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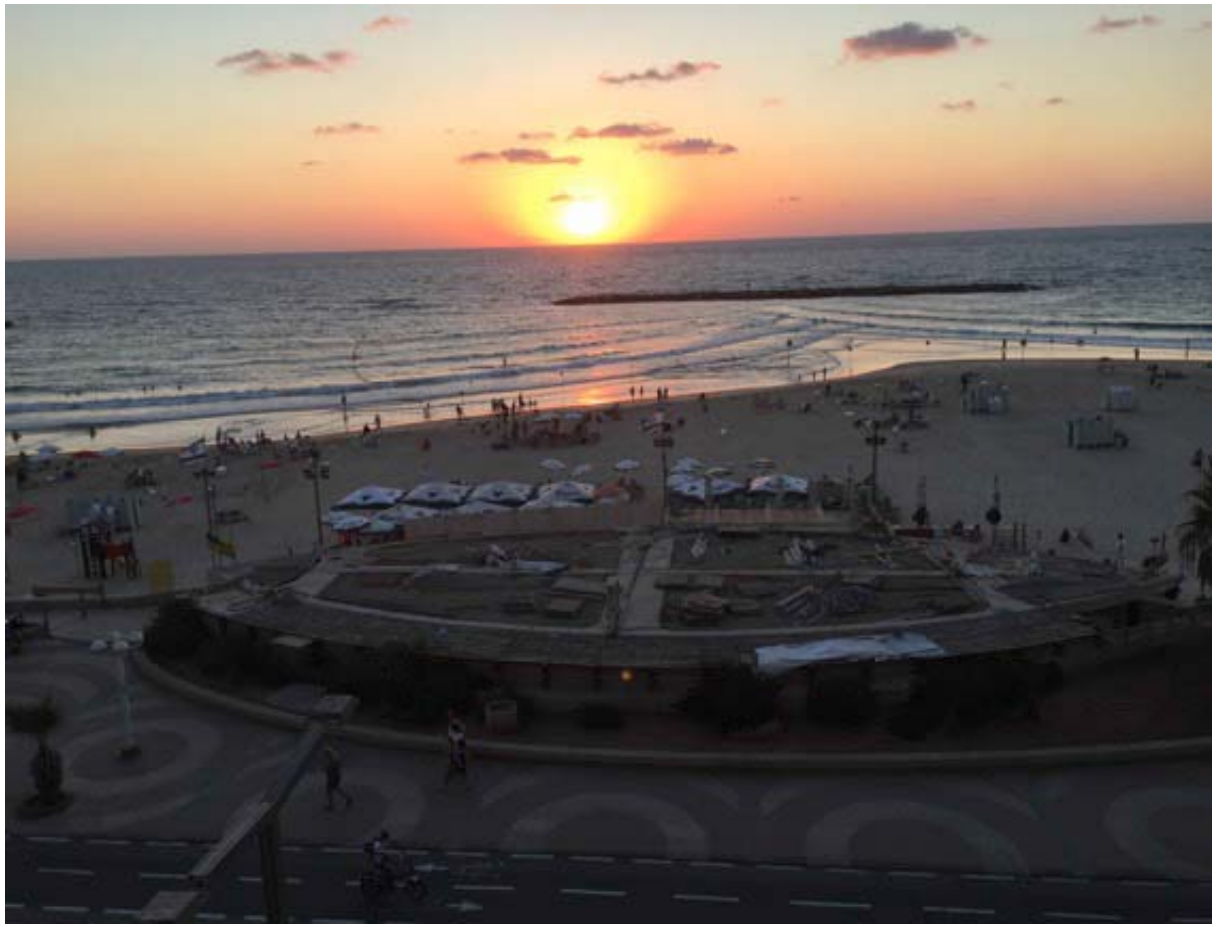
Medical Innovation in the U.S. Market: Maximizing Opportunities for Transactional, Regulatory, and Market Access Success

BIOMED 2017

Tel Aviv, Israel

May 24, 2017

TLV



Overview of Program

- Introduction to Reed Smith
- Market Access and Reimbursement
- DEALS, DEALS, DEALS
  - Compliance and Fraud and Abuse: How to Prepare for a Prospective Transaction
- Tel Aviv has Awesome Restaurants

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Reed Smith Introduction

Reed Smith Skills & Services

Food

Tel Aviv: Best food city in the world?

