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Compliance 2010

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Davis Wright
Tremaine LLP

DEFINING SUCCESS TOGETHER

Compliance 2010

presented by

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This presentation is for discussion purposes only and should not be considered as legal advice with respect to specific entities or factual situations. Important changes do occur in statutes, regulations, and payment program guidelines. Consult your counsel or representative in individual situations.

Overview

- Primary Fraud and Abuse Enforcement Provisions
- 2009 -10 Fraud and Abuse Developments
- Recovery Audit Contractor Program Progress
- Physician Supervision in Outpatient Settings
- Fraud and Abuse issues for Hospital/Physician Relationships
- Goals of Hospital/Physician Delivery Systems
- Structuring Hospital/Physician Relationships in Compliance with Fraud and Abuse Concerns

Primary Fraud and Abuse Enforcement Provisions – General

- Hybrid Civil/Criminal Nature
- Same actions can result in civil enforcement and/or criminal enforcement
- Qui tam – private civil action
- Variations in standards and procedures for determinations of violations and sanctions, but either may be a “bet the farm” scenario.
- Remember state enforcement as well

Primary Fraud and Abuse Enforcement Provisions – False Claims/Billing Fraud

- By far, the greatest percentage of actions
- Billing for services not provided
- Double billing
- Improper coding/upcoding
- Bundling/unbundling
- False cost reports
- But, expansion of issues for false claims allegations

Primary Fraud and Abuse Enforcement Provisions – Retaining Overpayments/Failure to Disclose

- [A provider or beneficiary] having knowledge of the occurrence of any event affecting
- (A) his initial or continued right to any such benefit or payment, or
- (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, **conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized ...**
- [is subject to penalties]
- 42 U.S.C. Section 1320a-7b(a)(3)

Primary Fraud and Abuse Enforcement Provisions – Antikickback/Prohibited Payment for Referrals

- Corruption of medical judgment
- Increase in unnecessary medical procedures
- Discouraged competition

Primary Fraud and Abuse Enforcement Provisions – Federal Antikickback Statute

Whoever knowingly and willfully solicits or receives [or offers or pays]any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

42 U.S.C. 1320a-7b

Primary Fraud and Abuse Enforcement Provisions – Stark Statute

- Prohibits a physician from referring Medicare patients (for certain designated health services that are payable by Medicare) to entities with which the physician has a financial relationship.
- Prohibits entities that furnish designated health services from billing Medicare or any other payer or individual for services performed as a result of a prohibited referral.
- Established statutory and regulatory exceptions

Primary Fraud and Abuse Enforcement Provisions – (but don't forget) Exclusion from Federal Programs

- Bases for exclusion include convictions for program-related fraud and patient abuse, licensing board actions and default on Health Education Assistance Loans.
- No payment will be made by any Federal health care program for any items or services furnished, ordered, or prescribed by an excluded individual or entity.
- Applies to the excluded person, anyone who employs or contracts with the excluded person, any hospital or other provider where the excluded person provides services, and anyone else, regardless of who submits the claims.

Primary Fraud and Abuse Enforcement Provisions – (and also) State Licensing Actions

Licensing enforcement actions can arise:

- independently,
- based upon citizen complaints,
- or communications from other regulatory agencies.

Primary Fraud and Abuse Enforcement Provisions – (and don't forget) State Prohibitions Against Corporate Practice of Medicine

Prohibition against corporate practice of medicine

- California law prohibits law individuals, organizations, and corporations from practicing medicine (B&P 2052 and 2400)
- Some, but not all, states have comparable statutes.

2009 -10 Fraud and Abuse Developments – Health Reform

- Obama administration increased focus on health care fraud and abuse prevention
- New Interagency Health Care Fraud Prevention & Enforcement Team (“HEAT”), which expanded the Medicare Fraud Strike Force operations from South Florida, LA, and Detroit to other urban centers.
- Sunshine Act of 2009
- Proposed RAC expansion

2009 -10 Fraud and Abuse Developments – Health Reform

- With election of Senator Brown as Edward Kennedy's replacement, what now?
- President Obama wants to push on.
- Republicans have new leverage.
- Back to square one?
- Piecemeal patchwork as a result?

