plans will need to become familiar with these new statutes–two of which are already in effect.

Developments in how these statutes are implemented, enforced and eventually interpreted by the courts will shape the impact of these laws.

Changes Under the New Laws

Brief descriptions of the new laws are provided below:

**Increased Transparency To Consumers.** HB 1385, sponsored by Rep. Dianne Primavera (D-Broomfield) and Sen. Gail Schwartz (D-Snowmass Village), directs the creation of an “apples-to-apples” consumer shopping guide for health insurance and requires insurance brokers to tell customers how much commission they make on each policy they sell. This law takes effect January 1, 2009.

**Financial Responsibility for Unfair Business Practices in the Sale of Insurance.** HB 1228, sponsored by Rep. Gwyn Green (D-Golden) and Senate Majority leader Ken Gordon (D-Denver), amends Colorado revised statue10-2-801 to allow the commissioner of the Colorado Division of Insurance to seek restitution damages against any infringing insurance company. It also prohibits insurance agents and companies from selling misleading insurance policies. This law became effective August 6, 2008.

**Strengthening Penalties for Unreasonable Conduct of an Insurance Carrier.** HB 1407, sponsored by House Speaker Andrew Romanoff (D-Denver) and Senate Majority Leader Ken Gordon, (D-Denver) purports to be a law regulating insurance. It creates private right of action in Colorado state court for first-party claimants whose benefits have been unreasonably delayed or denied. This legislation also prohibits insurance contract provisions that reserve discretion to an insurer, plan administrator or claim administrator to interpret the terms of the policy to determine eligibility for benefits. In addition, it requires insurance companies to pay double damages for any infraction. This law became effective August 6, 2008.

Potential ERISA Impact
It remains unclear how the consumer shopping guide for health insurance called for in HB 1385 will be assembled or maintained, or extent to which the Division of Insurance under HB 1228 will seek to review summary plan description and similar plan documents as potentially "misleading." It is evident, however, that HB 1407 makes a major change in the administration and review of health and disability claims.

Claims for benefits under most employee benefit plans are governed by federal law by means of the Employee Retirement Income Security Act of 1974 (ERISA). Employee benefit plans provide health, life, and disability coverage, often through the purchase of insurance. These policies typically contain language granting to the insurer the discretionary authority to determine eligibility for benefits and to interpret the terms of the policy and the plan.

Prohibition of Discretionary Clauses

In *Firestone Tire & Rubber Co. v. Burch*, 489 U.S. 101, 100 (1989), the Supreme Court held that when a plan contains a discretionary clause, the denial of benefits is reviewed by a court under the deferential, arbitrary and capricious standard.

There has been an effort in the past few years to prohibit the use of discretionary clauses in insurance policies and the deferential standard of review that flows from them. In 2002, the National Association of Insurance Commissioners (NAIC) adopted Model Act 42, which prohibits the use of discretionary language in health insurance plans. The NAIC expanded the Model Act two years later to include disability policies. Several states have enacted the Model Act or similar language, including Illinois, Maine, Montana, Utah, Nevada, and most recently, Colorado. The California Insurance Commissioner attempted to reach the same result via Opinion Letter.

The validity of such laws or regulations has been challenged, however, on the basis that the ERISA statute preempts all state laws “insofar as they may now or hereafter relate to any employee benefit plan.” 29 U.S.C. § 1144(a). The counter-argument asserts that the statute is saved from preemption as a state law that “regulate[s] insurance.” 29 U.S.C. § 1144(b)(2)(A).

Increased Court Involvement Likely

As noted above, two of these new laws are already in effect. As a result, courts will be much more involved. Perceived “errors” in administration can result in double-damages, as can unreasonable delays or denials of coverage. The term “unreasonable delay or denial” in this statutory context will have to be defined by the courts through litigation and will obviously vary from case to case.

If you have any questions about this legislation or how to prepare written documentation in compliance with these statutes, please contact Dirk de Roos at DdeRoos@faegre.com.
The Centers for Medicare and Medicaid Services (CMS) appears to have designated 2009 as the year in which it will move beyond the complex Stark physician self-referral prohibitions to address other perceived Medicare program abuses. The proposed Medicare Physician Fee Schedule for 2009 (2009 PFS proposed rule), published on July 9, 2008, contains proposals that would move well beyond the Stark Law and permit CMS to focus on Medicare program cost management using reimbursement rules.

If enacted, the rules likely would have a significant impact on how health care services are delivered, to whom payment for those services is made, and potentially expedite a significant realignment of players in the nation's health care delivery system.

Two of the more controversial proposals would, if enacted, deliver a one-two punch that would impact significantly diagnostic testing arrangements involving physician groups. These proposals and observations on their potential implications are reviewed below.

**IDTF Enrollment Requirements for Physician Offices**

The 2009 PFS proposed rule includes far reaching changes regarding independent diagnostic testing facilities (IDTFs)—a separate and distinct enrollment category and provider of diagnostic services under the Medicare program. It also proposes that physicians and nonphysician practitioner (NPP) organizations that furnish diagnostic testing services enroll each practice location that furnishes diagnostic testing services with Medicare as an IDTF. This represents a dramatic change from their current ability to furnish diagnostic tests as a physician office, clinic or group practice.

CMS based this proposal on concerns that diagnostic testing services may be performed without the benefit of qualified nonphysician personal. A "physician or nonpractitioner organization" would be defined as any physician or NPP entity that enrolls in the Medicare program as a sole proprietorship or organizational entity such as a clinic or group practice.

With this proposed enrollment requirement, CMS would require physicians, physician group practices, and physician clinics that furnish diagnostic tests to meet most of the stringent quality and compliance obligations applicable to IDTFs:

- Restricting physicians from supervising more than three IDTFs
- Requiring the IDTF's supervising physician to demonstrate proficiency in
The supervising physician requirements may prove to be particularly burdensome for physician offices because many local Medicare contractors require IDTFs to use only board certified specialists (e.g., radiologists) to supervise diagnostic tests within the IDTF. Thus, while Medicare already imposes diagnostic test supervision requirements that require general, direct or personal supervision of tests, the proposed rules could add an additional layer of compliance requirements by determining not only the level of supervision, but by whom (e.g., radiologist or other specialty) the supervision can be provided.

If adopted, the proposal effectively could bar general practitioners and many specialists other than radiologists from supervising tests furnished in their own offices for their own patients. It also would eliminate shared facility and similar leasing arrangements where two or more physician groups or other organizations lease the same facility or equipment to furnish diagnostic services to their respective patients. When coupled with proposed changes relative to the Medicare "anti-markup" rule discussed below, the proposed IDTF enrollment requirements could significantly undermine the viability of many physician-owned diagnostic testing arrangements.

If adopted, the proposed IDTF enrollment requirements would be effective on September 30, 2009, for practices that are currently enrolled with Medicare and billing for diagnostic tests, and on January 9, 2009 for new service providers. Penalties for noncompliance would include claims denial or revocation of the entity's billing privileges.

CMS requested comments on whether the enrollment requirements should be limited solely to organizations providing imaging services or advanced diagnostic testing procedures (e.g., MRI scans, CAT scans or PET scans). CMS also requested comments on whether the proposal should apply to all diagnostic testing services.

Ante-Markup Rule Changes

Background

A second, interrelated proposal, concerns the Medicare program's longstanding prohibition against "marking-up" the price of diagnostic tests. Since July of 2007, CMS has attempted to make sweeping changes to the Medicare program's historic diagnostic test "anti-markup" prohibition. Before 2007, the anti-markup rule effectively provided that where a test was "purchased" from an "outside supplier," the purchaser was required to indicate the outside supplier's actual charge for the test to the purchaser on the claim form, therefore limiting the price Medicare would pay for the test to the lesser of the Medicare fee schedule amount or the actual charge. Before 2007, the anti-markup rule applied solely to a diagnostic test's technical component (TC).
In the 2008 PFS final rule published on November 7, 2007, CMS expanded the anti-markup rule to apply also to the PC of diagnostic tests, but it declined to adopt its original proposal focusing on the legal relationship between the billing entity and the personnel performing the tests to determine whether the test is deemed to be "purchased"—electing instead to use an office-based approach to determine whether the anti-markup rule applies.

Specifically, the 2008 PFS final rule provided that the anti-markup provision would not apply to diagnostic tests performed in the billing supplier's office, but it defined "office" narrowly and in a manner that called into question many arrangements that were previously deemed to be acceptable. CMS received a firestorm of criticism regarding its narrow definition of "office" plus other provisions of the new rule, leading CMS to delay most aspects of the final rule until January 1, 2009. During the delay, the historic anti-markup rule continues to apply to the TC of any purchased diagnostic tests, while aspects of the new anti-markup rule now apply to all anatomic pathology services furnished in certain space, effectively eliminating "pod" anatomical pathology service arrangements.

**2009 PFS Proposed Anti-Markup Rule Changes**

In the 2009 PFS proposed rule, CMS proposes additional changes to the anti-markup rule that would address the provisions of the 2008 PFS final rule that were delayed. The agency set forth two alternative proposals.

**Clarification of "Purchased" Tests**

In all circumstances (and under both of CMS' alternative proposals), a physician practice would be subject to the anti-markup rule if the practice "purchases" the PC or TC of a diagnostic test. In the 2009 PFS proposed rule, CMS offered clarification on the factors one should use to determine if a test is "purchased" from an outside supplier, and it explicitly proposed that the technical component of a diagnostic test is not purchased if the technical component is (1) conducted and supervised in the office of the billing physician, and (2) the supervising physician is an employee or independent contractor of the billing physician.

CMS did not define "supervision" in this context, so this two-prong test could potentially require physician presence in the same building in which diagnostic tests are furnished—even for tests in which Medicare coverage rules require only general supervision. Moreover, the combination of this proposal with CMS's proposed requirement that physician or non-physician practitioner organizations must enroll as IDTFs, could effectively require the radiologist or other qualified specialist who is designated as the IDTF's supervising physician to be physically present in the same building as the ordering physician. This could be the case even if applicable Medicare diagnostic test supervision requirements governing the particular test do not require such physician presence.

CMS also proposed to clarify that where the anti-markup rule applies, the Medicare payment is limited to the lower of three changes, the lowest likely to be the "performing supplier's net charge." For purposes of determining this net charge, CMS proposed to define the performing supplier of the TC to be the
supervising physician, and the performing supplier of the PC to be the interpreting physician.

Two Alternative Approaches

In addition to imposing the anti-markup rule on tests that are “purchased,” the 2009 PFS proposed rule outlines two alternative proposed approaches to address concerns related to the 2008 PFS final rule’s definition of “office.” The first alternative focuses on whether test supervision is furnished by a physician who “shares a practice” with the ordering and billing physician. The second alternative provides a definition of a supplier’s “office” that is more pragmatic (and realistic) than was provided in the delayed 2008 PFS final rule.

Alternative #1: Share a Practice Test

Under the first proposal, a physician practice would be subject to the anti-markup rule if the TC or PC of a diagnostic test is purchased, or if the physician who either performs or supervises the PC or TC does not “share a practice” with the billing physician or physician organization. Where the supervising or performing physician shares a practice with the billing entity, the anti-markup rule would not apply.

CMS would define “share a practice” to mean that the supervising and/or performing physician has a relationship (either full-time or part-time) with only one physician organization as either an employee or independent contractor—meaning a single physician could “share a practice” with only a single physician or physician organization. CMS requested comments on how locum tenens and similar arrangements should be addressed.

Adoption of this proposal would eliminate the ability of two or more physician groups to share a single physician to supervise and/or perform diagnostic test interpretations. It would mean, for example, that where a single radiologist provides services to more than one physician organization or billing physician, the anti-markup rule would apply to all of the services supervised by that radiologist because the multiple contractual relationships would violate the “share a practice” requirement in every case. Thus, medical groups would need to employ or contract exclusively with a single radiologist to provide all of the group’s services. It would also likely encourage radiology practices to decline to enter into service relationships with third parties and encourage them to develop their own wholly-owned diagnostic imaging facilities, which would be exclusively staffed by the radiology group (and by radiologists who share a practice with one another).

Alternative #2: Office of Billing Physician or Other Supplier

Under CMS’s alternative proposal, the agency switches its focus from the relationship between the physician organization and the performing or supervising physician, to the location in which the diagnostic testing services are provided. Thus, this alternative would apply the anti-markup rule to the TC and PC of tests that are “purchased” from an outside supplier and to all tests performed at sites outside of the “office of the billing physician or other supplier.”

Under this alternative, the definition of the “office” would be expanded to include any space in which diagnostic testing is performed that is located in
the building in which the billing physician or other supplier regularly furnishes patient care. Mobile vehicles, vans and trailers would not be considered part of the same building such that a mobile diagnostic testing facility operated by the practice would be subject to the anti-markup provision.

In this proposal, CMS attempts to accommodate multi-specialty physician groups with multiple offices. CMS provides in such instances the “office” is the space where the ordering physician provides substantially the full range of patient care services that the ordering physician provides generally. As a result, a physician who provides substantially the full range of services in the “same building” could order a diagnostic test for a patient at a diagnostic testing facility located in the “same building” and, so long as that the applicable interpretation and supervision requirements are met, the anti-markup rule would not apply.

Under this proposal, interpretations performed by an employee or independent contractor of the practice would need to be performed in the same building in which the physician ordering the test provides substantially the full range of services. This alternative would apply the anti-markup rule to images that are transmitted to be interpreted by a physician at another group facility.

Likewise, the anti-markup rule would also apply to diagnostic tests referred to diagnostic testing centers by a physician in the same group who does not substantially practice in the “same building” as the testing facility. As a result, although centralized facilities are allowed under the Stark law, diagnostic tests furnished in centralized facilities would be subject to the anti-markup provision.

CMS recognizes that there may still be inherent problems with this proposal and has requested comments on an exception to the “same building” test for large group practices with multiple offices. In an effort to exempt certain arrangements from the anti-markup provisions, CMS is proposing an exception to the second alternative for diagnostic tests ordered by a physician in a physician organization that does not have any physician owners with rights to receive profit distributions. As a result, certain nonprofit physician organizations could bill for diagnostic tests furnished in any location without application of the anti-markup rule.

**What Does It All Mean?**

Keep in mind that the proposed changes are currently only proposals. While that’s the case, these and other proposed rule changes illustrate CMS’s concern with, if not outright hostility toward, the delivery of diagnostic services by physician organizations and practices.

In the face of the growth in expenditures for diagnostic services, CMS is using all available means to try to reign in costs, including applying different standards to organizations that are physician-owned vs. those that are not, and imposing the IDTF enrollment standards and anti-markup rules referenced above.

The practical effect of the proposals, if finalized without significant changes is relatively clear:

1. Physicians and physician groups that have helped to address
reimbursement cuts by developing in-office ancillary services will potentially find themselves with expensive equipment that is not capable of generating a profit when performing services for Medicare patients.

2. Certain sub-specialists (principally radiologists) are likely to be placed in the driver's seat in determining which, if any, relationships they elect to create with their non-radiologist colleagues.

