

Legal Primer for Physicians

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- Stark & Anti-Kickback
- HIPAA Privacy & Security
- Issues with Electronic Health Records
- Laws Controlling Clinical Research
- OIG Exclusionary Authorities

AKS & Stark

AKS

- Criminal/Civil
- Requires Proof of Improper Intent
- Applies to Any Referral Source
- Safe Harbors

STARK

- Civil Only
- Strict Liability
- Must be a Physician in the mix
- Exceptions

Healthcare Anti-Kickback Statute

Unlawful to:

- Knowingly and willfully solicit or receive
- Any remuneration (directly or indirectly, overtly or covertly, in cash or kind)
- In return for
 - referring for any item or service reimbursable by Federal health care programs, or
 - purchasing, leasing, ordering or arranging for (or recommending any of the same) any good, facility or service reimbursable by Federal health care programs

Healthcare Anti-Kickback Statute

Unlawful to

- Knowingly and willfully
- Offer or pay any remuneration (directly or indirectly, overtly or covertly, in cash or kind)
- To induce
 - referring for any item or service reimbursable by Federal health care programs, or
 - purchasing, leasing, ordering or arranging for (or recommending any of the same) any good, facility or service reimbursable by Federal health care programs

Healthcare Anti-Kickback Statute

- Shall be guilty of a felony and, upon conviction:
 - Fined not more than \$25,000;
 - Imprisoned not more than 5 years; or
 - Both
- Civil Penalties
 - CMP up to \$50,000, and/or 3x amount of improper “remuneration”
 - Exclusion

Definitions

- KNOWINGLY AND WILLFULLY

“We construe "knowingly and willfully" in § 1128B(b)(2) of the anti-kickback statute as requiring appellants to (1) know that § 1128B prohibits offering or paying remuneration to induce referrals, and (2) engage in prohibited conduct with the specific intent to disobey the law.”

The Hanlester Network V. Shalala, 51 F.3d 1390 (9th Cir. Ct. App. 1995)