2009 -10 Fraud and Abuse Developments – Enforcement Activities

- See OIG website for ongoing documentation of enforcement activities:
- <http://oig.hhs.gov/fraud/enforcementactions.asp>

2009 -10 Fraud and Abuse Developments - OIG Workplan

Investigations in conjunction with other law enforcement entities, such as the Federal Bureau of Investigation, the United States Postal Inspection Service, the Internal Revenue Service, and State Medicaid Fraud Control Units (MFCU).

- Individuals, facilities, or entities that bill or are alleged to have billed Medicare and/or Medicaid for services not rendered, claims that manipulate payment codes in an effort to inflate reimbursement amounts, and false claims submitted to obtain program funds.

2009 -10 Fraud and Abuse Developments - OIG Workplan

- Business arrangements that allegedly violate the Federal health care anti-kickback statute and the statutory limitation on self-referrals by physicians.
- Investigation of Medicaid Fraud in coordination with state fraud control units.

2009 -10 Fraud and Abuse Developments – OIG Workplan 2010 (Hospitals: Medicare Part A and Part B)

- Part A Hospital Capital Payments
- Provider-Based Status for Inpatient and Outpatient Facilities
- Part A Inpatient Prospective Payment System Wage Indexes
- Hospital Payments for Nonphysician Outpatient Services Under the Inpatient Prospective Payment System

2009 -10 Fraud and Abuse Developments – OIG Workplan 2010 (Hospitals: Medicare Part A and Part B)

- Payments to Organ Procurement Organizations
- Inpatient Rehabilitation Facility Submission of Patient Assessment Instruments
- Critical Access Hospitals
- Medicare Disproportionate Share Payments
- Provider Bad Debts

2009 -10 Fraud and Abuse Developments – OIG Workplan 2010 (Hospitals: Medicare Part A and Part B)

- Medicare Secondary Payer
- Reliability of Hospital-Reported Quality Measure Data
- Hospital Admissions With Conditions Coded Present-on-Admission
- Hospital Readmissions

2009 -10 Fraud and Abuse Developments – OIG Workplan 2010 (Hospitals: Medicare Part A and Part B)

- Adverse Events: Various Reviews
- Oversight of Hospitals' Compliance With the Emergency Medical Treatment and Labor Act
- Observation Services During Outpatient Visits
- Coding and Documentation Changes Under the Medicare Severity Diagnosis Related Group System

2009 -10 Fraud and Abuse Developments - OIG Workplan – RAC Program Referrals

And,

Review of CMS's oversight of Recovery Audit Contractors for identification and reporting to CMS of potential fraud and abuse, and CMS follow-up

2009 -10 Fraud and Abuse Developments – Recovery Audit Contractor Program Progress

- Medicare Modernization Act of 2003
 - 3-year demonstration project, NY, FL, CA
 - Now operating nationwide
 - Purpose: to recover Medicare overpayments and identify underpayments
 - RACs paid on contingency fee basis (over and under payments)

2009 -10 Fraud and Abuse Developments – Recovery Audit Contractor Program Progress

- RACs can keep 9% - 12.5% of provider payments identified as improper
- RACs can use statistical sampling and extrapolation findings to calculate overpayment (within certain guidelines).
- Three-year claims look-back allowed, but not beyond 10/01/07.
- New documentation limits - 2010

2009 -10 Fraud and Abuse Developments – Recovery Audit Contractor Program Progress

RACs do essentially two types of audits.

- In an automated audit, the contractor runs data queries and seeks out immediate claims denials for things such as situations when a provider may overreport the amount of time it takes to administer anesthesia.
- Complex reviews, which require more paperwork and man-hours from hospitals than an automated audit by the RAC, include reviews on patient status, DRG coding, or medical necessity reviews.

2009 -10 Fraud and Abuse Developments – Recovery Audit Contractor Program Progress

- Coming 2010, Complex Audits: Medical necessity
 - Whether or not the medical care given to a patient was appropriate as defined by Medicare guidelines in effect at the time of service
 - Compare with automated review, burden on provider
- Only 45 days to respond to RAC with documentation
- Expansion to physician claims review
- Are RAC auditors going to be second-guessing decisions made by treating physicians at hospitals and patients "to determine whether medical care given to a patient was necessary?"