3. Many physicians will find it increasingly difficult to survive economically without profits from diagnostic testing, which may lead them to form large physician groups or to integrate with hospitals and health systems.

In these and other instances where CMS is moving to restrict payment rules, the message is clear: physicians can't be trusted to order necessary diagnostic tests in response to patient needs, and if they do so, they can profit from the tests only under very limited circumstances. CMS' policy focus and approach is consistent with those which were to be addressed by the Stark Law nearly 20 years ago. Now, however, CMS appears to have moved beyond Stark, settling instead into its historical comfort zone by using reimbursement rules to address cost-control concerns.
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The Centers for Medicare & Medicaid Services (CMS) has been at it again. Over the course of a single year, the agency has taken one of the most complicated sets of regulations ever imposed—the federal physician self-referral Stark Law—and announced multiple actual or proposed changes to it.

The 2009 Inpatient Prospective Payment System final rule (2009 IPPS final rule) issued on July 31, 2008, made changes to the Stark rules. These final rules relate to previous final rules from the Stark II, Phase III final rule issued in September 2007 and several proposals from the 2008 Physician Fee Schedule proposed rule (2008 PFS proposed rule) issued in July 2007. CMS also proposed additional changes in the 2009 Physician Fee Schedule proposed rule (2009 PFS proposed rule) published in July 2008, so additional changes may be on the horizon.

This article outlines some implications these final and proposed rules may have for hospital-physician integrated delivery systems. The changes generally fall within two broad categories: (1) concerns with physician-owned entities, and the drawing of distinctions between those that are physician-owned and those that are not; and (2) the importance of technical regulatory compliance.

Drawing Distinctions Based on Physician Ownership

Changes to the Stark rules resulting from the 2009 IPPS final rule draw important distinctions based on whether an organization is owned, in whole or in part, by physicians.

Stand in the Shoes. CMS addressed a provision that was first finalized in the Phase III final rule published in September 2007, but subsequently delayed. Under that provision, referring physicians were considered to stand in the shoes of their physician organizations—meaning he referring physician was treated as having the same compensation arrangements with the entity billing or performing the designated health services as did his or her physician organization.

The Phase III stand-in-the-shoes provision changed how many physicians and physician organizations comply with the Stark Law. Arrangements that were previously compliant under the indirect compensation arrangements definition must now fit within one of the Stark Law’s exceptions for direct compensation arrangements. More pertinent to integrated delivery systems, the provision also called into question mission support payments involving components of
hospitals, integrated delivery systems and academic medical centers (AMCs). Widespread outcry over this change prompted CMS to delay the provision’s application to AMCs and nonprofit integrated delivery systems until December 4, 2008.

Under the new provisions set forth in the 2009 IPPS final rule, with one exception, only physicians who have an ownership or investment interest in a physician organization are deemed to stand in the shoes of that physician organization. The exception is in the case of physicians with only titular ownership interests in the physician organization (i.e., the physician does not receive any of the financial benefits of ownership through the distribution of profits, dividends, proceeds of sale or similar returns).

In the case of physicians who are not owners of their physician organization— including physicians who are part of integrated delivery systems which are affiliated with tax-exempt hospitals or health care systems—the 2009 IPPS final rule provides the flexibility to continue using the indirect compensation exception under Stark for non-owner physician employees (including titular owners) of physician organizations. And, by excepting titular owners from the stand in the shoes analysis, CMS accommodates the friendly professional corporation structure used in states where physician groups may not be employed by hospitals or other than physician-owned entities due to so-called corporate practice of medicine doctrines.

Under Arrangements Models. CMS also adopted changes first discussed in the 2008 PFS proposed rule to clarify the definition of “entity” in a manner that will prevent many under arrangements service delivery models involving physician-owned entities. As a general matter, under arrangements service delivery models involve one entity furnishing services to hospital patients, coupled with the hospital’s billing and reimbursement for those services under the Medicare reimbursement systems for either inpatient or outpatient hospital services. CMS took aim at these arrangements because many physician-owned and joint venture entities began using under arrangements models, for services previously furnished directly by hospitals. CMS concluded that, [t]here appears to be no legitimate reason for these arranged for services other than to allow referring physicians to make money on referrals... 72 Fed. Reg. 38122, 38186 (July 12, 2007).

CMS redefined “entity” in the Inpatient Prospective Payment System final rule to encompass most physician-owned joint ventures providing services under arrangements with a hospital. Under the new rule, an entity for purposes of the Stark Law includes the person or entity that bills and is paid for designated health services (DHS). The entity definition also includes the person or entity that actually performs the service—thereby including the under arrangements entity as an entity under the Stark Law. And where a physician has an ownership interest in the under arrangements entity, the physician may not make referrals to that entity absent compliance with one of the Stark Law’s ownership exceptions—the exception for rural providers being the only one available. The change is effective on October 1, 2009.

CMS’ expansion of the entity definition will significantly curtail under arrangements joint ventures involving physician-owned organizations. However, it will not affect under arrangements transactions involving physician
organizations that are not physician owned, including, for example, those involved in many hospital-affiliated integrated delivery systems where the physicians are employees of a captive subsidiary of a hospital or a health system parent. Provided that physician employees are paid fair market value for the services they personally perform, and their employment otherwise meets the basic requirements of Stark's employment exception, such under arrangements transactions among integrated delivery system affiliates could provide additional revenue support for the physician component of the system.

Moreover, as alluded to above, CMS' expansion of the entity definition will not affect under arrangements entities that qualify as rural providers under Stark. The Stark rule defines a rural provider as an entity that furnishes at least 75 percent of the DHS it furnishes to residents of a rural area. "Rural" is defined as an area outside a metropolitan statistical area (MSA)—as defined by the federal Office of Management and Budget—without regard to whether the area or any of its population groups are medically underserved or whether the hospital has obtained geographic reclassification for Medicare reimbursement purposes. Provided that substantially all (at least 75 percent) of the patients receiving services from the under arrangements entity are not MSA residents, the rural exception provides continuing opportunities for non-metropolitan hospitals and physicians to co-invest or otherwise collaborate in the provision of ancillary services to hospital patients.

Changes Related to Relations Between Integrated Delivery System Components

Per-Click and Percentage-Based Arrangements. The 2009 IPPS final rule made changes to Stark rules governing rental of office space, equipment, fair market value and indirect compensation arrangements that will now prohibit per-use or per-unit of service leases (commonly referred to as per-click arrangements), and certain percentage-based payments involving lease and service arrangements. The changes are effective October 1, 2009.

Importantly, the new rules do not prohibit per-click payment arrangements outright. Instead, the rules bar physician-owned entities from receiving per-click rental fees where the physicians' own referrals are involved. Likewise, the new rules don't prohibit per-click arrangements involving organizations that are not physician-owned—such as arrangements involving physician organizations within many hospital-affiliated integrated delivery systems in which the physicians have no ownership interest in their host organization. Finally, the new rules don't affect so-called block time leases—i.e., leases that specify a pre-determined period or interval of use.

The changes, in combination with the under arrangements and stand-in-the-shoes provisions discussed above, will still permit integrated delivery system physician organization involvement in service and other arrangements—but those relationships must be structured very carefully with compliance in mind. This may be particularly relevant to the relationships that are likely to be created as hospitals and their affiliated physicians seek to align financial and other incentives related to cost control, quality and other concerns, as discussed below.

Proposals Directed at Shared Savings and Incentive Payments. CMS has clearly
indicated its interest in incentive alignment along cost, quality and other
grounds as evidenced by a proposed new exception to the Stark law published
in the 2009 PFS proposed rule. In that proposal, CMS outlined a new exception
that would permit new shared savings and incentive payment programs
involving hospitals and physicians. Such programs would effectively build on
gain-sharing, cost management and quality focused programs (e.g., PQRI, pay-
for-performance) that are emerging as part of the agency's strategy to help
control in health care costs and promote quality.

The proposed changes to Stark regarding shared savings and incentive payment
programs are merely proposals, so a detailed discussion is not warranted here.
Suffice it to say that the proposals are, like all thing related to Stark, detailed,
lengthy and complex. Each would require documented programs focusing on
patient care, quality, cost-savings or similar measures; independent review and
similar requirements; unrestricted physician choice regarding treatment-
related matters; requirements that the arrangements be set forth in writing
and have specific minimum and maximum terms; and, requirements that the
remuneration payable under the programs would need to be set in advance,
not based on referrals and meet other compensation-related concerns.

Only time will tell whether the proposals will be finalized in their current
form, modified significantly or shelved all together. Nonetheless, publishing a
proposed rule indicates that CMS sees such arrangements and relationships as
having potential future value in the delivery of health care services. For
integrated delivery systems components, the proposal, combined with the new
rules related to physician ownership and others, may open up new
opportunities for physician-hospital alignment in the context of integrated
delivery systems.

In particular, more robust shared savings and incentive payment programs
might soon be possible between integrated delivery systems physician practice
and hospital entities focusing on resource deployment, quality and cost
management. Physician involvement and leadership will be key to the success
of such programs, as well as sharing the financial benefits with the physicians.

**Compliance Strategies and Best Practices**

The 2009 IPPS final rule added a modicum of flexibility in some areas but more
stringent standards in others, the net effect of which ramps up the importance
of Stark compliance.

**Limited Compliance Flexibility.** In terms of flexibility, the new rules provide
limited relief for deals that would otherwise be compliant but for the lack of a
signature arrangement. The 2009 IPPS final rule, under certain circumstances,
allows an entity to bill for DHS when the financial relationship between the
entity and the referring physician fully complies with a Stark exception, but for
the applicable exception's signature requirement. The exception permits
providers to avoid Stark Law penalties by obtaining the missing signature within
a defined period (typically 30 days) after the start of the financial relationship.
In all instances, the financial relationship must meet all the requirements of
the applicable exception except for the signature requirement, and entities
may only use the grace periods once every three years with respect to the
same physician.
Mandating Strict Compliance. CMS also made a number of changes and is embarking on other initiatives that emphasize the importance of strict compliance.

- **Period of Disallowance.** CMS finalized rules related to the applicable period of disallowance under the Stark law—defined as the period of time in which a physician cannot refer DHS to an entity, and the entity cannot bill Medicare, because the referring physician’s financial relationship with the entity failed to satisfy an applicable Stark law exception. In the 2009 IPPS final rule, CMS creates an outside limit on the period of disallowance. Where the non-compliance is not related to the payment of compensation, the period of disallowance will end no later than the date that the financial relationship satisfies all of the requirements of an applicable exception. Where the noncompliance is related to the payment of compensation, then the period of non-compliance will end no later than the date on which all excess compensation is returned, and the financial relationship satisfies all of the requirements of an applicable exception. While CMS appears to be trying to create bright line rules concerning how a Stark violation can be remedied, the regulation does not address many situations of potential noncompliance that an integrated delivery system may face.

- **Burden of Proof.** In the 2009 IPPS final rule, CMS put in writing its long-stated contention that the burden of proof is on the provider when Medicare denies payment due to Stark violations. This means that when payment for DHS is denied on the basis of a purported Stark violation, and the denial is appealed, the ultimate burden of proof at each level of administrative appeal will be on the entity submitting the claim to establish that the service was not furnished pursuant to a prohibited referral (e.g., that the entity fully complied with a Stark exception). CMS maintains that this approach is appropriate because, in most instances, the question of whether a Stark exception is met will depend on facts within the control of the provider or supplier submitting the claims (and not CMS or its contractors). Note that in False Claims Act and whistleblower suits, the burden of proof remains on the plaintiff—including the government where it intervenes—regardless of whether the falsity of the claim is predicated on a purported Stark violation.

Additionally, on August 15, 2008, CMS announced the implementation of a new Claims Adjustment Reason Code—No. 213—that Medicare contractors are to use when a DHS entity’s claim should be denied because of Stark. Thus, the agency appears to believe that the law and its exceptions are sufficiently clear and understandable to permit its contractors to engage in claims denials (and require the provider seeking reimbursement to prove that the denied claim does not violate the Stark Law).

- **Disclosure of Financial Relationships.** In the 2009 IPPS final rule, CMS also finalized provisions related to the use of a Disclosure of Financial Relationships Report (DFRR) to collect information concerning the ownership and investment interests and compensation arrangements between hospitals and physicians related to the Stark law.
CMS announced in the 2009 IPPS final rule that the DFRR will be sent to 500 hospitals, both general acute care hospitals and specialty hospitals, in order to (a) identify arrangements that may not comply with Stark, and (b) identify practices that may assist the agency in future rulemaking. The DFRR is characterized as a one-time information collection effort, although CMS reserved the right to use the DFRR or some another instrument to collect similar data in the future. Given that the DFRR requires hospitals (including those involved in integrated delivery systems) to disclose detailed information regarding their relationships with physicians, the new disclosures are likely to lead to new enforcement initiatives in addition to providing information to CMS regarding potential adjustments to the regulatory scheme.

Conclusion

CMS continues to make changes to the Stark regulations in an effort to address perceived loopholes and abuses that it believes are fueling overutilization of diagnostic and other ancillary services. Unfortunately for physicians attempting to make the most of traditional practice models while enhancing their income through the various arrangements discussed above, these changes coincide with significant cuts both in professional and ancillary service reimbursement and a tightening of other regulatory requirements. By illustration, in addition to the Stark changes, in recent years CMS has changed the reimbursement provided to ambulatory surgical centers, and adopted reimbursement and other changes related to diagnostic tests (including several actual or proposed changes to the diagnostic test anti-markup rule).

On the whole, these changes could significantly impact physicians’ interest and ability to remain in a traditional private practice model. Many may look to hospitals and integrated delivery systems as a more desirable location for their practices, as these entities continue to take advantage of Stark rule exceptions no longer be available to physicians and the entities they own.
In the face of increasing enforcement, physician frustration over the burden of on-call service, and yet another round of regulations under the Emergency Medical Treatment and Labor Act (EMTALA), some hospitals are revising their on-call strategies. Concluding that paying for on-call services and employing and recruiting more physicians are not necessarily the correct or only responses to physicians' EMTALA concerns, these hospitals are exploring a broader scope of arrangements.

This article reviews recent EMTALA regulations and discusses an alternative strategy to easing the burden of call for physicians: expanded use of mid-level providers in support of patient care in hospital emergency departments (EDs). Hospitals considering a mid-level provider strategy must assess the facts— and balance not only EMTALA requirements, but also state-specific scope-of-practice and licensure requirements and reimbursement restrictions for Medicare and other payers—in crafting an appropriate arrangement.

**EMTALA Requirements**

**EMTALA Obligations in General.** The Emergency Medical Treatment and Labor Act requires Medicare-participating hospitals to maintain lists of physicians who are on call to stabilize patients with emergency medical conditions in accordance with the resources available to the hospital. The Centers for Medicare and Medicaid Services (CMS) has stated it is a "reasonable expectation that a hospital be required to provide on-call coverage in any specialty offered to the hospital's patients."

