Fraud and Abuse Primer

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Outline of Presentation

- Agencies with investigative authority
- Criminal and Civil False Claims Statutes
- Anti-Kickback Statute/Safe Harbors
- Stark Self-Referral Prohibition
- Beneficiary Inducement Prohibitions
- Exclusions
Who Is the Government?

- Centers for Medicare and Medicaid Services ("CMS") (formerly HCFA)
- Office of Inspector General
- Federal Bureau of Investigation
- Department of Justice
- United States Attorneys’ Offices
- State Attorneys General Offices
- State Medicaid Fraud Control Units
Who Is the Government? (Cont’d)

• Internal Revenue Service
• Federal Trade Commission
• U.S. Postal Service
• U.S. Secret Service
• Federal Employee Health Benefits Program
• Managed Care Organizations
Who Is the Government? (Cont’d)

- Intermediaries, Carriers, and DMERCs under Contract with CMS
- Private Insurance Companies
- Private Organizations under Contract with OIG
- Medicare and Medicaid Program Beneficiaries
- Qui Tam Relators, Including Employees, Former Employees, and Competitors
Government Investigative Techniques

- OIG Subpoenas
- Grand Jury Subpoenas
- Search Warrants
- Civil Investigative Demands (31 USC 3733)
- Authorized Investigative Demands (18 USC 3486)
- OIG Demands for Immediate Access
- Interviews
Fraud and Abuse Issues

• Statutorily regulated areas of conduct
  – Claims for reimbursement
  – Relationships with referral sources
Criminal False Claims Statutes

• Medicare/Medicaid-specific statutes (42 U.S.C. §1320a-7b)
  – False claims
  – False statements
  – Failure to refund

• Federal Health Care Offenses
  – Scheme to defraud health care benefit program (18 U.S.C. §1347)
  – False statements relating to health care (18 U.S.C. §1035)
  – Obstruction of health care offense investigation (18 U.S.C. §1518)
Criminal False Claims Statutes (cont’d)

- Conspiracy to defraud the Government (18 U.S.C. §371)
- False statements (18 U.S.C. §1001)
- Mail fraud (18 U.S.C. §1341)
- Wire fraud (18 U.S.C. §1343)
- RICO (18 U.S.C. §§1961-64)
CIVIL FALSE CLAIMS ACT

• Prohibits
  – filing, or causing to be filed
  – “false or fraudulent” claims
  – Using false statement to “conceal, avoid or decrease” a government obligation

• Intent
  – “Intent to defraud” not required
  – Filing claims with “reckless disregard” of their truth or falsity is sufficient
    • “Honest mistakes”
Civil False Claims Act

• Liability
  – 3X Damages
  – $5,500 to $11,000 *per claim*
SAMPLE PENALTY CALCULATION

DEFENSE CONTRACTOR

• $100,000 damages X 3 = $300,000
• 12 (# of claims) X $11,000 = $132,000
• Total liability = $432,000
SAMPLE PENALTY CALCULATION

HEALTH CARE PROVIDER

- $100,000 damages X 3 = $300,000
- 2000 (# of claims) X $11,000 = $22,000,000
- Total Liability = $22,300,000
Civil False Claims Act

• *Qui Tam* Provisions
  – “private attorney generals”

  – Can proceed even if Government declines

  – Can receive up to 30% of recovery
Relationships With Referral Sources

• Anti-Kickback statute

• Stark self-referral prohibitions
  – State “Mini-Stark” statutes
Areas of Governmental Concern

- Additional Cost
- Over, Under, and Mis-Utilization
- Quality of Care
- Access to Care
- Patients’ Freedom of Choice
- Competition
- Exercise of Professional Judgment
Medicare Anti-Kickback Statute

- Prohibited Conduct
  - Knowing & willful
  - Solicitation or receipt or
  - Offer or payment of
  - Remuneration
Medicare Anti-Kickback Statute

• Prohibited Conduct *cont’d*
  – In return for referring a Program patient, *or*
  – To induce the purchasing, leasing, *or* arranging for or recommending purchasing or leasing items or services paid by the program
Medicare Anti-Kickback Statute

- Intent Issues
  - *Greber* “one purpose” test
    - *Hanlester* standard vs. *Jain* standard
“[Defendants] can not be convicted merely because they hoped or expected or believed that referrals may ensue from remuneration that was designed wholly for other purposes. Likewise, mere oral encouragement to refer patients or the mere creation of an attractive place to which patients can be referred does not violate the law. There must be an offer or payment of remuneration [with intent, at least in part, to gain influence over the reason or judgment of a person making referral decisions.]”