2009 -10 Fraud and Abuse Developments – Recovery Audit Contractor Program Progress

- Coding Issues
- Medicare's new severity adjusted IPPS system was designed to better identify the severity of a patient's condition. It created incentives to better document and code secondary diagnoses, according to MedPAC researchers.
- Will CMS take MedPAC's advice seriously to adjust hospital payments in future years to offset the increased payments resulting from coding improvements.
- Has CMS considered changes in severity and case mix at hospitals?

2009 -10 Fraud and Abuse Developments – Recovery Audit Contractor Program Progress

- Questions for consideration:
 - What is the effect of greater sophistication and improved qualifications of RAC auditors?
 - What changes in inpatient acuity (and cost) are occurring as more patients and procedures are moved to outpatient settings?
 - Will RAC auditors be second-guessing physicians in treatment decisions?

2009 -10 Fraud and Abuse Developments – Recovery Audit Contractor Program Progress

- Will more aggressive and complex RAC audits prompt undercoding/underbilling to avoid cost of adjustments?
- Will medical necessity reviews drive a wedge between hospitals/providers and physicians?
- How expensive will RAC compliance be, especially for medical necessity adjustments?

2009 -10 Fraud and Abuse Developments – Physician Supervision in Outpatient Settings

- **“Incident to” Services:**
- Medicare covers items and services provided by hospitals “incident to” a physician’s services. Many of the therapies that hospitals provide to outpatients fit under no other benefit category. CMS generally pays for these items and services under the Hospital Outpatient Prospective Payment System (OPPS).

2009 -10 Fraud and Abuse Developments – Physician Supervision in Outpatient Settings

42 CFR 410.27(a): OUTPATIENT HOSPITAL SERVICES AND SUPPLIES INCIDENT TO A PHYSICIAN SERVICE: CONDITIONS

(a) Medicare Part B pays for hospital or CAH services and supplies furnished incident to a physician or nonphysician practitioner service to outpatients, including drugs and biologicals that cannot be self-administered, if—

[furnished]

- (i) By or under arrangements made by the participating hospital or CAH, except in the case of a SNF resident ... ;
- (ii) As an integral though incidental part of a physician's or nonphysician practitioner's services;

2009 -10 Fraud and Abuse Developments – Physician Supervision in Outpatient Settings

(iii) In the hospital or CAH or in a department of the hospital or CAH, as defined in §413.65 of this subchapter;

and

(iv) Under the direct supervision of a physician or a nonphysician practitioner as specified in paragraph (f) of this section. Nonphysician practitioners may directly supervise services that they may personally furnish in accordance with State law and all additional requirements, including those specified in §§410.71, 410.73, 410.74, 410.75, 410.76, and 410.77.

2009 -10 Fraud and Abuse Developments – Physician Supervision in Outpatient Settings

(A) For services furnished in the hospital or CAH or in an on-campus outpatient department of the hospital or CAH, as defined in §413.65 of this subchapter, "direct supervision" means that the physician or nonphysician practitioner must be present on the same campus and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or osteopathy, as specified in §§410.47 and 410.49, respectively.

2009 -10 Fraud and Abuse Developments – Physician Supervision in Outpatient Settings

(B) For services furnished in an off-campus outpatient department of the hospital or CAH, as defined in §413.65 of this subchapter, "direct supervision" means the physician or nonphysician practitioner must be present in the off-campus provider-based department of the hospital or CAH and immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or osteopathy, as specified in §§410.47 and 410.49, respectively.

(Nov. 20, 2009, effective Jan. 1, 2010)

2009 -10 Fraud and Abuse Developments – Physician Supervision in Outpatient Settings

Recent “Guidance” Has Created Confusion and Potential Compliance Risks

- HISTORICALLY:
- CMS took the position that a physician’s mere writing of an order to the hospital for an item or service is not sufficient to bring the item or service within the scope of coverage as “incident to,” but that the physician supervision requirements were assumed to be met when the services were performed on hospital premises.

2009 -10 Fraud and Abuse Developments – Physician Supervision in Outpatient Settings

One problem lies in the differing understandings that have developed with respect to the meaning of the word “assumed.” Over time, the health care delivery and payment systems changed; however, the concept for coverage did not.