This standard has not been incorporated into EMTALA regulations out of concern it might establish an unrealistically high standard given variation in the size, staffing and capabilities of hospitals. CMS has, however, squarely placed the burden on hospitals to maintain adequate on-call rosters to meet patient care needs in their EDs.

**Recent EMTALA Changes.** As part of the 2009 Final Inpatient IPPS Rule, CMS clarified on-call obligations and adopted new rules for community on-call plans. These changes, which are effective October 1, may not materially ease
the burden of call.

**On-Call Lists.** CMS deleted language stating that a hospital is required to maintain an on-call list “in a manner that best meets the needs of the hospital's patients.” This change, as explained by CMS, was made to reduce confusion regarding the appropriate standard for an on-call list. CMS noted that existing regulations, which require that on-call lists be maintained “in accordance with the resources available to the hospital,” provide sufficient guidance that a hospital is required to provide on-call services based on the resources it actually has available at the time, including the availability of physicians and specialists.

In a cautionary note, CMS stated that “physicians should not perceive the change in the text of the regulation as confirmation they should limit their on-call availability”—an apparent nod to concerns that physicians (or hospitals) would seek to excuse non-compliance by claiming a specialist was not “available” as a resource.

**Community On-Call Plans**

At first blush, a community on-call plan presents an appealing solution to the call-coverage problem. Under such a plan, two or more hospitals in a geographic area would coordinate call coverage. To illustrate, let’s say Hospital A and Hospital B provide neurosurgery call on alternating weeks. If a head injury patient presents to Hospital A during Hospital B’s neurosurgery coverage week, Hospital A stabilizes the patient within its (limited) capacity. It then transfers the patient to Hospital B, where the patient can receive specialized neurosurgery treatment.

A community on-call plan must include the following elements:

1. Clear delineation of on-call responsibilities for each hospital
2. Description of the geographic area covered by the plan
3. Signature of an appropriate representative of each hospital
4. Assurances that local and regional emergency medical system protocols include information on community on-call arrangements
5. Statement reaffirming the obligation of each hospital to meet its EMTALA obligations to provide medical screening and stabilizing treatment with its capacity, and to comply with the EMTALA transfer requirements
6. Annual assessment of the community on-call plan by the hospitals

**Potential Obstacles to Community On Call.** Despite the potential benefits of such a strategy, several obstacles could discourage participation in community on-call plans. As a practical matter, a community on-call plan may require an unprecedented level of cooperation among competing hospitals. Will hospitals incur antitrust liability for market division? Should hospitals pay for on-call
services? And what about HIPAA?

CMS suggested that hospitals direct antitrust concerns to the Department of Justice and HIPAA questions to the Office of Civil Rights. It also noted that “financial arrangements made between an on-call physician and a hospital are between that physician and that hospital” and did not address potential Stark Law or anti-kickback implications.

Mid-Level Providers and EMTALA. Several years ago, CMS issued guidance to clearly allow mid-level providers, including nurse practitioners (NPs) and physician assistants (PAs), to assist in physician on-call responsibilities under certain limited circumstances. In response to public comment regarding use of PAs employed by orthopedic practices in addressing on-call requirements, CMS observed that “there may be circumstances in which a physician assistant may be the appropriate practitioner to respond to a call from an emergency department.” While this change opened the door to the use of mid-level providers in support of ED on-call obligations, hospitals are still exploring the potential benefits, limitations and models for use of mid-level providers to ease the burden of call.

Of course, EMTALA does not permit physicians to avoid “first call” by transferring on-call obligations to a mid-level provider (and mid-level providers cannot be listed in hospitals’ on-call lists in lieu of the on-call physician). However, under EMTALA regulations, mid-level providers may be appropriate responders to a call placed to an on-call physician by the ED physician. The on-call physician must make a case-by-case assessment whether aspects of the patient's care may be appropriately assigned to the mid-level provider, and the on-call physician remains ultimately responsible for the patient care. This approach may allow the on-call physician to satisfy his or her on-call obligation in a manner consistent with appropriate patient care and with minimal disruption to the competing obligations of private practice and family.

Medicare Billing Rules and Options for Mid-Level Providers. As a general matter, Medicare covers services provided by Medicare-participating physicians, PAs and NPs as long as the practitioners are appropriately qualified and services meet applicable billing criteria—including being furnished by a licensed/certified provider and falling within the practitioner's scope of practice. Licensed physicians enjoy the broadest scope of practice, while that available to mid-level providers and other practitioners is more limited for Medicare program purposes. Mid-level providers may not furnish or be reimbursed for services outside of their scope of practice, licensure and applicable supervision requirements. Medicare generally pays for mid-level provider services at 85 percent of the physician fee schedule amount.

Medicare billing rules effectively permit payment for professional services furnished in the ED where payment is made to a physician or a mid-level
provider's employer for the practitioner's personally performed, separately payable services. In addition, Medicare will also make a “shared service” payment to a physician, mid-level provider or their joint employer, for certain separately payable services that may be furnished and paid for as a “shared service” under Medicare. A brief discussion of the "shared services" option follows.

**Shared Services.** In 2002, CMS articulated a policy that permits mid-level provider and physician services to be combined for the purposes of billing evaluation and management (E/M) services furnished in hospitals. Under the Medicare “shared service” policy, when a mid-level provider and physician from the same employer, group or hospital, document a face-to-face encounter with a patient on the same day, the services of both practitioners may be considered when selecting the appropriate E/M code, and the service may be billed under either the physician's or the mid-level provider's number.

The shared service policy applies to the professional component of hospital inpatient services, hospital outpatient services and hospital ED services only. Consultations, services included in the global surgical package, procedures and critical care services generally may not be billed as shared services. Where Medicare criteria for a shared service cannot be met (e.g., mid-level provider and physician are not from the same group or employed by the same employer, or where the service cannot be “shared” under applicable billing rules), the mid-level provider and physician services can not be combined for billing purposes.

Shared services billing is not required in all instances. Indeed, to the extent separate services furnished by both mid-level provider and a physician are medically justified, and there is a separate current procedural terminology (CPT) code describing each service, both practitioners may bill under their respective Medicare numbers for the services they personally provide.

**Using Mid-level Providers to Enhance ED Services**

The revised EMTALA guidance, combined with Medicare billing requirements, supports several practical options to reduce the burden of physician on-call service.

**Enhanced Emergency Department Physician Services.** As a threshold matter, hospitals may certainly encourage ED physicians to furnish the full range of services that are properly within their scope of practice and specialty, and discourage them from making “early handoffs” to on-call physicians as a matter of course. The obvious exception to this being, however, where the services of the on-call physician in the applicable specialty are truly needed. Overall, however, separately billable professional services that are furnished within a performing practitioner's applicable scope of practice, and performed entirely
by a physician (e.g., ED physician or other physician), or by a mid-level provider in accordance with applicable supervision requirements, are separately payable by Medicare. In this context, there may be services that can be furnished by ED physicians or mid-level providers that don’t require involvement of on-call physicians.

**Private Practice Affiliated Mid-level Providers.** Hospitals may also wish to encourage private practice physicians (e.g., ED physician groups or other groups with substantial on-call obligations) to retain one or more mid-level providers as group employees—extending the services of group physicians and benefiting from the ability to furnish and bill for professional ED services that can be billed as “shared services.”

In the case of professional services outside of the scope of practice of an ED physician, *separately billable* professional services can be performed by a mid-level provider when: (1) the appropriate on-call specialty physician has first been contacted by the ED physician in accordance with EMTALA, (2) the on-call physician has determined the required services can be appropriately addressed by a mid-level provider within the mid-level provider's scope of practice and do not require the in-person services of the on-call physician, and (3) the on-call physician provides appropriate supervision of the mid-level provider and is ultimately responsible for the patient care.

Where the on-call physician determines a separately billable service may be properly furnished by a mid-level provider within the mid-level provider's scope of practice, the on-call physician may delegate the service to the mid-level provider, and the mid-level provider may separately bill for the service. Keep in mind, however, that where an ED patient requires specialized physician services (which are beyond the ED physician's scope of practice), the appropriate on-call physician must be contacted by phone as the appropriate first responder as required by EMTALA.

**Anti-kickback Compliance Concerns.** In most hospitals that permit mid-level providers to respond to on-call obligations, the mid-level providers are employed by the on-call physicians or their group practice—not by the hospital. Indeed, this is the fact pattern presented and approved by CMS in the preamble to the EMTALA regulations discussed above. Where a mid-level provider's services in the ED may be billed independently, mid-level provider services that support a community physician should not raise compliance issues because the mid-level provider (and his/her employer) can provide a service for which payment is provided.

However, where a hospital-employed mid-level provider provides on-call services in connection with an independent community physician's on-call obligations, and the independent community physician is the only practitioner who is able to bill for the service, the mid-level provider's services could be
viewed as a form of remuneration from the hospital to the community physicians, thereby raising anti-kickback statute compliance concerns.

Conclusion

While CMS appears to acknowledge the burdens of call, by adopting community on-call plan regulations, hospitals can consider other options, including a mid-level provider strategy to ease this burden. Any mid-level provider on-call strategy must be designed to comply not only with EMTALA, but also with state licensing laws and the Medicare reimbursement requirements.
Emerging and established hospital-physician integrated delivery systems (IDS) commonly question whether their legal and organizational structures will meet future needs.

Experience suggests that legal form should optimally follow function, goals and needs. Goals and objectives that may influence decisions regarding IDS organizational structure include:

- Addressing existing challenges in IDS governance, leadership or operations
- Promoting physician leadership and sense of “ownership” within the IDS
- Facilitating effective physician practice operations, including physician-organization specific human resources, compensation, revenue cycle management, and other practices
- Providing flexibility in employee benefit structures
- Enhancing physician practice management focus and information transparency
- Providing flexibility to access hospital-based and free-standing physician practice reimbursement rules, and to potentially avoid application of Joint Commission standards to free-standing IDS clinics

**Basic Structural Options**

While there are many different IDS structures, three basic models tend to be used in IDS affiliated physician practice relationships and operations.

**Direct Employment.** Under direct employment models, physicians are direct employees of a hospital. The physician practice component functions as an operating division within the hospital much like other hospital departments. Physicians are hospital employees, participants in hospital-employee benefits, and subject to legal and other restrictions relative to physician compensation in a direct employment relationship.

**Hospital-Captive Physician Practice Model.** Some hospitals directly own and operate “captive” subsidiary practice organizations in separate legal entities that are hospital-owned or controlled (hospital subsidiary). The host hospital will capitalize the organization and provide ongoing financial support. Physicians will become direct employees of the Hospital Subsidiary. In some communities a physician who is aligned with the hospital serves as the sole shareholder of a captive professional corporation or other physician practice legal entity. This “friendly physician” model will commonly be used in
“corporate practice of medicine” states that prohibit the direct employment of physicians by hospitals or other organizations that are not physician-owned. The medical practice infrastructure will also sometimes be coupled with relationships with a hospital affiliated management services organization (MSO).

**Health System Parent-Subsidiary Model.** Under the third common IDS structure, a health system will function as the sole owner or member of a subsidiary physician practice legal entity (health system subsidiary). The physician practice legal entity will constitute a brother/sister organization with one or more health system-affiliated hospitals, and all “sibling” organizations are subject to ultimate control by the health system parent. Financial support payments will commonly be provided from the health system to the health system subsidiary, and physicians will become health system subsidiary employees. This model may also be coupled with MSO structures to provide medical practice operational support and infrastructure.

**Comparing the Options**

No single structural option will automatically match every hospital or health system's needs. To the contrary, the “right” structure at a particular time will commonly be influenced by a host of legal considerations, business goals and other factors, including the IDS' maturity, operational effectiveness, current challenges and perceived future opportunities. Moreover, there are important differences between the three basic options referenced above related to governance, physician influence, operations and in other areas that should be considered in selecting the preferred structural model. Some of these differences are reviewed below.

**Governance and Leadership.** Each of the three basic structural options has implications for governance and leadership structures within the integrated system. Under a direct employment model, the hospital board and existing hospital management structures will typically function as leadership of the entire delivery system. The IDS will commonly retain a skilled administrator (e.g., a vice president of physician services) with a physician practice perspective to marshal the existing hospital resources and infrastructure in support of the IDS' physician practice component.

In the hospital subsidiary and health system subsidiary models, separate board and administrative structures are commonly used. Each subsidiary legal entity will have a separate board of directors, with potential membership overlap with the health system parent and/or hospital boards. Likewise, a focused management structure is typically developed to attend to the physician practice entity, along with practice entity-specific strategic and financial plans, budgets, and other management and operating systems.

**Physician Influence Systems.** The basic IDS structural options also vary in terms of how physicians commonly provide input and influence within the organization. Under a direct employment model, physician influence will commonly be exercised informally through an “operations committee” or similar body that provides input on clinical practice operations and other matters.

One or more operations committees will also commonly be used in a hospital subsidiary model, although the committees will commonly focus on the “local”
operations of one or more individual physician practices in order to promote
physician involvement in practice-specific budgets, staffing, scheduling, and
other issues. Advisory boards and similar bodies may also be used to provide
input to the hospital subsidiary's administrative leadership and governing
board.

The health system subsidiary structure may provide the greatest flexibility in
the range of potential physician involvement and participation opportunities.
In these systems, physicians may (but need not) play a more active role in the
enterprise's formal governance structure—subject at all times to the health
system parent's "reserve" powers. Common organizational structures will
frequently blend operations-specific committees that focus on individual
physician practice operations, with one or more physician advisory councils that
provide input to the subsidiary's management and board on strategic, quality
and other matters.

Other Variations

The range of issues and concerns influencing IDS legal and organizational
structure are numerous, and the three basic structural options outlined above
will vary along numerous lines.

Key differences among the basic structural options are summarized here. Each
structural alternative is subject to legal considerations under federal and state
laws, as well as organization-specific operational and other details.

Conclusion

Decisions on legal structure will frequently be influenced by current conditions
and future plans, including the existing structure's culture, strengths,
weaknesses, and operating experiences.

Many integrated systems elect to change legal and organizational structures to
help break free from existing cultural limitations and practices. These
organizations conclude that a truly new organization needs to be created in
law and in fact, and with it new management structures, practice operations,
financial management, human resources and other systems. Creating
something new is viewed as means to help enhance prospects for future
success.

In other settings, the physician component of the IDS' organizational structure
will be retooled within the existing legal and organizational platforms. The IDS
will try to fix what's broken, rather than create something new.

When it comes to IDS legal and organizational structures, "one size" rarely fits
all. Selection of the optimal IDS legal and organizational structure will
therefore require a close consideration of numerous factors including IDS near
and long term goals and objectives, Federal and State legal requirements and
others. A close consideration of these and other considerations will help to
ensure that the appropriate form is created for the IDS' intended function.
Using Quality-Focused Networks to Align Hospital and Medical Staff Relationships

Change is constant throughout health care markets nationwide. In both highly competitive urban areas and rural markets with sole community providers—as well as settings in-between—health care delivery environment and hospital-medical staff relationships are being reshaped.