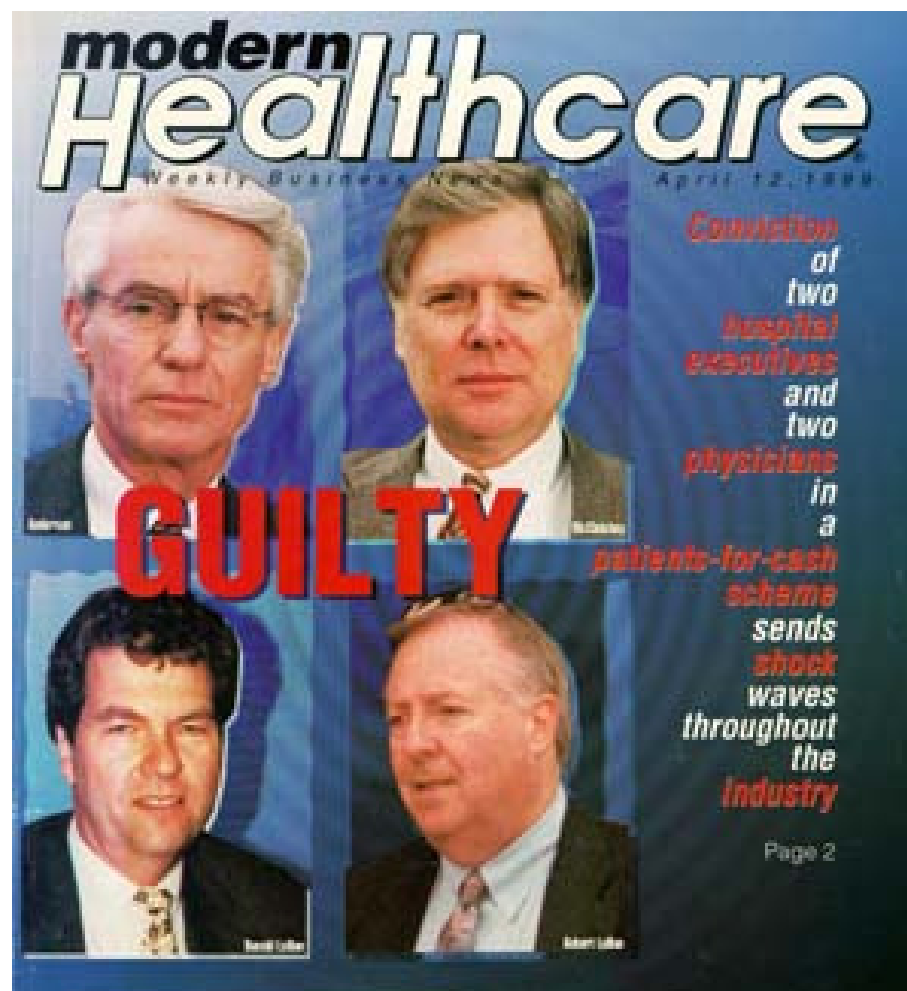
But—One Purpose Test

“We do not agree and hold that if one purpose of the payment was to induce future referrals, the Medicare statute has been violated.”

United States v. Greber, 760 F.2d 68 (3d Cir.1985)

What Does the AKS Prohibit?

U.S. v. Anderson, 85 F.Supp.2d 1047 (Kan 1999)



What Does the AKS Prohibit?

TAP PHARMACEUTICALS – Justice Dept. Press Release dated October 3, 2001

“The indictment charges that the **TAP** defendants offered to give things of value, including free drugs, so-called educational grants, trips to resorts, free consulting services, medical equipment, and forgiveness of debt, to physicians and other customers to obtain their referrals of prescriptions for Lupron to Medicare program beneficiaries, in violation of the anti-kickback statute.”

February 16, 2005: Dr. John Romano, (urologist), Plymouth, MA

- Billed for \$38,000 worth of Lupron samples received free from TAP representative
- \$20,000 fine, \$38,000 restitution
- Dr. Romano sentenced to 2 years probation (6 months home confinement w/electronic monitoring); community service—600 hours of free medical care to indigent patients

AKS Safe Harbors

- Investment Interests
- Space Rental
- Equipment Rental
- Personal Services and Management Contracts
- Sale of Practice
- Referral Services
- Warranties
- Discounts
- Employees
- Group Purchasing
- Waiver of Beneficiary Coinsurance and Deductible Amounts
- Increased Coverage, Reduced Cost-Sharing Amounts or Reduced Premium Amounts Offered by Health Plans
- Price Reductions Offered to Health Plans
- Practitioner Recruitment
- Obstetrical Malpractice Insurance Subsidies
- Investments in Group Practices
- Cooperative Hospital Service Organizations
- Ambulatory Surgical Centers
- Referral Agreements for Specialty Services
- Price Reductions Offered to Eligible Managed Care Organizations
- Price Reductions Offered by Contractors with Substantial Financial Risk to Managed Care Organizations

STARK Plain Language Restatement

If a **Physician** (or immediate family member) has a direct or indirect **Financial Relationship** with an **Entity**, unless an exception applies:

- the **Physician** may not **Refer** any **Designated Health Services (“DHS”)** to the **Entity**,
- the **Entity** may not bill for any **DHS** referred by the physician,
- no Medicare payments may be made for **DHS** referred by the physician, and
- the **Entity** must refund all moneys collected for **DHS** referred by the physician (unless no actual knowledge or reckless disregard re: the physician’s identity)

Stark - What's at Stake?