2009 -10 Fraud and Abuse Developments – Physician Supervision in Outpatient Settings

- CMS has long regarded the development off-site locations of hospital outpatient departments with disfavor, arguing that it required CMS to pay more for identical items and services that could also be provided at lower cost in a physician's office setting. In some circumstances, the acquisition of a physician's practice and conversion of that office into a hospital outpatient department arguably created exactly that result.

2009 -10 Fraud and Abuse Developments – Physician Supervision in Outpatient Settings

- Whether physician supervision ever approached the level CMS now describes is a debatable question. Providers began to treat the “assumption” of supervision as approaching an irrebuttable presumption. In other words, as long as physicians roamed the halls of the hospital, “supervision” occurred, and all was well.

2009 -10 Fraud and Abuse Developments – Physician Supervision in Outpatient Settings

CLOUDS OF CONFUSION?

- Mere clarification vs. substantive change ?
- If cannot assume direct physician supervision is available in main hospital, what is required there?
- Presence ?
- Immediately available?

2009 -10 Fraud and Abuse Developments – Physician Supervision in Outpatient Settings

- Who must be the supervising physician?
- Lack of immediate response in the hospital outpatient department = quality concern to CMS?
- If hospitals have not historically provided this level of supervision, the costs are not in the OPPS base
- Supervision of therapeutic vs diagnostic services?

2009 -10 Fraud and Abuse Developments – Physician Supervision in Outpatient Settings

Hospital/physician Relationships Within the Context of Compliance Obligations

Why Focus on Hospital/Physician Alignment?

Cost – Unsustainable Health Care Expense

- Health care expense is growing faster than GDP and personal income growth

Quality – High Variation in Care

- Health care cost and quality varies greatly between regions¹
- High cost doesn't correlate with high quality care – more ≠ better¹
- < 50% of all medical care in the U.S. is currently supported by evidence/best practices¹

¹

The Dartmouth Atlas of Health Care, 2009

Hospital Perspective

- *Payment Reform & Financial Sustainability* – How will hospitals be better positioned to address market reforms aimed at providing “value over volume”? How will they collaborate with physicians to maximize financial performance with shrinking reimbursement?
- *Care Coordination* – How will hospitals be able to better develop coordinated cost-reduction initiatives with physicians across the care continuum?
- *Quality* – How will hospitals establish disease management and evidence-based medicine initiatives, which require active collaboration among physicians, hospitals, and other providers?
- *Access and Coverage* – How will hospitals develop and leverage shared resources with physicians to increase efficiency and access?

Physician Perspective

- *Compensation* – How will the physician stabilize his/her compensation?
- *Administrative Burden* – How will the physician reduce his/her burden of operating an independent practice, which will allow more time for patient care activities?
- *Increased Scrutiny on Quality* – How will the physician meet the demands of payors and employers for transparency in quality and utilization management?
- *Payment Reform* – How will the physician adapt to new payment models, such as bundled payments, that require defined funds flow arrangements and structures between hospitals and physicians?

Current Alignment Strategies

Payment Focus

- *Pay for Performance* – incentive based payment, generally based on the achievement of pre-determined criteria (can be based on quality goals, patient satisfaction, peer review, utilization of resources, cost savings)
- *Gainsharing* – generally describes shared savings arrangement

Current Alignment Strategies

Structure Focus

- *Employment by Hospitals* – most straightforward way to align – only available in non-corporate practice states; how to incentivize physicians and control costs?
- *Use of Clinics* – proliferation in corporate practice states (e.g., physician foundations, hospital outpatient clinics, separately licensed stand alone clinics owned by hospitals)
- *Other Arrangements* – “captive or friendly” PC, hospital MSO, co-management and other jv models, co-branding/affiliation, unified use of EHR

The Future: What Does “Reform” Mean?

- Movement from volume-based to results-based payment (“pay for value”)
- Focus on wellness and prevention; care coordination (medical home / ACOs)
- Increased reliance on health information technology (HIT)

Senate Bill Provisions (HR 3590) – Cost Containment

- Establishment of an Independent Payment Advisory Board to submit legislative proposals recommending Medicare spending reductions if growth exceeds a target rate (hospitals & hospices exempt from cost reductions through 2019, labs exempt for 1 year)
- Allow ACOs meeting quality thresholds to share in their Medicare cost savings
- Creation of an “Innovation Center” within CMS to test, evaluate and expand in Medicare/Medicaid/CHIP different payment structures to reduce program expenditures while maintaining or improving quality
- Reduce Medicare payments to hospitals to account for excess (preventable) hospital readmissions and for certain hospital-acquired conditions