– Jury instruction No. 32
Medicare Anti-Kickback Statute

• Statutory Exceptions
  – Discounts
  – Bona fide employment relationships
  – GPO fees
  – Certain co-payment waivers
  – Certain managed care arrangements
Statutory Exceptions (cont’d)

• Regulatory Safe Harbors

• Advisory Opinions
  – Posted on OIG Website
    • www.hhs.gov/oig
Other Policy Statements

• Policy Statements
  – Special Fraud Alerts
  – Advisory Bulletins
  – Model Compliance Plans
  – Selected Correspondence Posted on the OIG Website
Medicare Anti-Kickback Statute

• Penalties
  – Criminal fines & imprisonment
  – Civil money penalty of $50,000 plus 3X the amount of the remuneration
  – Exclusion
  – False Claims Act liability?
    • *United States ex rel. McNutt v. Haleyville Medical Supplies, Inc, et al.* Case No. 04-14458 (11th Cir. 9/9/05)
Key Issues Under the Anti-Kickback Statute

- Joint Ventures
- Commissioned Sales Representatives
- Service Agreements
- Leases
- Discounts
- Group Purchasing Organizations
- Physician Recruitment
- Random Other Stuff
Joint Ventures

• Background
  – *Hanlester*

• 1989 Special Fraud Alert on Joint Ventures
  – Manner in which investors selected/retained
  – Nature of business structure
  – Financing/business structure

• 2003 Special Advisory Bulletin on Contractual Joint Ventures
  – JVs between existing suppliers and health care entities to services that entities patients are “suspect”
Joint Ventures (cont’d)

• Publicly traded entity safe harbor
  – Net tangible assets >$50,000,000
  – Registered w/SEC
  – Interest obtained on terms and price available to public over NYSE, ASE, or NASDAQ
  – Cannot market services differently to investors
  – Entity cannot loan purchase money to investor
  – Return proportional to investment
Joint Ventures (cont’d)

• Small entity safe harbor
  – <40% “tainted investors”
  – Terms same for “tainted” and non-“tainted” “passive investors”
  – Offer to “tainted” investor not based on referrals
  – No referral requirements or discriminatory marketing
  – <40% of revenue from investor referrals
  – Entity cannot loan purchase money to investor
  – Return proportional to investment
Joint Ventures (cont’d)

• Ventures in medically underserved areas
  – <50% held by “tainted” investors
  – Terms same for “tainted” and non-“tainted” “passive investors”
  – Offer to “tainted” investor not based on referrals
  – No referral requirements or discriminatory marketing
  – >75% of revenue from MUA services
  – Entity cannot loan purchase money to investor
  – Return proportional to investment
  – 3 year unwind if MUA status lost
ASC Safe Harbor: Common Requirements

- Medicare certified (42 C.F.R. part 416)
- Dedicated OR and recovery room
- Disclosure to patients
- Interest cannot be offered based on anticipated referrals
- No loans from ASC or investor to purchase interest
ASC Safe Harbor: Common Requirements (Cont’d)

• Returns proportional to ownership interest

• All ancillary services must be part of ASC services and not separately billed

• No discrimination against Program patients
Surgeon-Owned ASCs

- All investors are
  - General surgeons or surgeons sharing the same specialty
  - Surgical group practices
  - “unrelated persons”

- At least 1/3 of each surgeon’s practice income in the past year derived from ASC procedures
Single Specialty ASCs

- All investors are
  - Physicians in the same specialty, in a position to refer directly to the ASC
  - Group practices composed exclusively of such physicians
  - “Unrelated persons”

- At least 1/3 of each physician’s practice income in the past year derived from ASC procedures
Multi-Specialty ASCs

• All investors are
  – Physicians in a position to refer directly to the ASC
  – Group practices composed exclusively of such physicians
  – “Unrelated persons”

• At least 1/3 of each physician’s practice income in the past year derived from ASC procedures

• At least 1/3 of investor’s ASC procedures in the past year must be at the investment ASC
Hospital/Physician ASC Safe Harbor

- Investors are
  - One or more hospitals
  - Physicians meeting other ASC safe harbor requirements
  - “unrelated persons”

- ASC may not use hospital space or services absent a safe harbored agreement

- Hospital may not claim ASC costs on cost report

- Hospital may not be in a position to make or influence referrals to investors or ASC
Joint Ventures