Hospital medical staff configurations typically resemble one of the following:

- Some physicians, principally medical and surgical specialists, can be classified as "reluctant consumers" of hospital services. These owners of free-standing and/or group practice-affiliated ambulatory surgical, diagnostic and treatment facilities, are required to maintain staff privileges for more complex services requiring hospitalization.
- Other physicians, principally primary care and some office-based specialists, are fairly categorized as "absent users" of hospital services, since hospitalist programs have made active medical staff membership largely unnecessary for them.
- An increasing number of physicians have become "dual citizens" as health system employees in addition to their status as members of the hospital's medical staff.

The emergence of distinct groups within a single medical staff creates stress for both physician-to-hospital and physician-to-physician relationships. In some communities, tension emerges between dual-citizen physician staff members and reluctant-consumer and absent-user physicians on that same staff. Since physicians need to direct patients for care at a designated hospital or facility, an insider-outsider dichotomy and any related conflict can be a challenge for hospitals and health systems.

In response to these relationship concerns, among other vehicles, quality focused networks (QFNs) may represent a construct that can help align hospitals and diverse medical staff members to better achieve shared goals.

Quality Focused Networks

A QFN organizational structure includes hospital-employed and independent physicians who belong to a common medical staff, and become engaged collaboratively to deliver cost-effective, quality patient care. A QFN can help align divergent goals and needs of all three physician types around the shared goal of delivering patient care. This type of organization can also be instrumental in repairing strained relationships among hospital medical staff.

No two QFNs will be structured or operated in precisely the same way.
Nonetheless, common attributes typically include the following:

- Participation by one or more hospitals and a diverse representation among each hospital’s medical staff
- An interoperable electronic health record (EHR) serves as the data platform for quality and patient care initiatives, coupled with systems to access and assess claims data
- Focused programs are directed at quality and cost, including clinical protocol development, clinical best practices and monitoring linked to evidence-based medicine
- Genuine commitment is demonstrated by hospital-affiliated dual citizens, and hospital resources are deployed to help drive quality-focused initiatives
- Important payers are willing to incorporate quality and outcomes measurements, as well as price, in determining reimbursement for inpatient and outpatient health care services

**Regulatory Developments**
A number of regulatory, technological and operational changes are converging to facilitate the development of QFN-type organizations and initiatives:

- Government adoption of exceptions to the Stark physician self-referral law, and the expansion of safe harbors under the Anti-Kickback Statute that allow hospitals to actively support adoption of EHRs and associated technology. These rules permit hospitals and health systems to sponsor and pay a large portion of the costs associated with new technology that can serve effectively as a QFN’s central nervous system.
- Emergence of “clinical integration” as a valid basis, recognized by antitrust authorities including the Federal Trade Commission, for bringing together competing and otherwise unrelated providers for quality-focused payer contracting and other purposes without violating antitrust laws. Historically, competing providers could only engage in joint contracting activities by sharing financial risk—but a properly constructed clinical integration and quality-focused program is now recognized as a lawful mechanism for collaboration.
- An increase in the portion of funds devoted by public and private sector payers to quality and cost management in patient care services. The Medicare PQRI initiative is an important example in this regard.
- The government’s somewhat increased tolerance of exceptions for gain-share and related payment incentive programs and recognition of the potential value of in incentive alignment along cost, quality and other grounds. Among other actions, the Centers for Medicare & Medicaid Services (CMS) proposed new exception to the Stark law—published in the 2009 PFS proposed rule published in July—that would permit new “shared savings” and “incentive payment” programs involving hospitals and physicians. The programs would effectively build on gain-share, cost management and quality focused programs, e.g., PQRI, pay-for-performance, that are emerging as part of the agencies’ strategy to help rein in health care costs.

**Opportunities for Change**
A convergence of business, professional and regulatory variables creates opportunities that encouraging development of a QFNs and similar initiatives among hospitals and members of their medical staffs. No single initiative involving QFN development is likely to address all the complexities of hospital-medical staff relations, but the development of clinically integrated networks with a dedicated focus on quality, cost and related initiatives may be an effective strategy to help hospitals maintain positive relationships with the increasingly diverse members of their medical staff.
The Centers for Medicare & Medicaid Services (CMS) used the 2009 Medicare final physician fee schedule (2009 PFS) to make additional changes to the complex rules governing diagnostic testing.

Among the most significant of these provisions are changes to the Medicare program’s “anti-markup” rule. Other provisions include new standards requiring “mobile” diagnostic testing providers to enroll in the Medicare program as independent diagnostic testing facilities (IDTF) and bill Medicare directly for their services.

While CMS declined to adopt its July 2008 proposal to require physician practices that furnish diagnostic services to qualify and enroll as IDTFs, the agency also declined to take this proposal off of the table for potential future implementation—so more changes may be on the horizon.

The following article provides an overview of the anti-markup rule and other changes related to diagnostic testing services paid for by Medicare Part B.

**Anti-Markup Rule Background**

Medicare has historically prohibited physicians and other suppliers from “marking up” the amount billed under Medicare Part B for certain diagnostic tests. The Medicare anti-markup rule is based on authority contained in the Social Security Act that, by its terms, limits Medicare reimbursement for certain diagnostic tests where the physician performing or supervising the test does not “share a practice” with the billing supplier.

Until 2008, this anti-markup prohibition applied solely to the technical component (TC) of “purchased” diagnostic tests. But in the 2008 PFS, CMS applied the anti-markup rule to both the professional component (PC) and TC of “purchased” diagnostic tests.

Where the anti-markup rule applies, it acts to limit what Medicare will pay as reimbursement for the PC and/or TC of diagnostic tests to the lesser of the billing supplier’s actual charge, the “net charge” or the Medicare fee schedule.
amount. The anti-markup rule does not impact whether a diagnostic test may be furnished, but where the rule applies, it will limit what Medicare will pay for the services.

Provisions of the expanded 2008 rule went into effect on January 1, 2008, to eliminate “pod” anatomical pathology laboratory and similar arrangements. CMS delayed other aspects of the rule, however, including key requirements defining when tests would be deemed to be “purchased” and what constitutes the “office of the billing physician.” CMS outlined alternative proposals to address these concerns in the 2009 Medicare proposed Physician Fee Schedule, published in July 2009.

In the 2009 PFS final rule, CMS moved beyond the concept of purchased tests to focus instead on the statutory concept of whether the billing entity and the physician performing the PC or TC of the test “share a practice.”

New Rule Focuses on Relationships

In the 2009 PFS, CMS replaced the historic concept of “purchased” tests with a rule that looks at the relationship between key parties involved in the performance of diagnostic testing services. Specifically, the anti-markup rule payment limitation will only apply where the billing physician or other supplier and the physician performing the test do not “share a practice.”

While the “share a practice” analysis is critical to the rule's application as a threshold matter, other more basic circumstances must be present before the rule can apply.

Is the Rule Implicated?

Regardless of whether the billing entity and performing physician “share a practice,” the anti-markup rule will only be implicated in certain instances. First, while the rule governs reimbursement for virtually all diagnostic tests including X-rays, MRI, CT, PET/CT, sleep labs studies, it does not apply to clinical diagnostic laboratory tests and certain others tests. Therefore, assessing what tests are involved is critical to determining application of the rule.

Where diagnostic tests subject to the rule are involved, a two-step analysis is required to determine whether the anti-markup rule applies to limit what can be billed to Medicare.

Another prerequisite to the rule's application is that the “ordering” physician or other supplier, e.g., nurse practitioner or other non-physician practitioner (NPP) and the “billing” physician or other supplier must be either the same party or different parties related by common ownership or control. In this context, the ordering physician or NPP is the individual who requests a diagnostic test and who will use the test results in the care and treatment of
the ordering physician or NPP's patient. The billing physician or other supplier is the enrolled individual, entity or other Medicare supplier, e.g., clinic, group or independent diagnostic testing facility (IDTF) that requests payment from Medicare Part B for the PC and/or TC of the diagnostic test.

The rule will not be implicated—and the anti-markup analysis will not be required—where the ordering and the billing suppliers are neither the same nor related in any way. Such is the case when a physician group or IDTF bills for diagnostic tests ordered by physicians who are not related to and who are outside of the physician group or IDTF for the test.

**Does the Rule Apply?**

Even where the anti-markup rule is implicated, payment from Medicare will only be limited if the physician who performs the PC or TC of the test does not "share a practice" with the billing physician or other supplier. The "performing" physician for purposes of the rule is, in the case of the PC, the physician who performs the professional interpretation of the test, and in the case of the TC, the physician who supervises the test in accordance with the Medicare program's diagnostic testing supervision requirements.

Where the anti-markup rule applies, the rule limits the amount that can be billed to Medicare for the PC or TC and requires the billing supplier to identify the performing supplier and that supplier's "net charge" on the claim form. This makes the "share the practice" assessment critical to an evaluation of compliance with the rule.

**Share the Practice Alternatives**

In the 2009 PFS, CMS adopted an "either/or" approach, using two alternative means to meet the anti-markup rule's "share a practice" requirement. Both alternatives focus on the relationship between the diagnostic test billing supplier and the performing physician, but the two alternatives evaluate this relationship in different ways. The alternatives are just that—alternative approaches to avoiding the rule's application—so meeting either will suffice.

Since the anti-markup rule applies to both the PC and TC of diagnostic tests, each test component must be considered separately. Alternative 1 should generally be assessed before moving to Alternative 2, but if either is satisfied, the "share the practice" requirement will be met and the anti-markup rule's limitation on payment will not apply.

**Alternative 1: The "Substantially All" Test**

Alternative 1 permits the billing supplier to avoid the anti-markup rule's application as long as the performing physician furnishes "substantially all"—defined as at least 75 percent—of his or her professional services through the billing physician or other supplier. Alternative 1 does not require the
performing physician to be exclusively employed by or contracted with a single billing organization, but it does require at least 75 percent of the performing physician's medical practice services—generally measured by time—to be furnished through the supplier that is billing for the component of the diagnostic test performed by the physician.

Among other things, this "substantially all" requirement will permit:

- A physician who works part time (e.g., 3 days a week) to spend 75 percent of his/her work time (e.g., 2.25 out of 3 days) working for and billing through a single clinic, physician group or other billing supplier to which reassignment is made.
- A physician to spend 75 percent or more of his/her time working for one physician group, while working part-time for other practices. However, since the physician's part-time work will not involve "substantially all" (i.e., 75 percent or more) of the physician's time, the suppliers with whom the physician has part-time arrangements will not satisfy "share a practice" Alternative 1, so the part-time relationships must either satisfy Alternative 2, or the diagnostic tests performed and/or supervised by the physician in those part-time relationships will be subject to the anti-markup rule.

**Alternative 2: The "Office of the Billing Physician or Other Supplier"**

Under Alternative 2, the performing physician will be deemed to "share a practice" with the billing supplier where the physician performing the PC or TC of the test is an owner, employee or contractor of the billing supplier, and the test is performed in the "office" in which the ordering physician or other supplier regularly provides patient care, including space used for diagnostic testing located in the same building in which the ordering physician or other supplier regularly furnishes patient care.

In the case of billing suppliers that are defined as "physician organizations" under the Stark law, the office of the billing physician or other supplier is space in which the ordering physician provides substantially the full range of patient care services the ordering physician provides generally. This Alternative 2 permits a "site of service" alternative to be applied on a test-by-test basis. Where the PC and/or TC is performed in the "office of the billing physician or other supplier" by an owner, employee, or independent contractor of the billing supplier, then Alternative 2 will be satisfied and the rule's limit on the amount that can be charged Medicare will not apply.

Alternative 2 will have a number of practical implications, including the following:

- Diagnostic testing service locations that comply with the centralized building" option under the Stark law's in-office ancillary services
Avoiding the Rule and Additional Implications

Now that the anti-markup rule is final, the regulatory and operational landscape governing diagnostic testing services has changed. The new rule’s requirements are likely to effect diagnostic testing arrangements and service relationships in numerous ways, including the following:

- A physician “performs” the PC for purposes of the rule, when the physician interprets a diagnostic test. Therefore, where the ordering and interpreting physicians are in different locations, Alternative 2 will not be available and the interpreting physician must furnish substantially all of his/her services for the ordering physician’s group in order to avoid application of the rule.

- A physician performs the TC of a diagnostic test when the physician supervises the test in accordance with the Medicare program’s diagnostic test supervision requirements. Accordingly, where the relationship between the billing supplier and the performing physician does not meet Alternative 1 (because the performing physician does not furnish substantially all (75 percent) or more of his/her services for the billing supplier), to meet Alternative 2, the physician supervising the TC must be physically present in the building in which the TC is performed—even when the Medicare diagnostic test supervision rule requires only general supervision of the test.

- The practical implications of the requirement above will also vary depending on whether the billing supplier is a physician practice or an IDTF. In the case of physician practices, when the Medicare program’s diagnostic testing supervision rules require only general supervision, these requirements can be satisfied by any physician in the practice because Medicare does not impose specific qualifications or requirements on the supervising physician in physician groups.

- However, Medicare imposes more restrictive requirements on IDTFs. Accordingly, where the billing supplier is an IDTF and Alternative 2 is the only available option, the IDTF’s supervising radiologist or other specialist physician must be physically present in the IDTF when the TC is being performed.

Avoiding the Rule and Additional Implications

Now that the anti-markup rule is final, the regulatory and operational landscape governing diagnostic testing services has changed. The new rule’s requirements are likely to effect diagnostic testing arrangements and service relationships in numerous ways, including the following:
While CMS provided two alternatives to meet the new rule's “share the practice” requirement, Alternative 1—which requires the performing physician to furnish substantially all of his/her services for the billing supplier—provides the greatest operational flexibility. Groups with multiple practice locations will be less likely to meet the Alternative 2 office and site of service requirements. This is likely to be of even greater importance if CMS eventually requires physician practices that perform diagnostic testing services to enroll as IDTFs as the agency proposed the 2009 PFS proposal discussed below.

IDTF Enrollment Requirements

In the 2009 PFS, CMS declined to finalize proposals that would have applied the Medicare's IDTF enrollment standards to diagnostic testing furnished by physician and non-physician practitioner (NPP) organizations such as physician practices and groups. CMS declined to finalize the proposal due, in part, to the enactment of § 135 of the Medicare Improvement for Patients and Providers Act of 2008 (MIPPA), which requires the implementation of an accreditation process for entities that furnish and bill for Medicare Part B for advanced diagnostic testing procedures (e.g., MRI, CAT scans, nuclear medicine including PET Scans) by January 1, 2012.

Physician Organizations Can Retain Diagnostic Testing Arrangements

The agency's decision drew both criticism and praise from the physician community. Criticism originated from radiologists, pathologists and other specialists who have expressed concerns with non-specialist involvement in the delivery of diagnostic tests. These specialties have frequently advocated for the imposition of the more rigid IDTF enrollment and qualifying physician...
supervision requirements. Other segments of the physician community breathed a collective sigh of relief as CMS’ decision enrollment will permit the physician organizations to retain their existing diagnostic testing arrangements without having to comply with the IDTF standards that would likely increase costs and/or eliminate many common arrangements.