- \$15,000 CMP per improper claim
- \$100,000 penalty for schemes to circumvent
- Exclusion
- Improper claims may be pursued as false claims
- *Qui Tam* or “whistleblower” actions
 - Rapid City Regional

Definitions

Physician—MD, DO, Dentist, Oral Surgeon, Podiatrist, Ophthalmologist, Chiropractor

- Financial relationship with immediate family member of any of the above also implicates the rule

Definitions

Entity—a physician’s sole practice (not the physician him or herself), a practice of multiple physicians, any other person, sole proprietorship, public or private agency or trust, corporation, partnership, LLC, foundation, not-for-profit corporation or unincorporated association that furnishes DHS.

Furnishes DHS if: (1) CMS pays the entity for DHS, or (2) payment has been reassigned to the entity for DHS.

Definitions

- **Financial Relationship**—(can be direct or indirect)
 - **Ownership/Investment**
 - Includes equity, debt or other means
 - Stock, options, partnership, bonds, loans, etc.
 - NOT retirement plan interest, options received as compensation until exercised
 - **INDIRECT**—an unbroken chain of ownership/investment interests

Definitions

- **Financial Relationship (cont.)**
 - **Compensation**—any remuneration (payment or benefit, directly or indirectly, overtly or covertly, in cash or in kind) between a physician (or immediate family member) and an entity.
 - **Indirect Compensation**—(i) an unbroken chain of either compensation or ownership/investment interests between **Physician** and **Entity**, (ii) physician received compensation that varies with the volume or value of referrals, and (iii) the **Entity** has actual knowledge or acted with reckless disregard or deliberate ignorance of the physician’s financial relationship.

Definitions

- **Referral**—request (any form—written, oral, electronic, other) by a physician for, or ordering of, or certifying or recertifying the need for, any DHS paid including consultation by another physician, but not services personally performed by the referring physician (incident-to services are not personally performed)

Definitions

- **Designated Health Services**

1. **Clinical Laboratory Services**
2. **Physical Therapy, Occupational Therapy and Speech-Language Pathology Services**
3. **Radiology and certain other imaging services**
4. **Radiation Therapy services and supplies**
5. **Durable medical equipment and supplies**
6. **Parenteral and enteral nutrients, equipment, and supplies**
7. **Prosthetics, orthotics, and prosthetic devices and supplies**
8. **Home health services**
9. **Outpatient prescription drugs**
10. **Inpatient and outpatient hospital services**

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Exceptions to Stark Rule

- I. General Exceptions
- II. Exceptions that apply only to ownership/investment interest
- III. Exceptions that apply only to compensation arrangements

I. General Exceptions

- Group Practice
 - Personally performed services
 - In office ancillary services
- Services furnished by certain organizations (HMOs, prepaid plans, etc. as defined by the regulations) to enrollees.
- Academic medical centers (i) referring physician meets certain conditions (*bona fide* employee, *bona fide* faculty appointment, etc.), (ii) compensation paid to referring physician meets conditions (set in advance, FMV, etc.), and (iii) academic medical center meets conditions.
- Implants furnished by an ASC

I. General Exceptions

- EPO and other dialysis-related drugs furnished in or by an ESRD facility
- Preventive screening tests, immunizations, and vaccines
- Eyeglasses and contact lenses following cataract surgery
- Rural referrals for DHS to an immediate family member or an entity with which an immediate family member has a financial interest

I. General Exceptions

- Also:
 - Temporary Non-Compliance: new exception to the prohibition against billing
 - The financial relationship in question fully complied with an exception for 180 consecutive calendar days immediately preceding the non-compliance
 - The non-compliance is beyond the control of the entity, and the entity promptly takes steps to rectify (90 day limit), and
 - The financial relationship does not violate the anti-kickback statute.
 - Exception may only be utilized once every 3 years with respect to any physician.