• Advisory Opinion 98-12
  – Approved physician joint venture in an Ambulatory Surgery Center (ASC)
    • 3 Orthopedic Surgeons
    • 2 Anesthesiologists practicing pain management
  – “The Proposed Arrangement is the antithesis of the small entity investment safe harbor business structure.”
Commanded Sales Representatives

• W-2 Employment safe harbor
  – Bona fide employment under IRS rules
• Advisory Opinion 98-10 criteria for non-employee commissioned sales reps
  – Compensation based on % of sales
  – Direct program billing by seller
  – Direct contact between rep and physicians
  – Direct contact between rep and patients
  – Does rep have “undue influence”
  – Marketing of separately reimbursable items
Service/Management Agreements

- Safe Harbor Requirements
  - Signed written agreement
  - Covers all services to be provided
  - If part-time, contains schedule of services
  - One year term
  - Aggregated compensation set in advance at fair market value
  - Services do not include promoting illegal activity
  - Services “commercially reasonable”
Service/Management Agreements (cont’d)

• Application to hospital-based physicians
  – Management Advisory Report

• 1992 Special Fraud Alert: Hospital Incentives to Physicians
Space and Equipment Leases

- OIG Special Fraud Alert: Rental of Space in Physicians Offices By Persons or Entities to which Physicians Refer (February, 2000)
- Targeted arrangements in physician offices
  - CORF’s providing PT and OT
  - Mobile diagnostic services
  - DME “consignment closets”
Space and Equipment Leases

- OIG Focus
  - Appropriateness of the rental agreement
  - Rental amounts
  - Time and space considerations
Space and Equipment Leases

• Lease Safe Harbor
  – Signed written agreement
  – Covers all space/equipment leased
  – If part-time, contains schedule of use
  – One year term
  – Aggregate rental set in advance at fair market value
  – Lease “commercially reasonable”
Discounts

• Discount safe harbor
  – 3 buyer categories
    • Cost-report
    • HMO/CMP
    • Other
  – Disclosure of discounts
Discounts

• *Not* a discount
  – Cash or cash equivalents
  – Discounts on one item based on purchases of a different item
  – Reductions in price to one payer but not Medicare/Medicaid
  – Waivers of co-pay/deductible
Discounts

• 1999 Safe Harbor Revisions
  – Permits charge-based providers to receive year-rebates
  – Creates “offeror” concept
  – Eliminates requirement that charge-based providers report discounts on claims
  – Discounts on multiple items permitted when reimbursement methodology is the same

• “Prebates”: 7/17/00 M. Thornton letter
Discounts

• “Swapping”
  - Advisory Opinion 99-2
    • Discount arrangement between Ambulance Company and SNF for PPS and non-PPS transports
  - Advisory Opinion 99-13
    • Discount arrangement between Pathology Group and Hospitals or Physicians
Discounts

• OIG Indicia of “Suspect” Discounts
  – Discounted prices below fully loaded (not marginal) costs

  – Discounted prices below those given to buyers with comparable “account” volume, but without potential Program referrals
Discounts

• Subsequent Retreat
  – Discounts below fully loaded costs not *per se* unlawful

  – Must be a “linkage” between the discount and referrals of Program business

Letter of Kevin G. McAneny (April 26, 2000)
Discounts

• Compliance Guidance for Clinical Laboratories
  – 63 Federal Register 45,076 (August 24, 1998)

• Stark Exception for payments by physicians
Physician Recruitment

- Safe harbor
  - Written agreement
  - Term of 3 years or less
  - No requirement to refer
  - 75% of revenue from new patients
  - Non-exclusive staff privileges
  - Benefits cannot vary by referrals
  - Agree to treat Program patients
  - 75% of revenue from HPSA or MUP
  - No benefit to other referral sources
Other Random Stuff

- Managed care safe harbors
- Gainsharing
- Waiver of co-pay/deductible
- Professional courtesy
- “Freebies” to doctors
Stark Self Referral Prohibition

- Physician may not refer:
  - Medicare or Medicaid patients
  - For “designated health services”
  - to an entity with which the physician or
  - an immediate family member has
  - a “financial relationship”
Stark (Cont’d)

• “Designated health services”

  Clinical laboratory  Radiology

  Proposed inclusion of nuclear medicine

  Radiation Therapy  DME

  PEN  O&P

  Prosthetics  Home Health

  Outpatient drugs  Hospital services
Stark Exceptions

• General Exceptions
  – In-Office Ancillary Services
  – Physician Services
  – Services By Federally-Qualified HMO or Prepaid Health Plan with Medicare Contract
  – Regulatory Exceptions Where No “Risk of Program or Patient Abuse”
Stark Exceptions (Cont’d)