**Mobile Providers Must Enroll in and Bill Medicare**

CMS did, however, finalize standards applicable to mobile diagnostic testing service providers by requiring, effective January 1, 2009, that all entities that furnish mobile diagnostic services to Medicare beneficiaries must enroll in and directly bill Medicare for their services. These enrollment standards apply to mobile test providers regardless of whether the services are furnished in a mobile facility (e.g., truck trailer) or fixed-based (e.g., physician office) location.

The new rule requires mobile entities to comply with existing and additional IDTF performance standards that, among other things, will require mobile providers to:

- Use qualified physician or non-physician personnel to perform diagnostic tests;
- Ensure the mobile entity’s supervising physician demonstrates proficiency in the performance and interpretation of each type of diagnostic test performed by the IDTF, and prohibit a single physician from supervising more than three IDTFs; and
- Bar the mobile entity from sharing diagnostic testing equipment with other individuals or organizations enrolled in Medicare.

CMS stated the new rule is intended to create a single, universal standard for quality among all mobile imaging providers. Mobile entities that furnish services that are billed by a hospital “under arrangements” are required to qualify and enroll as IDTFs, but they are excluded from the new rule’s direct billing requirement.

The new rule will adversely affect certain arrangements between mobile testing entities and physician organizations. In particular, mobile entities that lease equipment and provide technicians to conduct Medicare payable diagnostic tests in a physician’s office will need to enroll in Medicare as an IDTF and bill Medicare directly for its services.

This same analysis would appear to apply to physician practices that make equipment and technicians available to other physicians on a similar basis (e.g., by leasing those services to an unrelated physician organization on a block of time basis). These physician practices would also likely need to enroll in Medicare as an IDTF and directly bill Medicare for the mobile services it provides.
Unfortunately, the new rule fails to provide a clear definition of what precisely is a “mobile diagnostic testing service provider.” It is unclear therefore whether the rule would apply to a physician practice in this second example, and also unclear whether the new rule will require physician practices with mobile facilities (e.g., mobile MRI trucks that qualify as centralized buildings under the Stark final rule) to enroll their mobile resources as an IDTF. As discussed above, if IDTF enrollment is mandated, the applicable IDTF standards will have dramatic implications for the manner in which the services are furnished and billed.

**Conclusion**

CMS continues to look for and implement new approaches to reign in the proliferation of diagnostic testing services and associated expenditures under the Medicare program. The expansion of the anti-markup rule and the application of IDTF enrollment standards to mobile entities are two tools that CMS has elected to use to address financial, quality and other concerns.

While physician practices may have dodged a bullet by avoiding mandatory IDTF enrollment in the 2009 PFS, it is far from certain the current approach to furnishing of diagnostic testing services will be permitted indefinitely.
Disability Discrimination, Reasonable Accommodation, and the ADA Amendments Act of 2008

I. DEFINITION OF DISABILITY DISCRIMINATION

State and federal laws prohibit discrimination against a qualified individual with a disability because of the individual’s disability.

A qualified individual with a disability is a person who can perform the essential functions of the job he or she holds or desires, with or without reasonable accommodation.

II. LEGAL ELEMENTS OF DISABILITY DISCRIMINATION CLAIMS

A. Disability Discrimination – In General

To establish a claim for disability discrimination, an employee must show that he or she:

1. has a disability as defined by state or federal law;
2. is qualified to perform the essential functions of the job with or without accommodation; and
3. suffered an adverse employment action because of the disability.

B. Failure to Accommodate

An employee or applicant may also claim that the employer failed to accommodate his or her disability. An employer must make reasonable accommodation to the known physical or mental limitations of an otherwise qualified individual with a disability unless the employer can show that the accommodation would impose an undue hardship.

III. DEFINITION OF “DISABILITY”

A. Original ADA

An individual has a “disability” under the original ADA if he/she: (1) has an actual disability, (2) has a record of a disability, or (3) is regarded as having a disability.

An actual disability is defined as an impairment that substantially limits one or more major life activities.

B. ADA Amendments Act

EEOC expected to define “substantially limits”
Inactive impairments may constitute a disability

Major life activities include: caring for oneself, performing manual tasks, seeing, hearing, eating, sleeping, walking, standing, lifting, bending, speaking, breathing, learning, reading, concentrating, thinking, communicating, working, and major bodily functions.

Major bodily functions include functions of: immune system, normal cell growth, digestive system, bowel, bladder, neurological system, brain, respiratory system, circulatory system, endocrine functions, reproductive functions

Mitigating measures must be disregarded (except ordinary eyeglasses/contact lenses)

“Regarded as disabled” - more broadly defined
  o perceived limitation on major life activities no longer matters
  o includes any perceived impairment except impairments that are both “transitory and minor”
  o transitory impairments have an actual or expected duration of $\leq$ 6 months

IV. REASONABLE ACCOMMODATION & THE INTERACTIVE PROCESS

A. Definition

A reasonable accommodation is a modification or adjustment to a job application process, the work environment, or the manner or circumstances under which a job is customarily performed.

B. Examples

Examples of actions that may constitute reasonable accommodation where appropriate include:

  - Modifying existing facilities
  - Job restructuring
  - Leave of absence
  - Modified or part-time schedules
  - Modified workplace policies
  - Reassignment
  - Acquisition or modification of equipment or devices

Examples of actions that are not reasonable accommodations include:

  - Lowering performance standards
  - Removing essential job functions
  - Ineffective accommodations
  - Hiring a helper
Changes that create an undue hardship

C. Interactive Process: What can you do?

The law generally requires that employers and disabled employees or applicants both engage in an interactive process regarding reasonable accommodation. The employer should document the process.

1. Requesting a Reasonable Accommodation

Employee’s Duty: Generally, it is the employee’s obligation to request accommodation.

An employee need not mention the ADA or use the phrase “reasonable accommodation.”

It is sufficient if the employee states that he or she is having difficulty or needs a modification because of a medical condition.

A family member, friend, health professional, or other representative may request reasonable accommodation on the employee’s behalf.

Requests for reasonable accommodation need not be in writing.

Employer’s Duty: An employer should initiate the reasonable accommodation interactive process without being asked if the employer:

Knows the employee has a disability;

Knows or has reason to know that the employee is experiencing workplace problems because of the disability; and

Knows or has reason to know that the disability prevents the employee from requesting a reasonable accommodation.

An employer may ask an employee with a known disability whether he or she needs a reasonable accommodation when it reasonably believes that the employee may need an accommodation.

2. Responding to Requests for Reasonable Accommodation

An employer who receives a request for accommodation must engage in an interactive process with the employee to:

Determine the nature of the disability and the employee’s functional limitations.

Clarify what the employee needs.

Determine what type of reasonable accommodation is needed.

An employer who does not initiate or participate in a dialogue with an individual who has requested a reasonable accommodation may be liable for not providing a reasonable accommodation.
An accommodation may be a reasonable accommodation, even if it is not the employee’s requested or preferred accommodation. An employer is free to offer a more cost-efficient, alternative accommodation, as long as it is effective.

D. Reasonable Accommodation for Job Applicants

An employer may tell applicants what the hiring process involves and ask whether they will need a reasonable accommodation for the process.

An employer may not ask an applicant about the need for reasonable accommodation to perform the job before making a conditional job offer, unless:

The employer knows that the applicant has a disability; and

The employer could reasonably believe that the applicant will need a reasonable accommodation to perform specific job functions.

V. COMPLIANCE WITH ADA AMENDMENTS ACT OF 2008

A. In General

Effective Date of Act - January 1, 2009

ADAAA = “Assume Disability Always Attempt Accommodation” - The EEOC will still need to define “substantially limits” but until then we recommend taking a conservative approach

B. Reconsider Policies/Processes for Disability Accommodation

Some examples of policies and practices that employers may wish to consider implementing include:

Adding a disability accommodation policy to Employee Handbook and training new and existing employees on the policy

Documenting requests for accommodation and the interactive process and potentially making one person in HR the “ADA Contact Person”

Defining essential job functions for each job - for example, regular attendance, lifting, ability to work specified hours/overtime, acceptance of supervision, ability to get along with others in the workplace, objective performance requirements
Hypothetical

During a routine physical, Sue was diagnosed with hypertension (high blood pressure). This was a surprise to her because she did not have any symptoms. Sue is an active person who plays golf, hikes and engages in other recreational activities. After the diagnosis, the doctor prescribed blood pressure medication, which Sue regularly takes as prescribed. After a month, a follow-up check revealed that her blood pressure had returned to normal levels.

During conversation at lunch in which her boss, several co-workers and Sue were bemoaning the effects of aging, one of the co-workers remarked that she wished she were as healthy as Sue. Sue responded by saying that she needed to take medicine for high blood pressure, which was successfully controlling her disease.

Three weeks after the lunch discussions, the employer instituted a reduction in force in Sue’s department. Sue was one of those whose employment was terminated. Sue filed a charge with the Equal Employment Opportunity Commission (EEOC) alleging that she had been discharged because of a disability.
The RAC Program Comes to Colorado: “All we want is 9%”
Steve Lokensgard
Special Counsel
Faegre & Benson

Agenda
- The RAC Demonstration
- Status of RAC Permanent Program
- Colorado’s RAC Contractor
- Preparing for the RAC audits
  - Compliance
  - HIM Department
  - Finance/Revenue Cycle
  - Law Department

The RAC Demonstration
- Recovery Audit Contractor (RAC)
- National Payment Error Rate
  - 9.8% in 2003
  - 3.9% in 2007 ($10.8 billion)
- Goal of RAC program: detecting past improper payments
- Goal of Medicare claims processing contractors: preventing future improper payments through pre-pay review and education
The RAC Demonstration

- March 2005-March 2008
- Began in NY, CA, and FL
- Expanded to MA, SC, and AZ
- Medicare’s first contractor paid on a contingency fee basis
- Recovered $992.7 million in overpayments
- RAC’s earned fees of $187 million

Types of Reviews

- Automated Review
  - The product of data analysis
  - Examples: unit errors (Neulasta, colonoscopy)
- Complex Review
  - Requires review of the medical record
  - Examples: wrong setting (chest pain, admission following cardiovascular procedure, inpatient rehab admission); coding error (excisional debridement, wrong principal diagnosis)

Overpayments Identified

- 85% from inpatient hospitals
- 4% from outpatient hospitals
- 40% were for medically unnecessary services
- 35% were for coding errors

“Because the Claim RACs were paid on a contingency fee basis, they establish their claim review strategies to focus on high-dollar improper payments, like inpatient hospital claims, which gave them the highest return with regard to the expense of reviewing the claim and medical record. CMS anticipates the permanent RACs will adopt a similar strategy at first.”
The Permanent Program

- All states by January, 2010
- Ramp up concept – state by state rather than whole country at once
- States next up in Region C:
  - Colorado
  - Florida
  - South Carolina
  - New Mexico
- On hold pending bid protest

Connolly Consulting by the Numbers

- RAC for NY and MA in Demonstration
- $266 million in overpayments
- $4.3 million in underpayments
- 35% of complex reviews resulted in an overpayment
- 9.1% = percent of overpayments appealed (compared to 22.5% for all RACs)
- 54.1% = percent of appealed claims overturned (34% for all RACs)
- 9.9% = percent of overturned overpayments
- 4.9% = overall percent of overpayment determinations overturned on appeal
- 9% = their contingency fee in Colorado!

Demonstration Ramp Up

![Bar chart showing overpayments collected by quarter, claim/RACs only.](chart.png)

Source: NHIC, invoice files and RAC Data Warehouse.
Average Value of Overpayment

Table 11: Average Overpayment Amounts: Cumulative Through 3/27/08, Claim RAC Only

<table>
<thead>
<tr>
<th>Type of Provider</th>
<th>Average Overpayment Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Per Claim</td>
</tr>
<tr>
<td>Inpatient hospital</td>
<td>$14,122</td>
</tr>
<tr>
<td>Physician</td>
<td>$772</td>
</tr>
<tr>
<td>Ambulatory Lab/Other</td>
<td>$100</td>
</tr>
<tr>
<td>Outpatient equipment</td>
<td>$174</td>
</tr>
</tbody>
</table>

*Average overpayment amount per claim based on number of overpayments collected from 10/1/07 to 3/27/08, where the collection amount was greater than $0.
Source: Derived by the HHSa.

The Good News

- Medical record request limits
- 3-year look back (no earlier than 10/1/07)
- New Issue Review process
- RAC cannot collect overpayment on claims appealed through first two levels (FI and QIC)
- RAC must repay any amount overturned on appeal

Compliance

- Review and address issues identified in the Demonstration
  - Ensure the company has a good process for documenting the medical necessity of inpatient admissions
- Response and Prevention during the RAC audits
- Provide guidance on appeals
HIM Department

- Centralize RAC record production
- Timely production (45 days)
- Review responses for completeness
  - Additional staff needed?
- Scan requests and all documents sent
- Consider document management software to track and manage RAC appeals

Finance/Revenue Cycle

- Should you establish a reserve?
- Management of RAC denials
  - Expertise lies in reworking and resubmitting claims, not necessarily appeals
  - Volume of high dollar claims
  - Involvement of clinical expertise (treating provider or physician consultant)
  - Assistance in drafting appeals
  - Appeals strategy

Appeals Process

- 1st level to FI within 120 days
  - 30 days to avoid recoupment
- 2nd level to QIC within 180 days
  - 60 days to avoid recoupment
  - Last opportunity to submit documents
- 3rd level to ALJ within 60 days
- 4th level to Departmental Appeals Board
- 5th level to federal district court
Law Department

- Provide guidance on appeal process
- Review appeals of high dollar claims
- Manage all appeals to second level and above

Final Puzzle Pieces

- Will CMS waive the timely filing limits?
- Clarification of medical record request numbers
- Resolution of the bid protest – when will the record requests start coming?
Hospitals, physicians, and other providers across the country will be introduced in 2009 to the new Medicare contingency-fee contractors. The national rollout of the Recovery Audit Contractor (RAC) program has been delayed, but RAC contractors will be unleashed on providers when a bid protest is resolved in February.

Recovery audit contractors will earn a contingency fee of between 9 percent and 12.5 percent for identifying improper Medicare payments. To nobody’s surprise, the vast majority of improper payments will be overpayments recouped from providers.

To mitigate audit-related risk, providers need to look at their processes and make changes now.

RAC Demonstration Offers Insights Into Permanent Program

As rollout of the RAC program approaches, providers are essentially studying for an open-book test. Looking at the results of a three-year demonstration of improper Medicare payment offers insights into questions that will be on that test.

Medicare’s national payment error rate in 2003 was 9.8 percent. Given this relatively high error rate, Congress gave the Centers for Medicare & Medicaid Service (CMS) authority to conduct a three-year demonstration using contractors to detect and correct improper payments in the Medicare fee-for-service program. And to incentivize contractors, Congress authorized CMS to pay them on a contingency fee basis.