II. Exceptions Related to Ownership/Investment

1. **Publicly Traded Securities**— (i) listed on NYSE or similar exchange that reports daily, (ii) stockholder equity exceeds \$75 million at end of last fiscal year or on average during previous three fiscal years.
2. **Mutual Funds**— defined in §851(a) of the IRC, assets exceed \$75 million at end of last fiscal year or on average during previous three fiscal years.
3. **Specific Providers**— ownership in (i) rural provider (not specialty hospitals), (ii) hospital in Puerto Rico, or (iii) whole hospital (not specialty hospitals)

III. Exceptions Related to Compensation Arrangements

1. Rental of Office Space
2. Rental of Equipment
3. *Bona Fide* Employment
4. Personal Service Arrangements
5. Physician Recruitment
6. Isolated Transactions
7. Certain Arrangements with Hospitals
8. Group Practice Arrangements with a Hospital
9. Payments to a Physician
10. Charitable Donations by a Physician
11. Non-Monetary Compensation up to \$300
12. Fair Market Value Compensation
13. Medical Staff Incidental Benefits
14. Risk-Sharing Arrangements
15. Compliance Training
16. Referral Services
17. Indirect Compensation Arrangements
18. Obstetrical Malpractice Insurance Subsidies
19. Professional Courtesy
20. Retention Payments in Underserved Areas
21. Community-Wide Health Information Systems

III. Exceptions Related to Compensation Arrangements

- Fair Market Value

- Generally, value in an arms length transaction, well informed buyers and sellers not otherwise in a position to generate business between them

- Physician Services—

- Average hourly rate for emergency room physician services in the relevant market
 - Hourly rate determined by averaging the 50th percentile national compensation level for physicians in same specialty in at least 4 of six listed surveys

III. Exceptions Related to Compensation Arrangements

- “Set in advance”—compensation will be considered same if—
 - An aggregate compensation, a time-based or per unit of service based amount, or a specific formula for calculating the compensation is set out in a agreement between the parties before services are furnished
 - Per unit OK and not related to volume or value of referrals if consistent with FMV and does not vary during the course of the agreement

III. Exceptions Related to Compensation Arrangements

Personal Service Arrangements—

remuneration to a physician, immediate family member or group practice (can be multiple arrangements) if

- Each arrangement is set out in writing, signed by parties, and specifies the services covered
- The arrangement covers all of the services furnished by the physician (or family member) to the entity (can cross-reference all agreements in each agreement or keep a master contract list)
- Aggregate services contracted for do not exceed what is reasonable and necessary for the legitimate business purposes of the arrangements

III. Exceptions Related to Compensation Arrangements

Personal Service Arrangements (cont.)

- Term of the arrangement is for at least 1 year (if terminated with or without cause, parties may not enter into substantially same arrangement during first year of the original term)
- Compensation is (i) set in advance, (ii) consistent with FMV, and (iii) except for physician incentive plan (as defined in regs), is not determined in a manner that considers volume or value of referrals or other business between parties

III. Exceptions Related to Compensation Arrangements

Non-Monetary Compensation up to \$300 compensation (except cash and cash equivalents) in the form of items or services that does not exceed \$300 per year if:

- Determination of the compensation does not take into account the volume or value of any referrals from the physician,
- The compensation may not be solicited by the physician (including staff) or immediate family member
- The arrangement does not violate the anti-kickback statute or laws/regulations governing billing/claims submission

Reporting Requirements

- Must submit information to CMS or OIG within 30 days of a request, the following information about all compensation or ownership/investment relationships (except publicly traded securities & mutual funds.)
 - Name & UPIN of each physician who has (or whose immediate family member has) a financial relationships w/ a reportable financial relationships
 - Covered services furnished by the entity
 - Nature of the financial relationship (extent/value of ownership or compensation)

Reporting Requirements

- Penalty for failure to report
 - CMP of \$10,000 per day for each day following the 30 day deadline established above

HIPAA Privacy and Security Back to the Basics

Issues resulting from the privacy regulations

- Understanding what and how much information can be used or disclosed with and without specific patient authorization
- Understanding what the patient's rights are and your obligation to your patients

Questions to ask

- How do we handle sharing information with family members?
- How can we use PHI in the clinics?
- How can we use PHI for research?
- Can we inquire about a colleague who is a patient?
- Can we bring visitors into the clinic or hospital?