• Ownership Exceptions
  – Publicly-Held Companies with Equity exceeding $75,000,000
  
  – Rural Providers
  
  – Ownership of Hospital as a Whole
    • Admitting Privileges Required
Stark Exceptions (Cont’d)

- Compensation Exceptions
  - Rental of Office Space
  - *Bona Fide* Employment
  - Personal Services Exception
  - Certain Physician Incentive Plans
  - Hospital Remuneration Unrelated to DHS
  - Certain Physician Recruitment Incentives
  - Isolated Transactions
  - Payments by Physicians
Stark (Cont’d)

• Sanctions
  – Denial of Payment
  – Refund of Amounts Collected as a Result of Improper billing
  – Civil Money Penalties of $15,000 per Item or Service Plus 2X the Amount Claimed
  – Civil Money Penalties of $100,000 for “Circumvention Schemes”
  – Exclusion
  – False Claims Act Liability?
Stark and the False Claims Act

- *United States ex rel. Barbera v. Tenet Healthcare Corporation* (SD FL)
  - March 24, 2004 settlement of $22.5 million to resolve alleged Stark violations by an acquired subsidiary (AMI) involving salaries paid to physicians in purchased practices
Stark Regulatory History

- Original Statutory (Stark I) Requirement of Final Regulations By October 1, 1991
- Proposed Stark I Regulations Published March 11, 1992
- Final Stark I Regulations Published August, 1995
- Proposed Stark II Regulations Published January, 1998
Stark Regulatory History

• “Phase I” Final Stark II Regulations Published January, 2001 (effective date of January, 2002 (delayed 1 year for part of regulation))

• “Phase II” Interim Final Stark II Regulations Published March 26, 2004 (effective date of July 26, 2004)
Stark Vs Anti-Kickback Statute

• Intent standard

• Compliance with exception/safe harbor

• Definition of “referral”
Key Definitions

• “Referral”
  – Request/ordering or certifying medical necessity (including tests ordered pursuant to consult)
    • Does not include personally performed services
    • Does include “incident to” (comments sought)
  – Referral imputed to physician if he/she “directs” or “controls” person making it
    • Preamble includes NPs and PAs in this category
Key Definitions (cont’d)

• Special rules for pathologists, radiologists and radiation oncologists
  – Pursuant to a request for a consultation
    • Physician’s opinion sought
    • Request documented on chart
    • Written report (Phase II retains this)
  – Under supervision of consulting physician
    • Supervision requirement met if at a level that meets Medicare coverage rules
Key Definitions (Continued)

• Inpatient and Outpatient Hospital Services
  – Lithotripsy not considered “inpatient or outpatient” hospital service
  – Caution: contractual arrangements between hospitals and physicians regarding lithotripsy constitute financial relationship

• Must qualify for an exception if physician refers patients to hospital for inpatient or outpatient service, or another DSH
Key Definitions (cont’d)

- “Financial relationship”
  - “Direct ownership/investment interests”
    - Includes secured debt
    - Does not include
      - Retirement plan
      - Stock options earned as compensation until exercised
      - Unsecured loans
      - “under arrangements” contracts
Key Definitions (cont’d)

• Indirect ownership/investment interest
  – Unbroken chain of any number (>1) of persons or entities between physician and entity furnishing DHS
  – Entity has actual knowledge (or reckless disregard or deliberate ignorance) of interest
  – Need not know precise composition of chain

• Phase II clarifies that common ownership does not create indirect ownership
Key Definitions (cont’d)

• Direct compensation arrangements
  – Any arrangement involving remuneration between a physician (or family member)
    • No person or entity interposed between them
Key Definitions (cont’d)

• Indirect Compensation Arrangements Defined:
  – “Unbroken Chain” of any number of entities between physician and entity
  – Compensation to physician from closest link in chain varies with volume or value of referrals to entity providing DHS
    • Compare with “takes into account” volume or value language interpreted for other exceptions
  – Entity providing DHS has actual knowledge or acts in reckless disregard of existence of such relationship
New Regulatory Exception: Indirect Compensation

• Exception
  – Compensation at fair market value w/o taking into account volume or value of referrals
    • Need not be “set in advance”- Per-use payments permitted even if referrals from physician can effect total units
  – In writing, signed by parties, that specifies covered services (not required for employment relationships)
  – Does not violate anti-kickback statute or Program billing rules
Physician Compensation