From March of 2005 to March of 2008, RACs identified more than $1.03 billion in improper payments and earned a contingency fee of $187 million. The RACs first reviewed claims in New York, California and Florida. They expanded the audits in 2007 to Massachusetts, South Carolina and Arizona.

Approximately 96 percent of the improper payments identified were overpayments. Of that amount, approximately 89 percent of the overpayments were paid by hospitals. About half of the roughly 500,000 claims containing improper payments were Part A claims, and half were Part B claims. Nearly $20 million in overpayments was recovered from physicians.

Focus Will Be on Largest Claims

RACs conducted complex reviews on nearly 490,000 medical records during the demonstration. Approximately 33 percent of all the records reviewed resulted in an overpayment. The average value of an overpayment varied among the contractors from $4,000 per claim to $12,000 per claim.

As CMS noted in its June, 2008 report on the demonstration, because RACs are incentivized by a contingency fee, they start with the highest dollar claims.

During the demonstration RACs established strategies to focus on high-dollar improper payments, like inpatient hospital claims, which gave them the highest return with regard to the expense of
reviewing the claim and/or medical record. CMS anticipates permanent RACs will adopt a similar strategy at first.

**Reviews Flag Both Clear and Likely Errors**

RACs perform two types of reviews: automated and complex.

Automated reviews, which are conducted through data mining, use proprietary techniques to detect clear errors. During the demonstration, automated reviews identified, for example, entities billing for multiple units of Neulasta. Providers used to bill for one unit for each milligram, but several years ago CMS changed the definition and directed providers to bill one unit for each vial of drug delivered. More than half of the errors associated with physician claims related to excessive/multiple units.

This type of review also found multiple colonoscopies being billed on the same patient in the same day. CMS says it would never be medically necessary to perform two colonoscopies on one patient the same day.

A complex review would be undertaken if an error is likely, but a review of the medical record is required. The contractor for New York, Connolly Consulting Inc., collected $88 million in overpayments for surgical procedures performed in an inpatient setting—claiming these should have been performed in an outpatient setting.

**Permanent Program Will Limit Record Requests**

After a year of the demonstration, Congress required CMS to expand the RAC program to all states by January 1, 2010. Contractors were announced in October, and meetings were scheduled with providers. But a bid protest was filed, and the national rollout was put on hold temporarily.

The bid protest will likely be resolved in February, and record requests could reach providers as early as April.

Meanwhile, CMS has made some changes to the permanent program to address certain criticisms of the demonstration. Most significantly, CMS announced a limit to the number of records that could be requested to perform complex reviews.

For inpatient hospitals, RACs cannot within a 45-day period request more than 10 percent of the average monthly Medicare claims, not to exceed 200. For outpatient hospitals, RACs cannot within a 45-day period request more than 1 percent of the average monthly Medicare services, not to exceed 200. These limits are actually tied to national provider identifier (NPI) numbers rather than tax ID numbers, causing some providers with multiple NPIs to question how the limit will be calculated. The American Hospital Association continues to work with CMS to clarify the record limits, particularly for hospitals with multiple NPIs.

**RAC Appeals Process Involves Multiple Levels**

According to the most recent data from the RAC demonstration, providers appealed roughly 22.5 percent of all RAC-initiated overpayments and were successful on 34 percent of all appeals. This shows that, at least in the demonstration, it pays to closely scrutinize RAC-initiated overpayments and adopt a vigorous appeals strategy.

Unlike the demonstration, the permanent program will allow providers to avoid recoupment by filing timely appeals to the first and second level. And RACs will be required to refund any contingency fees related to a recoupment that is overturned at any level of appeal.
The American Hospital Association is encouraging providers to closely track appeal information and associated costs so it can report the impact of the RAC program on providers. Clearly it is in a provider’s best interest to carefully manage and track RAC appeals, particularly at the outset, since RACs will be targeting the highest dollar claims first.

The structure of the appeals process is similar to the normal appeals process for denied Medicare claims.

**First Level**

The first level of appeal is to the Medicare contractor (fiscal intermediary, carrier, MAC). It is considered a request for redetermination. There is a 15-day rebuttal period to the RAC, but it doesn’t stop the 30-day clock running on the request for redetermination.

At least in the RAC demonstration, providers found the timeline for the rebuttal period to be too short to review the denial, evaluate the case, and draft a rebuttal. Plus, they had little success in changing the result. So most providers concentrated on the first level of appeal.

In the RAC permanent program, a provider has 120 days to file a first-level appeal. However, unless an appeal is filed within 30 days, the money will be recouped. Interest will accrue if an appeal is filed within 30 days but is eventually unsuccessful. This suggests that a provider shouldn’t adopt a practice of appealing all RAC overpayments without some analysis of the merits.

**Second Level**

The second level of appeal is to a qualified independent contractor (QIC). It is considered a request for reconsideration. Providers have 180 days to appeal to this level, but again, recoupment can be avoided if the appeal is filed within 60 days. For information about QIC jurisdictions, click here.

The most significant point about this level of appeal is that it is the provider’s last opportunity to submit documents that will eventually be part of the record should it be necessary to appeal to an administrative law judge (ALJ) or beyond. Therefore, providers would be well advised to have an attorney review the documents submitted to the QIC, if an attorney has not already been involved. If a provider is unsuccessful at this level, CMS will recoup the identified overpayment with interest.

**Third Level**

The third level of appeal is to the Office of Medicare Hearings and Appeals where the case will be reviewed by an ALJ. Hearings are usually conducted by phone or video teleconference. Providers have 60 days to appeal to this level following receipt of the reconsideration decision. During the RAC demonstration, approximately 5,000 claims were appealed to this level.

**Fourth Level**

The fourth level of appeal is to the Medicare Appeals Council, otherwise referred to as the Departmental Appeals Board (DAB). Providers have 60 days to appeal to this level. During the RAC demonstration, approximately 200 claims were appealed to this level.

**Fifth Level**

The final level of appeal is to a federal district court. Providers have 60 days to appeal to this level. The amount in controversy must be at least $1,220.
Audit Preparation Must Be Joint Effort

Within hospitals and other health care entities, personnel and management in a number of areas will need to work together in preparation for RAC record requests.

Compliance staff will need to study issues identified in the RAC demonstration and implement prevention strategies. For example, medically unnecessary hospital admissions have been an area of significant recoveries by RACs. This issue has not been an area of major focus in the past by many Medicare contractors. Compliance officers need to make sure their hospitals have adequate processes in place to review and document the medical necessity of inpatient admissions.

Finance officers will need to determine whether or not to set a reserve for future recoveries from RACs. If you know the average value of an inpatient, outpatient and physician claim, you can take into account the number of medical records that can be requested—and the fact that RACs found overpayments in 33 percent of all records requested. While this is one way to estimate the future impact, it does not take into account the impact of automated reviews. In any event, any actual recovery by a RAC is likely to be too speculative at this point to justify a reserve. Perhaps by the end of 2009 the picture will be clearer, and a reserve would be prudent.

Health information management departments need to be prepared to respond in a timely manner to medical record requests from RACs. Each request should be reviewed for completeness before it is produced to the RAC. All communication with the RAC, as well as documents produced, should be scanned and preserved so that they can be quickly reviewed when a denial is received. Tracking and preserving RAC-related records may require special software.

Revenue cycle management departments may be the central clearinghouse for RAC denials. They routinely receive and respond to denials from all third party payers. What is unique about RAC denials is that they will likely involve medical judgment, and the value of a claim denied by a RAC will be much higher than the average claim denied by Medicare. Is your RCM department able to request a redetermination from the fiscal intermediary, carrier or MAC? Who will review certain types of denials? Will outside experts be necessary? Should your RCM department obtain legal review on at least second level appeals and beyond?

Conclusion

Although some providers are tired of hearing about the impending RAC, it looks like, in 2009, they really are coming. And it’s time to get prepared.

If there is a bright side to these audits, it is that their focus and process is no mystery. The demonstration highlights areas where providers would do best to identify and mitigate RAC-related risk before they receive record requests.

To ensure their businesses do well when this test comes, providers need to be ready to submit records, review denials and submit appeals in a timely manner. Collaboration among a number of departments will be necessary. If internal resources are not sufficient for some of the required tasks, entities may wish to consider adding or developing personnel or engaging outside assistance.
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Practices
ERISA Litigation
Insurance Coverage

Education
Indiana University School of Law
J.D., Law Review (1971)
Dartmouth College
A.B., with distinction (1968)

Bar Admissions
Colorado
Indiana
Nebraska

Court Admissions
U.S. Court of Appeals for the Eighth Circuit
U.S. Court of Appeals for the Tenth Circuit
U.S. District Court for the District of Arizona
U.S. District Court for the District of Colorado
U.S. District Court for the District of Nebraska
U.S. Supreme Court
U.S. Tax Court

Experience

Dirk W. de Roos is a partner in Faegre & Benson’s Denver office. For three decades, he has represented employers in employment and employee benefit litigation. In state and federal court at the trial and appellate levels, Dirk has extensive courtroom experience, usually defending claims under Title VII, the ADEA, the ADA, federal and state civil rights and pay statutes, and ERISA.

Some matters representative of his litigation and trial work include the following:

- Successfully defended employer against claimed violations of the ADA by a terminated employee with sleep apnea.
- Defended, and settled through mediation, two related multi-plaintiff cases alleging violations of Title VII, ADEA, and the Pregnancy Discrimination Act.
- Obtained summary judgment for employer in case involving ADA and FMLA claims by a terminated employee with a heart ailment.
- Won summary judgment for an employer against claims for $5,000,000 arising from alleged wrongful termination and denial of medical benefits coverage.
- Obtained summary judgment for insurance company client in bad faith action arising under E&O policy in claim by insured’s former employee (with HIV) that his termination and subsequent loss of medical benefits was based upon an administrative error.
- Represent non-profit Board in six related pending cases seeking to enforce rights under E&O policy against negligent medical insurance plan administrator retained by the Board.

Some matters representative of his ERISA litigation practice include the following:

- Obtained summary judgment on breach of fiduciary duty claims for the pension plan, fiduciary and administrator of a Fortune 50 company in three related cases
- Defeated a putative class and obtained dismissal on a Motion to Dismiss for a large western United States employer in a matter alleging partial
Presentations

Dirk is a frequent speaker on a variety of insurance, litigation and related topics for organizations such as the Colorado Bar Association, the Denver County Bar Association, the National Center for Continuing Legal Education, the Federation of Defense and Corporate Counsel and the American Bankruptcy Institute. Presentations on insurance topics include the following:

- **Enforcing or Invalidating Class Arbitration Waivers**
  Legal Trends and Best Practices in Class Arbitration, Colorado Bar Association CLE (2008)

- **Current Issues: Insurance Problems in Litigation and Bankruptcy**
  X/S Surplus Lines Association Annual Convention, Naples, FL

- **Economic Crime, Insurance and Civil Recovery Under the American System**

- **Insurance Insolvency Issues**
  American Bankruptcy Institution, Winter Leadership Conference, Phoenix, AZ

Trade Organizations

- American Arbitration Association
- American Bankruptcy Institute
- Association of American Business and Insurance Attorneys
- Federation of Defense and Corporate Counsel
- International Asset Recovery Team
- Society of Insurance Receivers
- The Defense Research Institute

Professional Recognition

- **Super Lawyers**, Civil Litigation Defense, 2007; Employment Litigation,
2006
- American Bankruptcy Institute Distinguished Service Award
- Outstanding Lawyers of America, since 2003
- Best of the Bar, nominated for Insurance Law, 2004

Publications
- **Three New Laws Aim to "Rein in Health Insurance"**
  Faegre.com (2008)
- **Further Regulation Not the Answer to Mortgage Problem**
  *The Denver Post* (2008)
- **Weathering the Economic Downturn Successfully**
- **Current Issues in Insurance Law**
- **Insurance Defense Strategies**
  Successfully Defending Insurance Litigation, Aspatore Books (2007)
- **"Looking Down a Rocky Road", Winning Legal Strategies for Insurance Law**
- **Risk Management/Managing ERISA Risks; Some Thoughts on Limiting Liability**
  TRENDS (2006)
- **Insurance and Tort Desk Reference Handbook**
  *Couch on Insurance*
- **Advertising Injury**
  *Insurance and Liability Reporter*
- **The Dangers of Conventional Wisdom**
  Excess/Surplus Lines Claims Association
- **Editorial Board**
  *Insurance and Liability Reporter*
- **Editorial Board**
  *Municipal Liability Reporter*
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Practices  
Health Care Regulatory  
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Health Care Transactions

Industries  
Health Care  
Medical Technology  
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Education  
University of Houston Law Center  
J.D., cum laude (1995)  
University of Colorado, Boulder  

Bar Admissions  
Colorado  
Texas

Court Admissions  
U.S. District Court for the Western District of Texas

Experience

Faddick joined Faegre & Benson in 2001, following more than five years of health law practice in Texas. Colleen's practice includes advising clients regarding the structure of hospital, physician and other health care relationships with the special federal and state regulatory environment, fraud and abuse and self-referral law issues, Medicare and Medicaid reimbursement issues and appeals, managed care contracting and certification, compliance plans and physician contracting.