Research

- Do we access PHI for research?
- Do we understand what research is?
- Do we have an authorization from the patient to do so?
- If not, do we have an IRB waiver of authorization?
- If not, has the information been de-identified?

Security measures

- Are our patient records in a secure cabinet?
 - Is it locked?
 - Who has access?
- Do we maintain information on our laptop, PDA, etc.?
 - How is the privacy protected?
 - Do we really need this information on the device?

Disposal of PHI

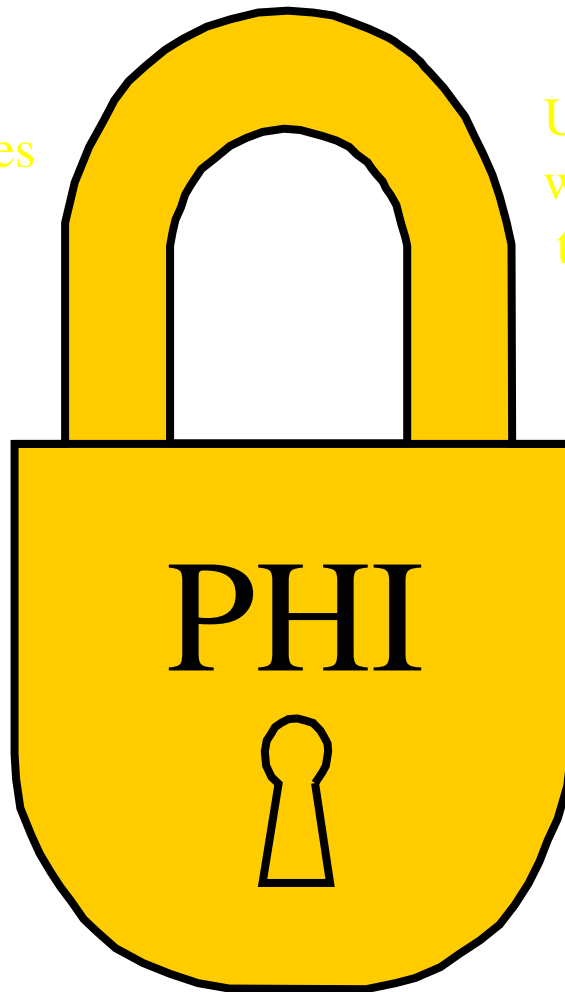
- How do we handle paper PHI?
 - Is it shredded?
 - Do we find PHI in the trash?
- How do we handle PHI in electronic form?
 - Can someone remove an unencrypted disk with PHI from our facility?



Uses & Disclosures
for TPO



Uses & Disclosures
w/an opportunity
to object



Uses & Disclosures in
the public interest



Authorization

Patient Rights

- Right to Privacy
- Confidential Communications
- Right to Request Restriction of Use and Disclosures for TPO and 164.510
- Accounting of Disclosures
- Right to Access
- Right to Request Amendment
- Right to Notice of Privacy Practices

Electronic Medical Records have the same privacy protections as hard copy records. To keep electronic medical records secure you should:

- 1) Never share your user ID or password.
- 2) Log off of the workstation when you leave.
- 3) Remember that you are accountable for any activity that occurs under your user ID and password.
- 4) Secure all electronic records which will be sent outside of the Hospital or U of L network.

Ways to Use and Disclose PHI in Research

- Privacy Board or IRB waiver or alteration of authorization
- De-identified data
- Limited Data Set
- Preparatory to Research
- Information on Decedents
- Authorizations

De-identified data?