Reed Smith Represents Several Israel-based Start-up Medical Device Companies

Reed Smith Israel Business Team

- 40 lawyers
- Reed Smith's Israel Business Team provides a wide range of legal services to Israel-based and Israel-related clients who conduct business in the United States, Europe and Asia
- Reed Smith advises 8 of the top 12 companies on the Tel Aviv Stock Exchange listed on the Tel Aviv-125 Index

Life Sciences Contracting and Transactions

Leading Transactional Practice Serving Sector Clients

- Practice combines global capabilities of a large firm with small, consistent client teams to build a relationship to serve you better
- Team comprised of lawyers in the US, EU and China serving life sciences clients in entire range of corporate services on a global scale
- Significant experience with life sciences companies in all manner of contracts and arrangements entered into to discover, develop, manufacture and commercialize biotechnology, pharmaceutical and medical technology products
- In-depth understanding of life sciences clients' businesses, operations, strategies and objectives
- Team combines its knowledge of the industry, product development and management requirements, regulatory demands, and litigation risks to execute the full range of strategic domestic and international transactions
- Team works closely with colleagues knowledgeable in U.S. and international antitrust, IP, tax, FDA approval and compliance, health care (including fraud and abuse compliance and price reimbursement matters), product liability, insurance recovery, bankruptcy, real estate, employment and other areas

Practice Breadth

- Mergers and acquisitions
- Corporate, private equity & venture financing
- Product acquisition and divestitures
- Strategic alliances
- Joint ventures
- Collaboration and licensing
- Research and development
- Clinical trial and CRO agreements
- Manufacturing, tolling and supply arrangements
- Sales, promotion, marketing and other commercial arrangements

Reimbursement

- Our lawyers Health Care Group provide strategic guidance to clients on complex reimbursement, coverage, coding and third-party payment issues
- Detailed knowledge of reimbursement systems has been critical to our effectiveness in assisting providers and manufacturers in all types of regulatory enforcement actions, including Medicare/ Medicaid audits, recoupments and claims denials as well as Department of Justice ("DOJ") and state Medicaid fraud investigations
- We have extensive experience with CPT codes, ICD-10 codes and APC new technology and device pass-through reimbursement.
- Extensive experience advising clients on government price regulation programs, including Medicaid drug rebates, 340B and Veterans Health Care Act.
- Development of commercial pricing strategies

Practice Breadth

- Current Medicare fee schedule coding and payment systems
- CPT, HCPCS, and ICD-9 and ICD-10 CM coding strategies
- Local and national Medicare coverage and utilization restrictions
- Proposed changes affecting reimbursement levels, fee schedules, and per-diem payments
- Regulatory processes governing waivers and Medicaid managed-care programs
- Systemic reimbursement challenges

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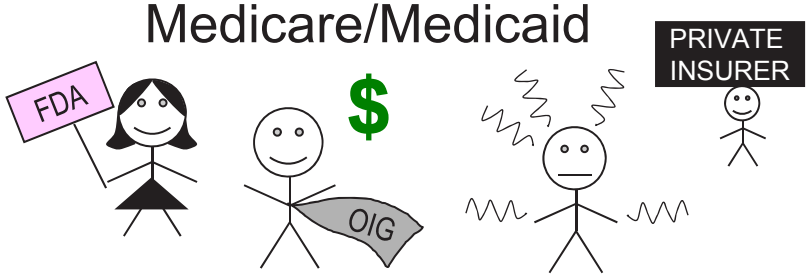
Market Access