Examples of Colleen's health care experience include:

- Advising medical device manufacturers and suppliers in sales and marketing operations, relationships with referral sources, product pricing
- Representing medical device manufacturers and other healthcare providers in connection with criminal and civil investigations under federal fraud and abuse laws and regulations
- Assisting various health care provider entities and medical device manufacturers and suppliers in development and implementation of corporation compliance plans including plan design, risk assessments, internal reviews, self-audits, voluntary disclosures and repayments to governmental and private health programs
- Advising health care providers with respect to Medicare reimbursement issues (Parts A and B) and Medicaid reimbursement
- Advising various health care provider entities and physician groups in structuring business arrangements and physician compensation in conformity with fraud and abuse laws
- Representing various hospitals in the Medicare reimbursement appeals before the Provider Reimbursement Review Board (PRRB) and federal courts
- Advising health care providers regarding the maintenance of electronic medical records and privacy of health information under HIPAA
- Colleen is a frequent speaker to national audiences on topics including compliance issues for medical device manufacturers, structuring relationships between health care providers under the Anti-Kickback Statute and the Stark Law, and Medicare billing and reimbursement issues.
Trade Organizations

- American Health Lawyers Association
- American Bar Association
- Health Care Compliance Association
- Texas Bar Association
- Healthcare Financial Management Association, Colorado Chapter

Professional Recognition

- Outstanding Young Healthcare Lawyers, Nightingale's Healthcare News (2005)

Publications

- Colleen has authored and contributed to numerous articles and book chapters regarding health care fraud and abuse and reimbursement matters.
Practices
Health Care Litigation
Health Care Regulatory
Compliance and Reimbursement
Health Care Transactions
White Collar Criminal

Industries
Health Care
Medical Technology

Education
Notre Dame Law School
J.D., magna cum laude (1997)

University of Colorado, Boulder
B.A., Phi Beta Kappa (1993)

Bar Admissions
Colorado
District of Columbia

Experience
Jeffrey Fitzgerald joined Faegre & Benson as an associate in 2003, following more than five years of health law practice in Washington, D.C. Jeffrey's practice includes representing clients with respect to fraud and abuse, Medicare reimbursement, compliance, and other regulatory issues, including:

- Representing hospitals, physicians and other healthcare providers in federal False Claims Act investigations and litigation
- Conducting internal investigations in response to allegations of fraud or other non-compliance with state or federal healthcare laws
- Preparing voluntary refunds of overpayments and the disclosure of non-compliance
- Advising health care entities in development and implementation of corporate compliance plans including plan design, risk assessments, internal reviews, self-audits, voluntary disclosures and repayments to governmental and private health programs
- Advising health care providers with respect to Medicare reimbursement issues (Parts A and B) and Medicaid reimbursement
- Advising clients with respect to structuring financial relationships under the fraud and abuse and self-referral laws

Media Mentions
- Quoted in "Compliance Officer Is Accused of Second Contracting Scam; Feds Seek to Revoke Bail"
  *Report on Medicare Compliance* (October, 2008)

Presentations
- **E.M.T.A.L.A. & You**
  Exempla Good Samaritan Medical Center (2008)
- **Outside-the-Box Compliance Initiatives**
  HCCA's 12th Annual Compliance Institute (2008)
- **Case Study: Compliance Investigations and Settlement Agreements**
  HFMA Colorado Chapter, Compliance/Law Conference (2008)
- **Reevaluating and Developing the Company’s Compliance Program in Light of New Rules and Laws**
  State False Claims Summit (2007)
- Re-Energizing Your Compliance Program: Preserving the Strength of Fraud Avoidance
  American Urological Association Practice Management Conference (2007)
- HIPAA Civil Enforcement Update
  HCCA Mountain Local Annual Conference (2006)
- Strategies for Resolving Billing Mistakes or Alleged Misconduct
- Protecting Your Practice Against Embezzlement
- Responding to a Fraud and Abuse Investigation
- Representing Health Care Providers in Civil and Administrative Fraud and Abuse Matters

Publications

- What CMS Gives, the Courts Take Away: Patients in Ambulances and EMTALA
  HCCA Compliance Today (2008)
- Implications of Stark Rule Changes and Proposals for Integrated Delivery Systems
  Faegre.com (2008)
- Companies Cannot Be Put In Jail, But They Can Be Executed
  TRENDS (2007)
- Medicare Exclusion and Health Care Employers
  HCCA Compliance Today (2006)
- Employer Beware: Hidden Risks of Medicare-Excluded Workers
- Importing Drugs from Canada is more Mirage than Miracle
- Fixing Past Mistakes
  MGMA Connexion (2003)
- A Guide to Employee Interview Techniques for Healthcare Organizations in a Fraud Investigation (co-author)
  Healthcare Fraud and Abuse Newsletter (2000)
- Employee Interview Techniques for Healthcare Organizations Responding to a Fraud Investigation
  The Health Lawyer (1999)
- Health Care Providers Encounter the Civil False Claims Act
  The Colorado Lawyer (1999)
- Key Issues in Defending Civil Investigative Demands under the False Claims Act (co-author)
  A National Initiative and the Civil False Claims Act and Qui Tam Enforcement (1998)
- Curbing False Claims Act Abuse (co-author)
Experience

Bruce brings both legal and management perspectives to health care-related legal issues. Bruce’s extensive experience as a health care attorney and consultant includes providing representation and services to medical groups, hospitals, academic practice plans and other health care enterprises in a variety of operational, regulatory and transactional matters. Bruce has extensive experience in the application of the Stark self-referral prohibition, Medicare and Medicaid fraud and abuse, tax-exempt organizations, antitrust, and other legal issues to health care business transactions.

Examples of Bruce’s health care related experience include:

- Providing representation regarding the application of the Federal physician self-referral or “Stark” law to health care business transactions and relationships
- Assisting medical groups and other health care organizations in regulatory compliance activities
- Advising tax-exempt organizations including hospitals and academic practices regarding physician/hospital collaborative strategies including joint ventures
- Facilitating the planning, development and implementation of group practice formation and practice mergers
- Assisting with the establishment and on-going operation of physician and hospital-affiliated organizations, including integrated delivery systems, group practices and similar enterprises
- Assisting medical groups and hospitals with the development and implementation of physician compensation strategies, practice transition and other arrangements
- Assisting tax-exempt organizations in assessing the reasonableness and fair market value of physician compensation levels to promote compliance with exempt organizations and other laws

Bruce Johnson is the originator and site manager for the Medical Group Management Association’s StarkCompliance Solutions product and Web site. He has authored and contributed to numerous books and articles, and serves as a regular faculty member on many national education programs.

Presentations
I want to reduce my call and time in practice...and I don't want my
income to drop!"
MGMA 2005 Midwest-Western Sections and Nevada MGMA Conference, Reno NV (2005)

- Federal Limitations on Physician Recruitment
  Medical Group Management Association Audio Conference and Webcast (2005)

- Economic Credentialing and Selective Contracting: Current Legal Issues
  MGMA Annual Conference, Nashville, TN (2005)

- Physician Compensation in 2005 and Beyond: Issues and Trends

- Strategic Integration—Crafting a Winning Model for Hospitals and Physicians

- Collaboration with Local Hospitals: Legal Issues and Ancillary Service Strategies
  MGMA Annual Conference, Nashville, TN (2005)

- Physician Compensation: State of the Art and State of the Mind
  MGMA Annual Conference, San Francisco, CA (2005)

- Whole Practice Productivity
  Louisiana MGMA Annual Conference, Bilouxi, MS (2005)

- Whole Practice Productivity
  Kansas MGMA Annual Conference, Wichita, KS (2005)

- Mastering Physician Compensation
  Colorado Bar Association (2005)

- Stark and Other Legal Compliance Issues for Academic OB/GYN Practices
  Association of Managers in Gynecology and Obstetrics Annual Meeting, Chaleston, SC (2005)

- Stark and Other Laws: Understanding the Opportunities, Issues and Risks with Ancillary Services
  American Urological Association, Anaheim, CA (2005)

- Ancillary Services and the Law: Understanding the Opportunities, Issues and Risks
  AUA Annual Conference, San Antonio, TX (2005)

- Physician Recruitment and the Law: Issues and Options
  Physician Recruiting Expo, Orlando, FL (2005)

- Stark Law Compliance Implications for OB/GYN Practices
  MGMA OB/GYN Assembly Annual Conference, San Diego, CA (2005)

- New Opportunities for Private and Academic Practice: Business and Legal Considerations
  American Academy of Neurology, 57th Annual Meeting, Miami, FL (2005)

- Succession Planning for OB/GYN Practices

- Physician Compensation Models for OB/GYN Practices

- Stark II Final Regulations
  Minnesota Hospital Association (2004)

- Compensation and Compliance: What Does the Financial Manager
Need to Know?
MGMA, Las Vegas, NV (2004)

- Enhancing Practice Income Through Ancillary Services: Business and Legal Considerations
- New Business Ventures in Urology: Business and Legal Considerations
- Physician Compensation: State of the Art and State of the Mind (with Deborah Walker, MBA, FACMPE)
  MGMA Annual Conference (2004)
- Regulations and Marketing—Understanding the Full Impact of Stark II, Phase II
  Physician Practice Annual Hospital Users Meeting (2004)
- Stark II, Phase II—Implications for Hospital-Physician Relationships
  Health Care Compliance Association (2004)
- Medical Group Revenue Enhancement Strategies: Business and Legal Considerations
  MGMA Eastern/Southern Section Conference (2004)
- Medical Group Revenue Enhancement Strategies: Business and Legal Considerations
  MGMA Western/Midwestern Section Conference (2004)
- Stark II, Phase II—What Does It Mean for Your Practice?
  Louisiana MGMA Conference (2004)
- Compensation and Compliance: What Does the Practice Manager Need to Know?
  Louisiana MGMA Conference (2004)
  MGMA Audio Conference (2004)
  MGMA Legislative Conference (2004)
- "Better Performing" Physician Compensation Plans
- Physician Practice Transitions
- Stark II, Phase II—A Briefing
  Faegre & Benson Seminar (2004)
- Structuring Hospital/Physician Relationships Under the Stark Law
  HFMA Colorado Presentation, Denver, CO (2004)
- Structuring Hospital/Physician Relationships Under Stark Law
  Health Care Financial Management (HFMA) Western Region (2004)
- Mastering Physician Compensation
  ALI/ABA Conference, Snowmass (2004)
- Current Regulatory Issues for Physicians: Revenue Diversification and Related Opportunities (with Gerald Niederman)
  Colorado MGMA 2003 Fall Conference (2003)
- Business and Legal Considerations in Group Practice Ancillary
Service Development

- Developing New Services in Medical Groups: Business and Legal Considerations (with Darrell Schryver, DPA)
- Legal Issues in Hospital/Physician Compensation Arrangements
  Strategic Research Institute, Education Program (2003)
- Keeping Your Job: Maximizing Physician Compensation
  MGMA Western/Midwestern Section Conference (2003)
- Medical Group Revenue Diversification Strategies
  Missouri MGMA Annual Conference (2003)
- Physician Compensation Models: Is There a "Better Performing" Compensation Plan?
  Missouri MGMA Annual Conference (2003)

Whole Practice Productivity

- Stark, Medicare and OIG Updates
  BONES Annual Conference (2003)
- Developing a Better Performing Physician Compensation Plan, presented with Deborah Walker, MBA
  MGMA Audioconference (2002)
- Whole Practice Productivity, presented with Deborah Walker, MBA
- Developing and Implementing a "Fair" Compensation Plan, presented with Suzette Jaskie, MBA

Stark Law
VHA Audio Conference (2002)

- Physician Compensation—How to Do it Well and Legally (with Deborah Walker, MBA, FACMPE)
  Audioconference Physicians Practice, Inc. (2002)
- Better Performing Compensation Plans and Benchmarking
- Enhancing the Bottom Line in 2002 and Beyond: Business Issues and Alternatives
  American College of Health Care Executives, CO Chapter and University of Colorado Health Administration Alumni Association Joint Meeting, Denver, CO (2002)

Stark Law Final Rule

- Moderator, "Stark Law and Final Rule Panel Discussion"

Stark II: How to Comply
HcPro Audioconference (2002)

Legal Issues and Physician Compensation
Management Education and Development (MED Program), Southwest Missouri State University, Springfield, MO (2001)
  Medical Group Management Association Annual Conference, San Antonio, TX (2001)
- Maximizing Physician Productivity (with Deborah Walker)
  Medical Group Management Association Annual Conference, San Antonio, TX (2001)
- Stark II Final Rule
  MGMA Center for Education Audio Conference (2001)
- Benchmarking for Success in Academic Practices
  Academic Practice Assembly/Group on Faculty Practice, Arlington, VA (2001)
- Better Performing Physician Compensation Plans
  MGMA Center for Education Audio Conference (2001)
- Better Performing Physician Compensation Plans
  MGMA Annual Conference (2001)
- A Prescription for Healthy Physician Relationships: Valuation, Documentation and Compliance Issues in Physician Compensation Arrangements
- Better Performing Compensation Plans and Benchmarking
  MGMA Annual Conference, Atlanta, GA (2000)
- Physician Compensation in Urology Practices
  UAA (Urology) Annual Conference, Kansas City, MO (2000)
- Physician Retirement Strategies
  UAA (Urology) Annual Conference, Kansas City, MO (2000)
- Issues and Trends in Physician Compensation
  AOHA (Oncology) Annual Meeting, Seattle, WA (2000)

Trade Organizations
- Medical Group Management Association Health Care Consulting Group
- American Health Lawyers Association

Professional Recognition
- The Best Lawyers in America, Health Care Law, 2009
- Super Lawyers, Health Care, 2006–2008

Publications
- 2009 Final Physician Fee Schedule Makes More Changes Directed at Diagnostic Tests
  Faegre.com (2008)
- Using Quality-Focused Networks to Align Hospital and Medical Staff Relationships
  Faegre.com (2008)
- Perspectives on Integrated Delivery System Legal and Organizational Structure
  Faegre.com (2008)
- "On-Call" Obligations and Mid-Level Providers: Balancing Business Goals With EMTLA Compliance Concerns
  Faegre.com (2008)
CMS Poised to Move Beyond Stark With Additional Proposals Directed at Diagnostic Tests
Faegre.com (2008)

Stark Rules Change—Again
Faegre.com (2008)

Integrated Delivery System Structural Options: One Size Doesn’t Fit All
MGMA Connexion (2008)

Physician Compensation Plans—State-of-the-Art Strategies, with Deborah Walker Keegan, PhD, FACMPE
Medical Group Management Association (2006)

Medical Practice and Compensation Plans
Chapter in “Physician Practice Management” (2005)

Federal and State Regulations

Corporate Compliance in a Medical Practice Setting

Building Practice Revenue—A Guide to Developing New Services, with Darrell L. Schryver, D.P.A. and Daniel Stech, MBA
Medical Group Management Association (2003)

Stark Compliance Solutions
www.starkcompliance.com (2001)

Managed Care Contract Negotiations
Chapter in the American College of Physicians’ “The Practice Environment” Book Series

Managed Care Contracting, with Darrell L. Schryver, D.P.A.
Medical Group Management Association (1994)

New Medicare Rules Will Impact Many Common Diagnostic Service Arrangements
Faegre & Benson (2007)

2007 Physician Fee Schedule Proposals Would have Implications for Diagnostic Testing Services
Faegre & Benson (2006)

Perspectives On What Is A "True" Group Practice
Faegre & Benson (2006)

Making Sense of New Legal Guidance on Ancillary Services
MGMA Connexion (2005)

Stark II, Phase II—What it Means for Physician Compensation
MGMA Connexion (2004)

Stark II, Phase II: Implications for Health Care Providers
Faegre & Benson (2004)

Steering Clear of IRS Intermediate Sanctions Violations
Faegre & Benson (2003)

Specialty Hospitals Under Fire
Faegre & Benson (2003)

HealthSouth in Transition: A Quick Guide for Assessment and Action
Faegre & Benson (2003)