- A) Names;
- (B) Street address, city, county, precinct, zip code, and equivalent geo-codes
- (C) All elements of dates (except year) for dates directly related to an individual and all ages over 89
- (D) Telephone numbers;
- (E) Fax numbers;
- (F) Electronic mail addresses;
- (G) Social security numbers;
- (H) Medical record numbers;
- (I) Health plan ID numbers;
- (J) Account numbers;
- (K) Certificate/license numbers;
- (L) Vehicle identifiers and serial numbers, including license plate numbers;
- (M) Device identifiers/serial numbers;
- (N) Web addresses (URLs);
- (O) Internet IP addresses;
- (P) Biometric identifiers, incl. finger and voice prints;
- (Q) Full face photographic images and any comparable images; and
- (R) Any other unique identifying number, characteristic, or code.

Limited Data Set?

- A) Names;
- (B) Street address, **town or city, county, precinct, zip code, and equivalent geo-codes**
- **(C) All elements of dates (except year) for dates directly related to an individual and all ages over 89**
- (D) Telephone numbers;
- (E) Fax numbers;
- (F) Electronic mail addresses;
- (G) Social security numbers;
- (H) Medical record numbers;
- (I) Health plan ID numbers;
- (J) Account numbers;
- (K) Certificate/license numbers;
- (L) Vehicle identifiers and serial numbers, including license plate numbers;
- (M) Device identifiers/serial numbers;
- (N) Web addresses (URLs);
- (O) Internet IP addresses;
- (P) Biometric identifiers, incl. finger and voice prints;
- (Q) Full face photographic images and any comparable images; and
- **(R) Any other unique identifying number, characteristic, or code.**

Uses or Disclosures Preparatory to Research

- To prepare a research protocol
 - Researcher provides the following assurances
 - The information will not be removed from the CE
 - Use or disclosure is sought solely to prepare research protocol
 - The PHI is necessary for the research purpose
- To recruit subjects
 - If the researcher is a member of the CE workforce information can be accessed
 - If researcher is not a member of the CE workforce then a partial waiver must be obtained.

Privacy Rule versus Common Rule

- The privacy rule applies to PHI.
- The Common Rule applies to research on human subjects.
- Thus the privacy rule may apply when the Common Rule does not.
- Data or specimens exempt from Human Subjects regulations may still require compliance with HIPAA.
- Common Rule kicks in once data is recorded, HIPAA kicks in when data is viewed.

Reminder

- The covered entity must account for disclosures that are not
 - For TPO
 - With an authorization
 - In a LDS
 - As an incidental disclosure
 - To the subject of the information
 - For national security purposes
 - Pursuant to 164.510
 - Prior to 4/14/03
 - To correctional institution

HIPAA Security Rule

- The security rule has three different groups of safeguards
 - Administrative
 - Physical
 - Technical
- Each set of safeguards has numerous standards
- Each standard might have one or more implementation specifications
- Implementation specifications may be required or addressable.

Why should you care?

- Improperly securing information on your pocket PC could make you liable for a security rule breach
- Communicating with a patient via email without properly securing the PHI could make you liable for a security breach.
- For those of you starting your own practice soon, you need to understand this.

HIPAA enforcement

- Enforcement by the federal government has not been very strong however
 - OCR receives the most complaints about HIPAA from physician practices
 - The OIG has begun a security audit
- The bigger concern
 - State law tort actions

HIPAA Privacy and Security Issues for EHRs

- What is an electronic health record?
- Reasons to Use an EHR
- Reasons Not to Use EHR
- Compliance Issues for EHR

What is an Electronic Health Record?