• Percentages of revenues or collections for personally performed services (Phase II)
  – Established with specificity prospectively
  – Objectively verifiable
  – Not changed over course of agreement based on volume or value of referrals or other business generated
• “Other business generated” does not include personally performed services; it includes technical component of personally performed services
Physician Compensation (cont’d)

• Physician’s compensation may be conditioned on referrals if:
  • In writing
  • Set in advance/fair market value
  • Must comply with an exception
  • Requirement does not apply
    – Patient choice
    – Payer rules
    – Best interests of patient per physician

• Only applies if referral relates solely to services covered under arrangement and requirement is reasonably necessary to effectuate legitimate purpose of compensation relationship (Phase II)
Unrelated to Volume Or Value

• “Set in Advance” may be per-unit rather than aggregate
  • Percentage agreements permitted as of Phase II
• “Volume or value of referrals” test does not preclude time-based or unit-of-service based compensation (even including services referred by the physician)
Fair Market Value

• “Fair market value”
  • Any commercially reasonable valuation method
  • “does not take into account volume or value of referrals” may preclude use if comparables involving persons in a position to refer buildings
  • May not adjust rentals/leases to reflect value of lessee’s proximity/convenience
  • Provides two methods for determining physician personal services hourly rates
    – Based on ER rates
    – Based on 50th percentile of national compensation survey
In-Office Ancillary Exception

- DHS ancillary to referring physician’s professional services
- Furnished by physician, group practice member, or person supervised by them
- Centralized building or same building in which referring physician provides some services unrelated to DHS
- Billed by physician or group practice
In-Office Ancillary Exception (cont’d)

• “Furnished” if
  – In a location where the service is actually performed, or
  – When an item is dispensed in a manner sufficient to meet coverage and payment rules
In-Office Ancillary Exception (cont’d)

• DME permitted under exception if
  – Blood glucose monitor
  – Ambulatory infusion pumps
  – Crutches, canes, walkers, folding manual wheelchairs, etc. if
    • Necessary for patient to ambulate and leave the office
    • “Same building” requirements met
    • Medicare supplier standards met
    • Anti-kickback statute not violated
  – No mark-up prohibition
In-Office Ancillary Exception (cont’d)

- “Direct Supervision”
  - “Incident to” strict personal presence requirements no longer apply
  - Independent contractor physicians who are not “members” of the group are permitted to supervise
In-Office Ancillary Exception (cont’d)

• Building requirement
  – Single street address
  – Need not be adjacent to where non-DHS provided
  – Can not be a mobile vehicle, internal loading dock or parking garage (Phase II)
  – Can be a SNF, other facility or patient’s home
  – Shared facilities permitted

• Centralized Building
  – Group practices only
  – Can included mobile vehicle
  – No shared facilities
In-office Ancillary Exception (cont’d)

• Same Building Requirement (Phase II)
  – Must meet one of three tests
    • Office is open to patients 35 hours per week and referring physician or group members regularly practice at location at least 30 hours per week
    • Office is open to patients at least 8 hours per week and referring physician furnishes services at location at least 6 hours per week
In-office Ancillary Exception (cont’d)

- Same Building Requirement (cont’d)
  - Office is open to patients eight hours per week and referring physician or group member furnishes services at location at least 6 hours per week
    - Referring physician must be present and order DHS in connection with patient visit or group member is present while DHS is furnished
In-Office Ancillary Exception (cont’d)

• Billing Requirement
  – Billed by physician performing or supervising performance of service
  – By physician’s group practice
  – By an entity wholly owned by group practice
    • DHS entity that is wholly owned by group practice and has its own number meets requirement
  – By third-party billing agent
Group Practice Definition

- Group of 2 or more physicians organized as a legal entity
- Through which each member provides substantially the full range of their patient care services
- “Substantially all” of the members’ services are furnished and billed through the group
Group Practice Definition (cont’d)

• Expenses and revenues distributed by predetermined methods (“unified business” test)

• Members not compensated based on volume or value of referrals (except for permitted profit or productivity distributions)

• Group members conduct 75% of all patient encounter
Group Practice Definition-Regulatory Gloss

• Single Legal Entity
  – Any legal form recognized
  – Primary purpose must be physician group
  – Need not have a physician owner as long as at least two physicians employed
  – Hospital employed physicians are not a group practice unless part of a separate legal entity
  – Can include a solo practitioner organized as a legal entity if a second full-time physician employed
  – Can be two entities in contiguous states if there is identical ownership, governance and operation and state licensing laws
Members of Group