Crazy World of Market Access in the US

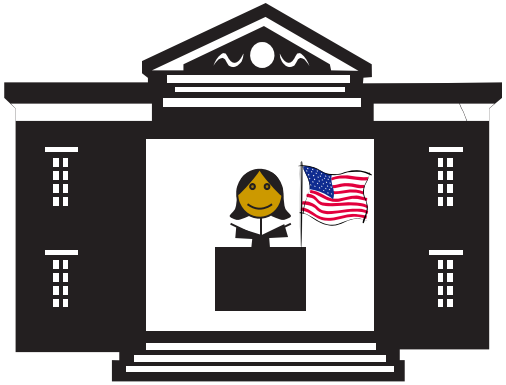
DEPT. OF JUSTICE

Medicare/Medicaid

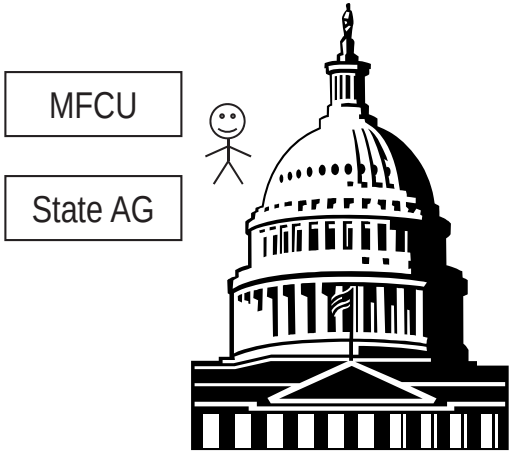


HEAT

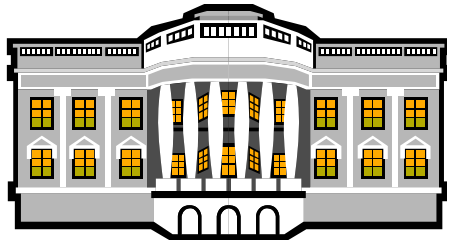
WHITE HOUSE



COURTS



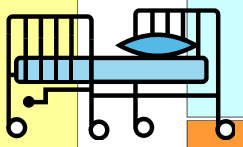
CONGRESS and STATE CAPITOLS



Health Care Reform

Identifying the Key Participants

- Providers and Suppliers
  - Hospitals (acute care, LTACHs, IRFs)
  - Nursing Homes/SNFs
  - Ambulatory surgical centers
  - Home Health Agencies
  - Hospice
  - Outpatient Therapy
  - Physicians
  - Pharmacies
  - DMEPOS
  - Clinical laboratories
  - X-Ray/MRI



- Innovators
  - Medical devices
  - Pharmaceuticals
  - Biotechnology

- Other
  - Group purchasing organizations
  - Distributors
  - Trade associations
  - Technology companies (billing software, electronic health record vendors)
  - Integrated delivery networks

- Health insurance
  - Government-funded (and partially government funded)
  - Private
  - Workers' compensation
  - Government (VA, DoD, Tricare)