- A comprehensive electronic system
- Institute of Medicine 8 core delivery functions an EHR could be capable of performing
 - Health information and data
 - Result management
 - Order management
 - Decision support
 - Electronic communication and connectivity
 - Patient support
 - Administrative processes and
 - Reporting

IOM report published 7/31/03

Reasons to Use an Electronic Health Record

- Electronic Health Records provide advantages over paper records
 - Improved patient care
 - Reduction of costs
 - Improve revenue
 - Improve efficiency

Improved Patient Care

- Information is available quickly
 - Allows results to be reviewed more promptly to initiate appropriate treatment more promptly

Improved Patient Care (continued)

- Integration with other systems
- Improves patient safety
 - Improves legibility
 - Knowledge support
 - Alerts for contraindications
 - Prompts for additional tests or services

Reduce Costs

- Storage of records
- Transcription cost savings
 - Use of templates
 - Use of menu-driven data input
 - Voice recognition
- Efficiency
 - Decreased time looking for information
 - Allows for easier search of information
 - Allows for easier compilation of data

Improve Revenue

- Prompt documentation helps ensure that services billed match services provided based on documentation
- Improved documentation can assure that all services are captured

Reasons Not to Use EHR

- Costs
 - Systems may be expensive
 - Budgets are tight
- Integration issues
 - Existing systems
 - In-Patient versus Out-Patient systems
- Identification of the “official” patient record
- Providers can get or continue to be lazy

Compliance Issues

- Fraud and Abuse Issues
 - Signatures
 - Templates
 - Dual systems
 - Teaching physician notes
 - Intermingling of multiple provider notes

Signatures

- Electronic signatures
 - Requirements for electronic signatures
 - Suggestions for electronic signatures
- Teaching physician signatures
- Legal requirements for signature
 - Medicare conditions of participation
 - State Law
- Signing paper versus electronic record
- Provider discipline change in master table
 - RN changes to Nurse Practitioner

Templates

- Cookie cutter templates
- Pulling in data from prior encounters
- Note macros
- Automatic coding tools

Dual Systems

- Maintaining a paper & an electronic copy of a document
- Which is the “official record”?
- Ensuring that paper records get scanned into electronic record
- If the same data is maintained both places you lose the cost benefit of electronic records

Teaching Physician's Notes

- Can you tell who created the note?
- What is the process to get the resident's note to the teaching physician?
- Do you allow macros for the teaching physician's note?
- Can the teaching physician cut and paste the resident's note?
- Can the resident cut and paste the medical student's note?

Multiple Provider's Notes

- Notes by non-physician practitioners
- Notes by nurses and other ancillary staff

Compliance Issues

- HIPAA Issues
 - Access issues
 - Patient access issues
 - Other issues
 - Audit trails
 - Data integrity
 - Disaster recovery

Access Issues

- Authorized users
 - Defining levels of access
 - Unique user names and logons
 - Strong training regarding “need to know”
- Unauthorized users
 - Appropriate protections against external access

Patient Access Issues

- HIPAA requirements to inspect and copy
 - How does the record print out?
 - Is it user-friendly?
 - What happens if patient wants to inspect?

Other Issues

- Audit Trails
 - Can the system tell you who has viewed what data?
- Data Integrity
 - Authorization to change information
 - Finalizing or closing documents

Disaster Recovery

- Disaster recovery plan
 - Offsite server back-up
 - Replacement equipment
- Data Back-up
 - Storage offsite
 - Storing data on a local drive

Clinical Trials and Related Legal Requirements

Clinical Trials Billing

Important Medicare Basics

- Statutory basis for Medicare coverage follows this principle:
 - Medicare covers items and services that are “reasonable and necessary to diagnose or treat illness or injury”
 - Medicare is not a preventive care program – the patient must present with something wrong
 - Congress has allowed limited exceptions for coverage of preventive care

Clinical Trials Billing

Important Medicare Basics

- “Reasonable and necessary” rule is the basis for all coverage analysis performed by CMS and local Medicare contractors
- Certain “stand-alone” rules serve as exceptions to the basic principle so that certain items and services that may be “reasonable and necessary” are statutorily excluded from coverage:
 - Self-administered drugs in hospital outpatient setting
 - Hearing aides
 - Benzodiazepines under Part D

Where are the Medicare Rules?