- Shareholders and employees are members
  - Leased employees are members if *bona fide* employee under IRS rules
- Locum tenens and on-call physicians are members
- Independent contractors and leased employees are not “members” but are “in the group” for
  - Profit-sharing and productivity bonuses
  - Supervision purposes
Group Practice Definition- Regulatory Gloss (cont’d)

• “Full range” of patient care services
  – Includes any physician task that address the medical needs of specific patients, patients in general or that benefit the practice
  – If physician practices exclusively in one group practice, all services deemed covered
  – If physician practices in and out of the group, services to group’s patients must be comparable in scope to those outside the group
Group Practice Definition- Regulatory Gloss (cont’d)

• “Substantially all” test
  – 75% of member’s patient care services furnished and billed through the group
  – Default measure: actual time spent
  – Alternate measures:
    • Reasonable
    • Fixed in advance
    • Uniformly applied
    • Verifiable/documentated
“Substantially all” test

- *All* services inside and outside the practice must be aggregated
  
  - Free clinic services and certain academic medical services provided by physicians in group count towards services provided by group (Phase II)
  
  - Multiple group billing numbers permitted
  
  - Start-up groups and addition of newly recruited physician: one year grace period

  - Not applicable to groups in HPSAs
Group Practice Definition-Regulatory Gloss (cont’d)

• “Unified business”
  – Test
    • Centralized decision-making by a representative body
    • Consolidated billing, accounting and financial reporting
    • Phase II eliminates centralized utilization review
  – Cost center and location-based accounting permitted
  – Multiple payment methodologies permitted
Group Practice Definition-Regulatory Gloss (cont’d)

• Physician-Patient encounters
  – “Members” must provide at least 75% of the group’s patient encounters
    • Measured per capita, not by time
    • Independent contractors not “members”; as of Phase II, leased employees meeting IRS *bona fide*
      employee requirements can be members
Group Practice Definition-Regulatory Gloss (cont’d)

• Compensation
  – Physicians may not be compensated directly or indirectly based on the volume or value of referrals by that physician, *except*:
    • Productivity bonus
    • Profit sharing
Group Practice Definition- Regulatory Gloss (cont’d)

• Bonus/profit sharing permitted based on services personally performed or services “incident to” such services
  – Supervision requirements
• May not be directly related to volume or value of referrals of DHS (unless meets criteria above)
• Can segregate DHS revenue
• Profits can be based on entire group or any subgroup of at least 5 physicians
  – Phase II clarifies that any combination of 5 is acceptable
Group Practice Definition - Regulatory Gloss (cont’d)

• Profit-sharing deemed not to relate directly to volume or value
  – Per-capita profit split
  – % of DHS revenue based on % of non-DHS revenue
  – Any method if DHS < 5% of total revenue and < 5% of any physician’s compensation

• Any other method if:
  – Reasonable and verifiable
  – Not directly related to referrals of DHS
  – Set in advance
Group Practice Definition-Regulatory Gloss (cont’d)

• Productivity bonus deemed not to relate directly to volume or value:
  – Total patient encounters or RVUs
  – % compensation based on non-DHS
  – Any method if DHS < 5% of total revenue and < 5% of any physician’s compensation

• Any other method if:
  – Reasonable and verifiable
  – Not directly related to referrals of DHS
  – Set in advance
Whole Hospital Exception

• Hospital Ownership
  – Referring physician is authorized to perform services at hospital
  – Ownership is in *entire* hospital
  – Hospital may not be a specialty hospital
Specialty Hospitals
MMA 2003/Transmittal 62

• “Whole hospital” exception altered by MMA 2003
• 18-month period (December 8, 2003 until June 8, 2005)
• “Specialty Hospital” is hospital in 50 states or D.C. “primarily or exclusively” engaged in care of patients:
  – With cardiac condition
  – With orthopedic condition
  – Receiving surgical procedure
  – Others designated by Secretary (none at this time)
Specialty Hospitals
MMA 2003/Transmittal 62
(Cont’d)

• What is not a Specialty Hospital:
  – Psychiatric hospital
  – Rehabilitation hospital
  – Children’s hospital
  – Long-term care hospital
  – Certain cancer hospitals
  – “Grandfathered” hospitals
• Grandfathered Hospitals
  – In operation or “under development” as of November 8, 2003 if:
    • Number of physician investors has not increased
    • Specialized services furnished by hospital has not changed
    • Increase in number of beds only on main campus and not exceeding greater of 5 beds or 50% of hospital beds
Specialty Hospitals
MMA 2003/Transmittal 62
(Cont’d)