- Government
  - HHS
    - FDA
    - CMS
    - OIG
  - DOJ

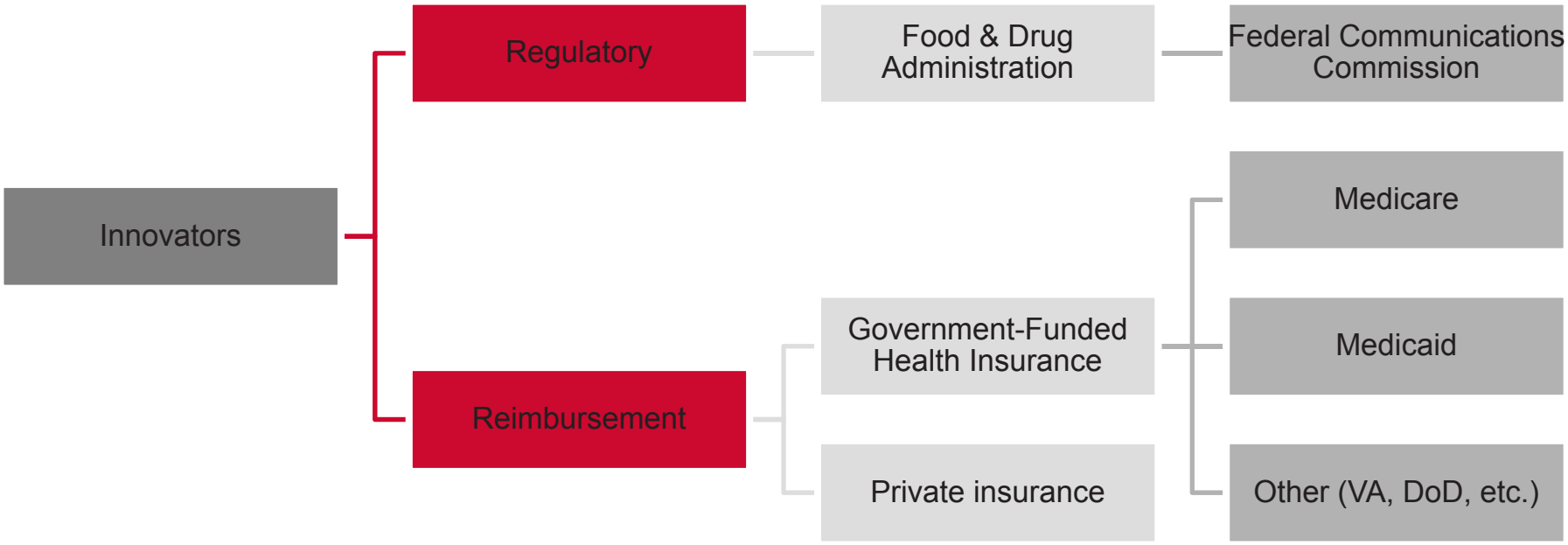
U.S. Market Access

Embarking on your US Market Access Journey

- Who is your intended patient and what is their age?
- Determining your regulatory pathway – Are there similar products on the market or is this truly new and innovative?
- Where will your device/product be used?
  - Inpatient
  - Outpatient
  - ASC
  - Physician office
- Determining your reimbursement pathway
  - Who are the primary payers?
  - Is CPT and ICD-10 coding available?
  - Is coverage available?
  - Is payment sufficient?

U.S. Market Access

Regulatory and Reimbursement Overview



Regulatory

- Devices must be approved/cleared by the FDA
  - Regulatory pathway
    - PMA approval – Clinical study must demonstrate safety and effectiveness
    - 510(k) premarket notification/clearance – Uses predicate devices to determine substantial clinical equivalences
    - De Novo – Alternate pathway to classify devices of low to moderate risk

- Determine the appropriate regulatory pathway to commercialize your product

Regulatory

- Drugs must be approved/cleared by the FDA in order to be marketed in the US
  - Regulatory pathway varies depending on type of drug
    - Investigational New Drug Application (IND)
    - Biologic License Application (BLA)
    - Generic Drug Review
    - Over-the-Counter (OTC) Drug Review
    - Biosimilars
    - Rare Diseases and Orphan Drugs
  - Drug/Device Combination (e.g., drug eluting stents, prefilled syringes)
    - Approval pathway varies