Senate Bill Provisions (HR 3590) – Cost Containment

- Prohibition of federal payments to states for Medicaid services related to health care acquired conditions
- Provider screening, enhanced oversight periods for new providers/suppliers and enrollment moratoria in areas identified as being at elevated risk of fraud
- Requires all Medicare and Medicaid program providers and suppliers to establish compliance programs

Senate Bill Provisions (HR 3590) – Cost Containment

- Restructure payments to Medicare Advantage plans, with bonus payments for quality, performance improvement and care coordination
- Reduce annual market basket updates for Medicare providers
- Establishment of the Patient-Centered Outcomes Research Institute to conduct research that compares clinical effectiveness of medical care

Senate Bill Provisions (HR 3590) – Quality Improvement (Medicare)

- Establishment of a Medicare pilot program to develop and evaluate paying a bundled payment for hospital services, physician services and post-acute care services for an episode of care that begins 3 days prior to hospitalization and spans 30 days following discharge
- Create the Independence at Home demonstration program to provide high-need Medicare beneficiaries with primary care services in-home and allowing providers to share in any savings based on health outcomes and patient satisfaction
- Establishment of a Medicare value-based purchasing program to pay hospitals based on performance on quality measures (expansion planned for other providers)

Senate Bill Provisions (HR 3590) – Quality Improvement (Medicaid)

Creation of demonstration projects in Medicaid:

- To pay bundled payments for episodes of care that include hospitalization
- To make global capitated payments to safety net hospital systems
- To allow pediatric medical providers organized as ACOs to share in cost-savings
- To provide Medicaid payments to institutions of mental disease for adult enrollees who require stabilization of an emergency condition

And if there is no reform legislation...

... incremental change is still coming.

Reform Driven By Market Necessity

How to create a delivery model that provides better outcomes for less cost:

- Market movement towards consolidation, benchmarking and incentive payment arrangements utilizing both cost and quality factors
- Geography plays a role – markets with more history and experience in managing risk based payments / working in a delegated environment are ahead of the curve
- Implementation of current “alignment” structures, while struggling with the payment mechanisms until the Feds catch up

Payment Conundrum

If we want providers to work together to control costs and provide coordinated, quality-driven care, how should they be paid?

Ideal System:

- Global payments for episodes of care
- Pay for performance
- Shared upside for reducing cost / achieving quality and satisfaction

Payment Conundrum

What if we don't trust the motivations of our providers?

Current System:

- Stark law
- Anti-kickback Statute
- CMP Rule
- Corporate Practice of Medicine prohibition (some states)

Transparency

- Congress and state legislatures are pushing for greater transparency throughout health care
- Empowers regulatory and enforcement activities and provides opportunity for individual plaintiffs to highlight perceived wrongdoing

Sunshine Act of 2009

- S. 301 introduced by Senators Grassley and Kohl Jan. 22, 2009 – now included in the Senate Health Bill
- Requires all drug and device makers to publicly disclose all monetary compensation over \$100 given to physicians (either as individuals or to a group practice) on a federal website accessible by the public
- Current terms enable states to enact additional, more onerous requirements

Sunshine Act of 2009 *(cont'd.)*

Items requiring disclosure:

- Consulting fees
- Other compensation
- Honoraria
- Gifts
- Entertainment
- Food
- Travel
- Education
- Research
- Charitable contributions
- Royalties/Licenses
- Ownership interests
- Compensation for CME
- Grants
- Travel
- Other determined by HHS

Sunshine Act of 2009 (*cont'd.*)

Physician ownership in private companies must be reported, including:

- Dollar amount invested
- Current value
- Any payment or transfer of value to the physician, including dividends

Transparency – Medical Staff Requirements

- There is no law that currently mandates that hospitals must require their medical staff members to disclose their financial relationships with medical device / implant distributors
- Increasingly, hospitals are requiring disclosure as part of their compliance plans, and the industry is moving towards transparency – certain AMC's have developed their own codes of ethics and standards, and some are disclosing financial relationships on their websites

What can we look forward to?

December is the toughest month of the year. Others are July, January, September, April, November, May, March, June, October, August, and February.

- Mark Twain

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