• Grandfathered Hospitals (cont’d)
  – “Under Development:” CMS to make case-by-case determinations by considering whether:
    • Architectural plans were completed
    • Funding was received
    • Zoning requirements were met
    • Necessary approvals from appropriate state agencies received
  – CMS advisory opinions
Rural Provider Exception

• Rural Provider (Phase II)
  – Rural provider is one that furnishes at least 75% of its total DHS to residents of rural area
  – May not be a specialty hospital
  – Impact of change of status
Compensation Exceptions

• Space and Equipment Leases (Phase II)
  – Must be in writing
  – Space/Equipment may not exceed what is reasonable and necessary and must be exclusively used by lessee
  – Term must be at least one year
  – Rental charges must be set in advance and may not account for referrals or other business generated
  – Must be otherwise commercially reasonable
Compensation Exceptions (cont’d)

• Space and Equipment Leases (cont’d)
  – May terminate with or without cause but may not enter into another lease for 1st year lease term
  – Month-to-month holdovers allowed up to 6 months
  – Operating and capital leases are eligible
  – “Exclusive use” includes subleases if lessee does not share rented space/equipment with lessor when rented
  – “Per click” payments permitted
Compensation Exceptions (cont’d)

• **Bona Fide** Employment Relationships
  – Employment must be for identifiable services
  – Remuneration must be consistent with fair market value and except for certain productivity bonuses does not account for referrals
  – Agreement would be commercially reasonable even if no referrals were made to employer
Compensation Exceptions (cont’d)

- *Bona Fide* Employment (Phase II)
  - Protects physicians who are employees under usual common law and Internal Revenue Code definitions
  - Permits productivity bonuses based on services personally performed by physician
  - May not receive payment for generating referrals of DHS performed by others
Compensation Exceptions (cont’d)

• Personal Service Arrangements (Phase II)
  – Arrangement is in writing, signed by the parties, specifies the services covered
  – Arrangement covers all services to be provided by physician to entity
  – Aggregate services contracted for may not exceed those reasonable and necessary for the legitimate business purposes
  – Term must be at least one year (if terminated may not enter into the same arrangement during the first year of the original term)
Compensation Exceptions (cont’d)

• Personal Service Arrangements (cont’d.)
  – Compensation must be set in advance and except for physician incentive plans, does not take into account the volume or value of referrals or other business generated between the parties.
  – Services may not involve the counseling of an unlawful business arrangement
Compensation Exceptions (cont’d)

• Personal Service Arrangements
  – Requires agreement to cover all services provided by physician to entity
  – Allows either incorporation by reference of all other agreements or cross reference to master list of contracts maintained centrally
  – Permits physician incentive plan exception to include downstream payments
Recruitment & Retention

• Phase II “substantially modifies” the proposed rule in several respects:
  – Focuses on relocation of recruited physician’s medical practice, rather than physician’s residence
  – Eliminates relocation requirement for residents and physicians who have been in medical practice less than one year
  – Permits recruitment by federally qualified health centers ("FQHCs") in addition to hospitals, but not nursing homes or home health agencies
  – Permits recruitment payments made through existing group practices under certain conditions
Recruitment & Retention (Cont.)

- Permits limited retention payments to physicians with practices in HPSAs
- Modifies language regarding recruited physician maintaining staff privileges to clarify original intent of avoiding use of recruitment payment to lock physicians into using recruiting hospital
  - Exceptions for separate employment or contractual arrangements
  - Exception for economic credentialing (“reasonable credentialing restrictions on physicians becoming competitors of a hospital”)
- Refuses to permit teaching hospitals to recruit local community physicians to teach in light of academic medical center, personal services, and employment exceptions
Recruitment

• Requirements for recruitment payment *directly* to a physician:
  – Recruited physician relocates medical practice to the geographic area served by hospital
    • Move medical practice at least 25 miles; or
    • New medical practice derives 75 percent of revenues from professional services furnished to new patients
    • Reasonable expectation of meeting test sufficient during initial “start up” year
    • Not applied to residents or physicians in practice 1 year or less
  – Arrangement set out in writing and signed by parties
Recruitment (Cont.)

• Requirements for recruitment payment *directly* to a physician (cont.):
  – Arrangement not conditioned on physician’s referral of patients to the hospital
  – Recruitment payment not determined (directly or indirectly) based on the volume or value of actual or anticipated referrals
  – Recruited physician allowed to establish staff privileges at any other hospital and to refer business to any other entities (except as otherwise permitted under employment arrangement, services contract, or potentially economic credentialing)
Recruitment (Cont.)