- Determine the appropriate regulatory pathway to commercialize your product

Reimbursement

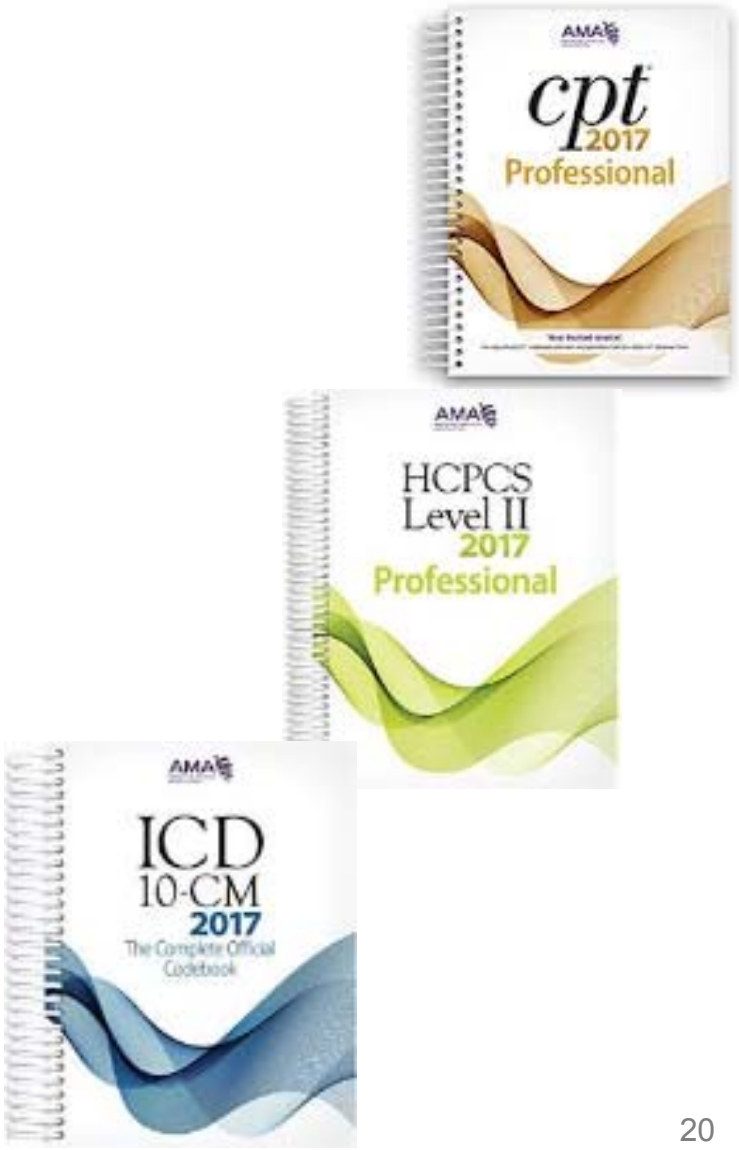
- Three main components of reimbursement:
  - **Coding**
  - **Coverage**
  - **Payment**

- A reimbursement strategy should be developed so that your product can be reimbursed by the wide variety of payers in the US

Reimbursement

Coding

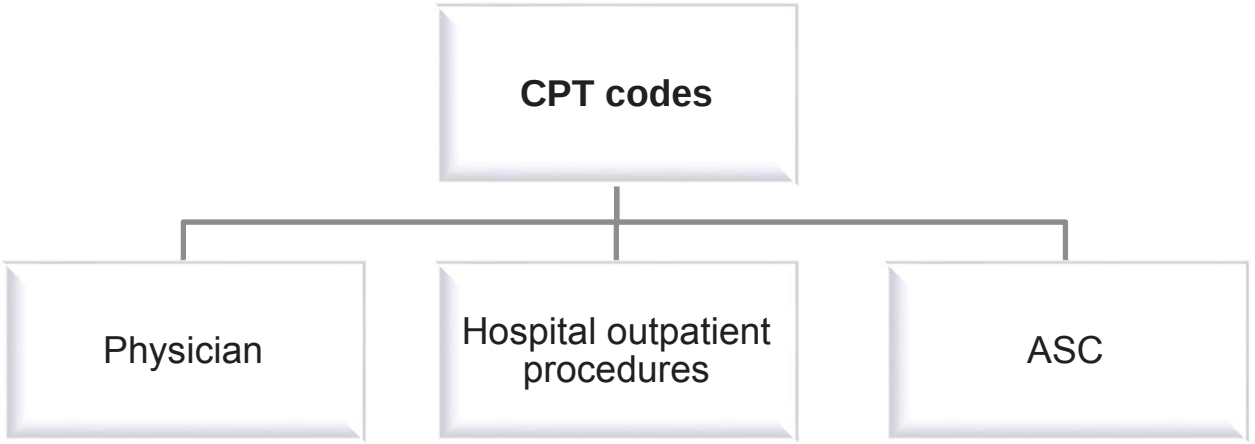
- A means to communicate with payers
- Systems of numbers and letters that describe:
  - Patient conditions/diagnoses
  - Services provided
  - Procedures/tests performed
  - Products/devices supplied