- **Statutes (Congress)**
- **Regulations (HHS)**
- **Federal Rules (CMS)** – focus: what is reasonable and necessary?
 - National Coverage Determinations (NCDs)
 - Policy Manuals (best source: Benefit Policy Manual)
 - Transmittals
 - Misc Communications
- **Local Rules** (local Medicare contractors)
 - Local Coverage Determinations (LCDs)
 - Articles
 - Informal individual determinations by Medical Director

When Medicare is Silent

- CMS and local Medicare contractors have written rules for only approximately 15% of items and services that are covered by Medicare.
- If there is no Federal or local coverage rule and the item or service is not excluded from coverage, then Medicare covers the item or service if it is “reasonable and necessary” to diagnose or treat illness or injury.
- When utilizing the reasonable and necessary rule alone, it is critical that the medical necessity of the service be documented in the medical record and when assuming medical necessity for hypothetical patients (e.g., clinical trial enrollees), the file should contain the reasoning for why the service would be “reasonable and necessary” for every enrollee who receives the service.

Medicare Coverage: Basic Techniques

1. Look to list of NCDs for topic
2. Look to Benefit Policy Manual
3. Look to LCD for region
4. Look to persuasive LCDs from other regions (if no LCD for region)
5. If no rules, then: Is item or service reasonable and necessary to diagnosis or treat illness or injury?

Medicare Coverage: Basic Techniques

- Safety valve:
 - Local Medicare medical director!
 - If medical director can be convinced that an item or service is reasonable and necessary, then coverage is approved
- Presenting issues to the local Medicare medical director is a good approach if an investigator disagrees with a coverage analysis

Medicare Clinical Research Policy: Basics

- **The Clinical Trials NCD Rule:**

- Medicare covers “routine costs” during “qualifying clinical trials” as long as the routine costs:
 - Are not paid for by sponsor;
 - Are not promised free in the informed consent; and
 - Are ordinarily covered by Medicare

Medicare Clinical Research Policy: Basics – Qualifying Clinical Trials

- 3 Necessary Requirements:
 1. The study must investigate an item or service that falls within a Medicare benefit category:
 - See list of Medicare benefit categories
 2. The study must have therapeutic intent:
 - The protocol must have therapeutic benefit as a primary objective
 3. The study must enroll patients with diagnosed disease:
 - A study that focuses on preventive care is not a QCT

Medicare Clinical Research Policy: Basics – Routine Costs

- In QCTs, Medicare only potentially covers items and services that are “routine costs”
- Routine costs are:
 - Conventional care
 - Detection, prevention and treatment of complications
 - Administration of investigational item

Medicare Clinical Research Policy: Basics – Routine Costs

- Conventional Care
 - Goal: Identify objective sources
 - Medical Societies; Professional Associations
 - Medical Literature (articles & textbooks)
 - Guidelines.gov
 - Disease Associations (e.g., AHA)

Medicare Clinical Research Policy: Basics – Routine Costs

- Detection & Prevention of Complications
 - Identify some nexus between service and potential complication
 - Drugs: look to pharmacology section of protocol
 - Look to explanations in the informed consent

Medicare Clinical Research Policy: Basics – Routine Costs

- Not routine costs:
 - Items and services paid for by the sponsor
 - Items and services promised free in the informed consent
 - Items and services that are for research purposes only
 - The investigational item or service (generally)

“All other Medicare rules apply”

- **Any items and services that are “routine costs” must be reviewed against normal Medicare rules to determine whether coverage would exist outside the trial**

Compliance Issues with Clinical Trials Billing

- How do you separate the charges?
- How do you identify who to charge?
 - Sponsor
 - Third party payor
 - Subject
- Do all the documents for the trial say the same thing regarding billing?
- Is the sponsor providing anything for free?

Compliance Issues with Clinical Trials Billing

- How do you identify clinical trial services if you are the secondary provider?
 - Radiology
 - Pathology
 - Anesthesia

OIG Exclusionary Authority