• Additional requirements for recruitment payment (i) indirectly through another physician or group practice or (ii) directly to physician to join an existing physician or group practice:
  – Written agreement signed by party to whom payments are directly made
  – Remuneration passed directly to and remain with recruited physician, except actual costs incurred by physician or group practice
  – For income guarantee, costs allocated to recruited physician limited to actual additional incremental costs attributable to recruited physician
Recruitment (Cont.)

• Additional requirements (cont.):
  – Records of actual costs and passed through amounts retained for at least 5 years
  – Remuneration not take into account volume or value of referrals by recruited physician, group practice, or any physician in group practice
  – Physician or group practice may not impose additional practice restrictions on recruited physicians (e.g., a non-compete agreement), except related to quality of care
  – Arrangement does not violate anti-kickback statute
  – Arrangement does not violate any federal or state law or regulation governing billing or claims submission
Retention (Phase II)

• Requirements for retention payments *directly* to physician:
  – Physician is on hospital’s medical staff
  – Payment is to retain physician’s medical practice in geographic area served by hospital, which is HPSA (without regard to physician’s specialty)
    • Payment also permitted for areas with demonstrated need for physician determined through advisory opinion
  – Arrangement set out in writing and signed by parties.
  – Arrangement not conditioned on physician’s referral of patients to hospital
Retention (Cont.)

• Requirements for retention payments (cont.):
  – Retention payment not determined (directly or indirectly) based on volume or value of actual or anticipated referrals
  – Physician allowed to establish staff privileges at any other hospital and to refer business to any other entities (except as otherwise permitted under employment arrangement, services contract, or economic credentialing)
Retention (Cont.)

• Requirements for retention payments (cont.):
  – Physician has *bona fide* firm, written recruitment offer from an unrelated hospital (or FQHC) that
    • specifies remuneration being offered and
    • requires physician to move practice at least 25 miles *and* outside geographic area served by hospital
  – Retention payment is limited to the *lower of*:
    • Amount obtained by subtracting (i) physician’s current income from (ii) income for comparable services in *bona fide* recruitment offer over no more than 24 months; or
    • Reasonable costs of hospital recruiting new physician to geographic area served by hospital to replace physician
Retention (Cont.)

- Requirements for retention payments (cont.):
  - Retention payment subject to same obligations and restrictions on repayment or forgiveness as *bona fide* recruitment offer
  - Hospital not enter into retention arrangement with particular referring physician more frequently than once every 5 years
  - Amount and terms of retention payment not altered during term on account of volume or value of referrals
Retention (Cont.)

- Requirements for retention payments (cont.):
  - Arrangement otherwise complies with all condition of this section
  - Arrangement does not violate anti-kickback statute
  - Arrangement does not violate any federal or state law or regulation governing billing or claims submission

- Retention exception “does not protect payments made indirectly to a retained physician via another person or entity, including a physician practice”
Payments Made by a Physician

• To a lab in exchange for clinical lab services; or
• To an entity as compensation for any other items or services furnished at a price that is consistent with fair market value and that are not specifically excepted under another provision
New Phase II Regulatory Exceptions:
Temporary Noncompliance

- Temporary Noncompliance is excepted if:
  - Arrangement unavoidably, temporarily noncompliant for reasons out of entity’s control
  - Must have complied with another exception for 180 days prior
  - Only applies to DHS during temporary period up to 90 days
  - Not applicable to non-monetary compensation arrangements/medical staff benefits
  - May only be used once every 3 years
  - Need to contemporaneously document steps taken to rectify compliance
Regulatory Exception: Anti-kickback Safe Harbors

- No “wholesale importation” of anti-kickback safe harbors
- Permits exceptions for remuneration that meets conditions of the following safe harbors:
  - Referral services
  - Obstetrical malpractice insurance subsidies
Reporting Requirements (Phase II)

- Requires entities (except those furnishing 20 or fewer services per year) to submit certain information upon request.
- Reportable financial relationships include any ownership or investment interest and compensation arrangements except such relationships that fit an exception.
- Failure to report may result in assessment of a civil money penalty of up to $10,000 for each day
Beneficiary Inducements

• Unlawful to offer or give remuneration
  – To a Medicare/Medicaid beneficiary
  – If, know or should know, likely to influence beneficiary to choose a particular provider, practitioner or supplier
  – For a Medicare/Medicaid covered service

• $10,000 civil money penalty
Exclusions (42 U.S.C. 1320a-7)

• Mandatory vs. Discretionary

• Definition of “conviction”

• Effect of exclusion

• “Exclude first, appeal later”