Reimbursement

Current Procedural Terminology (CPT©)* Codes

Used to report and bill services and procedures

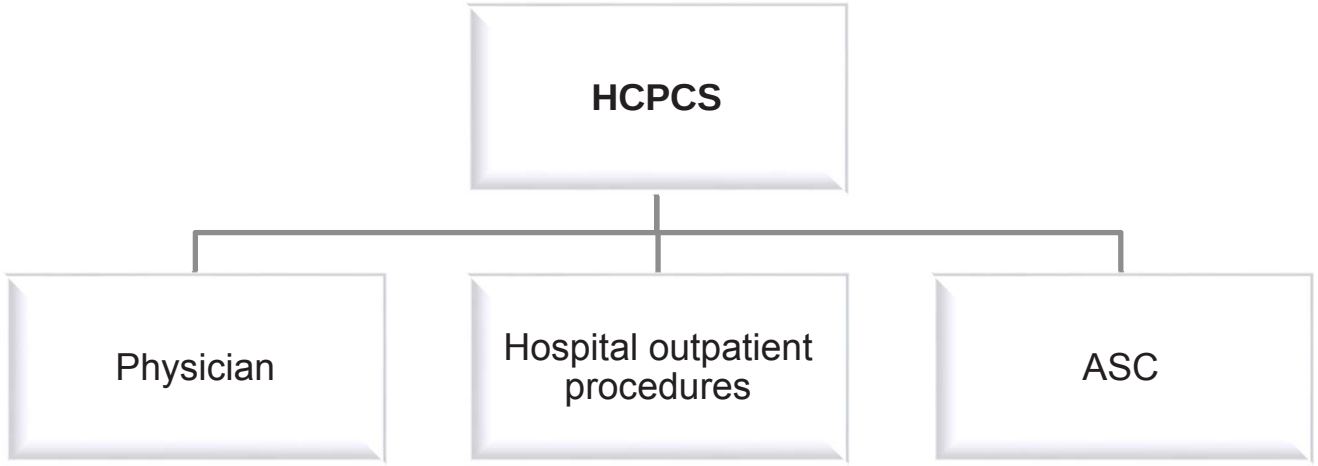


*Managed and administered by the American Medical Association (AMA).

Reimbursement

Healthcare Common Procedure Coding System (HCPCS) Codes

Used to report and bill certain drugs, devices, services and some procedures

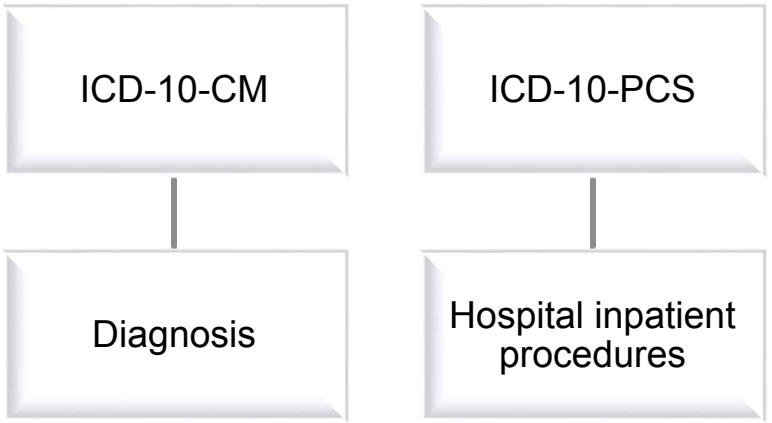


Managed and administered by Centers for Medicare & Medicaid Services (CMS).