Practice Buy-in, Buy-out and Transition—Keys to Success
- Trends in Physician Compensation: Specialist Physician Growth Coupled with Primary Care Stagnation
  Hospital Physician (2003)
- Clean Dealing: Legal Considerations for Buy/Sell Agreements
  MGMA Connexion (2002)
- Can your group pass the Stark law test?
- Expanding Beyond Professional Service Revenues—Experiences, Regulatory Issues and Lessons Learned. Co-authored with Gerald Niederman
- Revenue Stream Diversification: A Legal Overview for Medical Groups, Hospitals and Other Health Care Providers
  Faegre & Benson (2002)
- Trends in Physician Compensation Among MGMA Member Practices: Compensation Growth Trend Slows Slightly
  Hospital Physician (2002)
- Test Your Knowledge of the Physician Self-Referral Law
  MGMA Connexion (2001)
- Stark Reality: What Services Are and Are Not Covered by the Self-Referral Law
  MGMA Connexion (2001)
- Trends in Physician Compensation: Growth in Work Continues to Outpace Increases in Compensation
  Hospital Physician (2001)
- In Search of the 'Better Performing' Compensation Plan
- Physician Compensation: 12 Areas to Consider
  Medical Group Management Update (MGMA) (2000)
- Legal Issues Update
  Chapter in Integrated Health Care: Lessons Learned (1999)
- Physician-Hospital Gainsharing—Is it Gone Today and Here Tomorrow? (with Gerald Niederman)
  Medical Group Management Update (MGMA) (1999)
- How to Build a Specialty MSO (with Bette Waddington)
  Medical Group Management Journal (1998)
- New Stark Regulations: Key issues for health care decision-makers (with Gerald Niederman, Laury Bowman and Ann McCullough)
  Medical Group Management Journal (1998)
- Resolving Distressed IDS-Physician Marriages
- Proposed Stark II Regulations Can Only Go So Far in Remedy a Bad Law (commentary with Gerald Niederman, Laury Bowman and Ann McCullough)
  Medical Group Management Update (MGMA) (1998)
- Creating a Pediatric Health Care Alliance (with Lane France, MD)
  Medical Group Management Update (MGMA) (1998)
- Converting New Antitrust Guidance into Action
Medical Group Management Journal (1997)
- Handbook on Direct Contracting
  MGMA Office of State Government Relations (1996)
- Summary of Managed Care Laws - Focusing on any Willing Provider, Due Process, Freedom of Choice, Patient Protection Acts, Maternity Length of Stay, Prohibitions on Gag Clauses, Consumer Protection and Direct Access Laws (co-authored)
  MGMA Office of State Government Relations (1996)
- Managed Care Legal Issues: A Practical Guide for Health Care Decision-Makers, with Gerald Niederman, Esq.
  Medical Group Management Association (1996)
- Healthcare Trends—Trends in Managed Care Legislation
  Journal of Health Information Management Association (1996)
- Trends Emerging on Direct Contracting Regulation
  MGM Update (1996)
- Any Willing Provider Debate Shifts to Judicial Forum
  MGM Update (1996)
- Patient Protection—Type Provisions Popular in States
  MGM Update (1996)
- Is Antitrust Relief for Health Care on the Horizon?
  MGM Update (1996)
- Who’s Watching the Utilization Review Organizations?
  MGM Update (1996)
- Sorting Out the Confusion About Direct Contracting
  MGM Update (1996)
- States Continue to Focus on Certificate of Need
  MGM Update (1996)
- Integration from the Small Group Perspective (with Darrell L. Schryver, DPA)
  Healthcare Financial Management (1996)
- Foundational Keys to Developing Successful Alliances
  Orthopaedic Insight (1995)
- Summary of State Managed Care Legislation—Focusing on Any Willing Provider, Freedom of Choice and Due Process Provisions
  MGMA Office of State Government Relations (1995)
- Scrutiny of Integration Increases
  MGM Update (1995)
- Tort Reform Progress Report Indicates Action in Many State Legislatures During 1995 Sessions
  MGM Update (1995)
- State Managed Care Legislation Marches On
  MGM Update (1995)
- Travelers Decision May Refocus ERISA Options
  MGM Update (1995)
- Proliferation of Integrated Delivery Systems Could Spawn More State Regulation and Oversight
  MGM Update (1995)
- State Action Attempts to Calm Antitrust Storm
  MGM Update (1995)
- Medical Savings Accounts
MGM Update (1995)
- Tort Reform—A Roadmap
  MGM Update (1995)
- State Reform Efforts May Hinge on ERISA Waivers
  MGM Update (1995)
- Integrated Delivery System Legal Issues
- Positioning for Integration Through Clinics Without Walls (with Darrell L. Schryver)
  Medical Group Management Journal (1994)
- Integrated Provider Networks—A Primer (with Gerald Niederman)
  Medical Group Management Journal (1994)
- Provider Integration in Colorado—A Primer (with Gerald Niederman)
  Colorado Medicine (1994)
- Budget Bill Expands Stark Referral Ban (with Kelly L. Phillips)
  Minnesota Physician, Vol. VII, No. 8
- Clinics Without Walls: From Concept to Reality (with Darrell L. Schryver and Gerald A. Niederman)
- Establishing a Group Practice 'Without Walls' (with Darrell L. Schryver and Gerald A. Niederman)
- The Corporate Practice of Medicine: A Trap for the Unwary
  The Colorado Lawyer (1991)
- The Cause, Incidence and Transmission of AIDS
Steve Lokensgard is a member of the Faegre & Benson health care and nonprofit organization practice. As a former assistant attorney general and the chief compliance officer for a large regional health care system, Steve has extensive experience with identifying and managing regulatory and financial risk. He assists health care clients with a variety of claims appeals and compliance matters, including preparation for and response to Medicare Recovery Audit Contractor audits.

Steve also provides counsel on issues related to transactions, fraud and abuse enforcement, privacy, billing and reimbursement, and general health law.

His experience includes:

- Drafting and revising policies to address compliance, privacy and security matters
- Advising on nonprofit/tax exemption issues
- Performing legal compliance reviews
- Advising on claims audits and overpayment issues
- Interpreting Medicare and Medicaid participation, coverage and reimbursement criteria
- Providing counsel concerning statutory fraud and abuse enforcement
- Advising on health care entity transactions, including acquisitions, mergers and entity formation

Presentations

- Compliance Update: Tools for Quarterly Board Reporting
  HCPro Webiner (2009)
- Getting it Right the First Time—Documentation of Medical Necessity for Short Stay Patients
  National Medicare RAC Summit (2009)
- Compliance Hot Topics
  Panel Discussion, Health Care Compliance Association Upper Midwest Annual Conference (2008)
- Preparing for Compliance Awareness Week
  Society of Corporate Compliance and Ethics (2008)
- Community Benefit and Nonprofit Hospitals: New Developments in Enforcement

- **Tax Exemption Challenge**
  Health Care Compliance Association Annual Compliance Institute (2006)

- **A New Standard for Collection Practices and Pricing for the Uninsured**
  Association for Community Health Improvement Annual Conference (2006)

**Civic Associations**

- Minnesota Army National Guard, staff judge advocate (1994-present)

Examples of Ann's health care experience include:

- Drafting and negotiating a variety of health care contracts, joint ventures and acquisitions involving compliance with laws governing physician self-referrals (commonly referred to as the “Stark” law) and anti-kickback safe harbors
- Advising health care organizations regarding medical staff credentialing, peer review, antitrust and other provider relationship matters
- Advising nonprofit tax-exempt health care organizations regarding IRS constraints on joint ventures, physician recruitment, physician practice acquisitions, physician compensation and other private inurement and intermediate sanctions matters
- Advising and representing hospitals and their medical staffs in anti-patient dumping matters, known as “EMTALA”
- Advising health care organizations, employers and other entities concerning privacy of health information, including the federal privacy law known as “HIPAA”
- Development and operation of integrated specialty and multi-specialty provider networks, including antitrust counseling
- Advising health care facilities and individual providers on licensure matters
- Preparing corporate governance documents, policies and procedures for the implementation and ongoing operation of health care organizations
- Advising health care entities on regulatory compliance activities, including policy development, auditing, and internal investigations
- Advising health care providers on reimbursement matters, including Medicare and Medicaid reimbursement, managed care contracting and
compensation strategies

- Advising health care providers on legal issues concerning informed consent, refusal of treatment, right to die, patient confidentiality and other patient care related matters

Trade Organizations

- American Health Lawyers Association
- Colorado Bar Association Health Law Council
- Health Care Compliance Association

Professional Recognition

- The Best Lawyers in America, Health Care Law, 2009
- Outstanding Hospital Lawyer, Nightingale's Healthcare News, 2008
- Super Lawyers, Health Care, 2006-2008

Publications

- "On-Call" Obligations and Mid-Level Providers: Balancing Business Goals With EMTLA Compliance Concerns
  Faegre.com (2008)
Gerald A. Niederman
Partner

GNiederman@faegre.com
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3200 Wells Fargo Center
1700 Lincoln Street
Denver, CO 80203-4532

Experience

A partner at Faegre & Benson, Gerry represents health care organizations and related nonprofit entities in Colorado and throughout the United States. His clients include facilities, practitioner groups, and related businesses, as well as trade associations and other enterprises serving the health care industry. He is a frequent author and speaker on a variety of contemporary health care issues.

Gerry offers clients a detailed understanding of legal and business variables involving the delivery and reimbursement of health care services. He has extensive experience working in the managed care field, developing integrated networks, and helping hospitals and physicians build and sustain innovative business arrangements. He is actively engaged in addressing challenges and opportunities related to health care reform initiatives.

Gerry's practice includes transactional and regulatory work on behalf of numerous traditional and emerging clients in the health care arena. Key projects include the following matters:

- Service as general counsel for the Medical Group Management Association, the nation's largest professional association for physician practice administration
- Service as general counsel for the Colorado Ambulatory Surgery Center Association
- Representation of other national and regional health care trade associations
- Developing numerous single and multi-specialty ambulatory surgical centers, and providing ongoing compliance and operational counsel for various ASCs
- Establishment of a physician-owned acute care hospital
- The successful defense of a state antitrust investigation of a physician group
- Obtaining a favorable FTC Advisory Opinion on antitrust compliance and provider information exchanges
- Negotiation of various managed care contracts involving hospitals, physician groups and other providers, and providing counsel related to out-of-network contracting strategies
- The successful prosecution of a multi-million dollar appeal to the DHHS
Gerry frequently confronts complex regulatory and related business issues including antitrust, exempt organization, Medicare/Medicaid fraud and abuse, and Stark Law self-referral considerations. In addition, his representation of acute care and ambulatory health care facilities, as well as ancillary service providers, involves numerous third-party reimbursement, insurance law, licensure, contracting and related matters on an ongoing basis.

Presentations

- **Update on Legal Issues Affecting ASCs**
- **Fiduciary Responsibilities and Board Members: What State Associations Need to Know**
  MGMA State Leaders Conference (2008)
- **Deemed Status and ASC Licensure: Background and Issues**
  CASCA Accreditation Roundtables (2007)
- **Current Antitrust Issues for Physician Groups**
  Medical Group Management Association Annual Conference (2006)
- **Stark Law and Related Regulatory Issues in Physician Imaging**
- **Strategies for Improving ASC/Insurer Relationships**
- **Selective Contracting and ASCs: Legal and Strategic Issues at the State Level**
- **Selective Contracting and ASCs: Current Legal Considerations**
- **Selective Contracting and ASCs: A View from the Trenches**
  Federated Ambulatory Surgery Association 2006 Legislative and Compliance Seminar (2006)
- **Economic Credentialing and Selective Contracting: Current Legal Issues**
  Medical Group Management Association Annual Conference (2005)
- **Revenue Diversification Issues and the ASC Platform**
Colorado Ambulatory Surgery Center Association (2005)
- Current Regulatory Issues for Physicians: Revenue Diversification and Related Opportunities
  Colorado MGMA 2003 Fall Conference (2003)
- Stark, Medicare and OIG Updates
- Legal Issues that Impact the Practice of Allergy
  60th Anniversary Meeting of the American Academy of Allergy, Asthma & Immunology (2003)
- The HIPAA Privacy Rules and Integrated Delivery Systems
  The Privacy Work Group of The Colorado Health and Hospital Association (2002)
- A Practical Guide to HIPAA Privacy Law: General Principles and Compliance
  Association of Community Radiation Recovery Centers (2001)
- Legal Issues in Technology for Physician Group Practices
  Medical Group Management Association Annual Meeting (2001)
- Current Compliance Issues: Fraud and Abuse and Privacy
  Montana Medical Group Practice Association Annual Conference (2001)
- The Health Insurance Portability and Accountability Act
  Faegre & Benson LLP Privacy Seminar (2001)
- Stark and Fraud and Abuse Update: So What Does a Physician Practice Do Now?
  Financial Management Society and Managed Care Assembly of the Medical Group Management Association (2001)
- Legal Issues for Physician Hospital Joint Ventures
  Medical Group Management Association Annual Conference (2000)
- The Impact of Rising Prescription Drug Costs
- Technical Issues Related to Physicians and Prescription Drug Risk
- Legal Issues on Integration: Current Developments
  Medical Group Management Association Annual Conference (1999)
- Legal Issues Related to ‘Devolution’ of Integrated Systems
  Institute for Health Care Strategies (1999)
- The New Frontier: Legal and Business Issues in Hospital-Physician Gainsharing
  Health Facilities Management Association (First Illinois Chapter) Annual Meeting (1999)
- Regulatory Update for Hospital Executives
- Current Legal Issues in Health Care Integration
  Medical Group Management Association Annual Meeting (1998)
- Fraud and Abuse Compliance Issues
  Orthopedic Assembly of the Medical Group Management Association (1998)
- Stark II Compliance Issues
Professional Recognition

- The Best Lawyers in America, Health Care Law, 2006-2009
- Super Lawyers, Health Care, 2006-2008
- Best of the Bar Award for Health Care, Denver Business Journal
- Ally Award, Women’s Vision Foundation

Civic Associations

- Colorado Coalition for the Medically Underserved, board of directors
- Colorado Lawyers Committee Health Care Reform Task Force
- Mental Health Association of Colorado, past president

Publications

- Using Quality-Focused Networks to Align Hospital and Medical Staff Relationships
  Faegre.com (2008)
- The Good, the Bad and the Ugly: New Federal Regulation of Specialty Hospitals
- The End Of The Moratorium: A SWOT Analysis for Specialty Hospital Decision-Makers
  Faegre.com (2006)
- The FTC’s Evanston Northwestern Case: A New Day for Healthcare Antitrust Enforcement (co-author)
  Faegre.com (2006)
- The Return of Gainsharing (co-author)
- Legal Issues and Community Health Information Networks (co-author)
- Understanding the Final Rule Under Stark II (co-author)
- All About ABNs
  Physician Practice Management (2004)
- Take Two-Bytes and Call Me in the Morning: The use of e-mail by health care providers
- New Legal Standards for Physician/Hospital Joint Ventures
- Scope and Effect of the Final HIPAA Privacy Regulations (co-author)
- Breaking Up is Hard to Do: Business and Legal Issues of Physician Practice Divestitures (co-author)
  Medical Group Management Association (2000 and 2001)
- Evaluation of the Legal Environment
- "Legal Issue Update" in Integrated Health Care: Lessons Learned (co-author)
  Medical Group Management Journal (MGMA) (1999)
- New Stark Regulations: Key Issues for Health Care Decision-Makers
  Medical Group Management Journal (MGMA) (1998)
- Proposed Stark II Regulations Can Only Go So Far in Remedying a Bad Law
  Medical Group Management Update (MGMA) (1998)