PIZZA

International Classification of Diseases, 10th Rev., (ICD-10) Codes

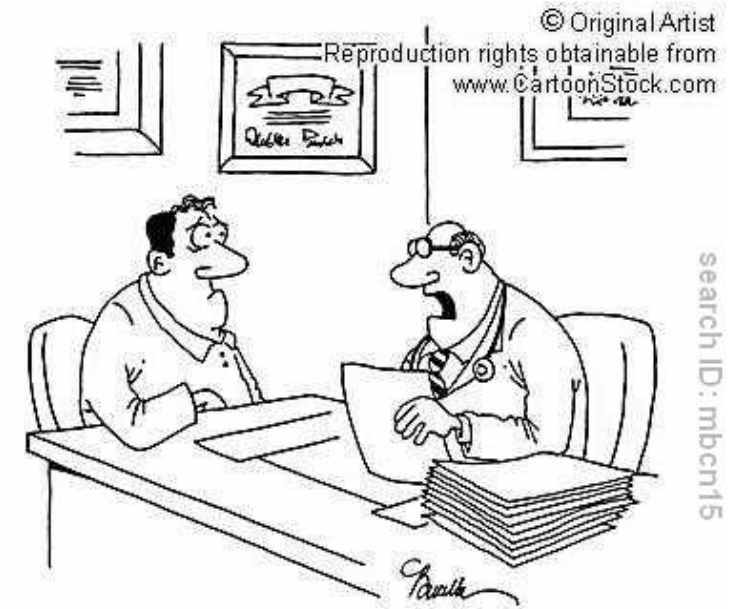
Used to report diagnosis and hospital inpatient procedures



Reimbursement

Coverage

- Coverage is the process, criteria and policies used by payers to determine whether or not to pay for services or procedures
- Payers may develop specific policies indicating whether they will cover or not cover a procedure/technology
- Keys to coverage
  - Peer-reviewed published literature
  - Society support
  - Clinical champions
- Coding ≠ coverage



Reimbursement

Criteria for Coverage and Medicare and Private Insurers Standards

- FDA approval/clearance
- Peer reviewed, published scientific evidence demonstrating clinical effectiveness of procedure/technology
- Medicare standard
  - Reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member (Social Security Act §1862(a))
- Private insurers standard
  - Technology/services must improve net health outcomes
  - Must be as beneficial as established alternatives (e.g., gold standard)
  - Improvement must be obtainable outside of investigational setting

Reimbursement

Payment

- Payment is the amount of money a payer is willing to pay for a given service, procedure or device

"Your insurance only pays 80% of my fee, so I only took out 80% of your appendix."

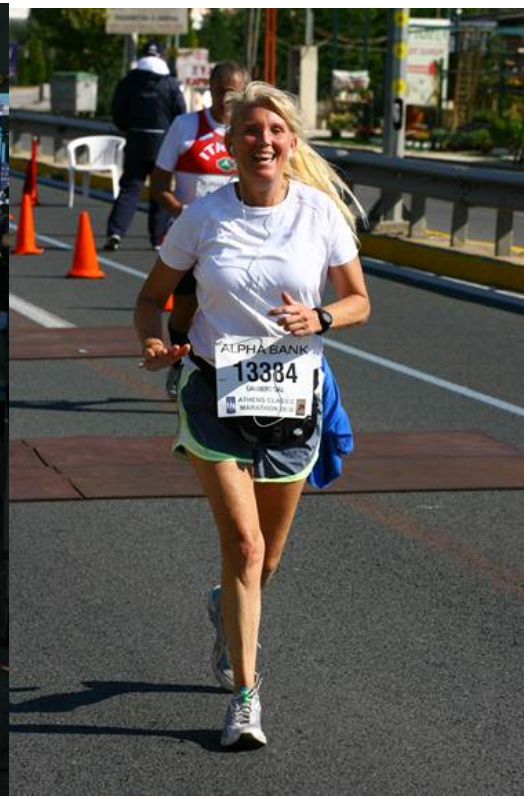
Reimbursement

Special Medicare Payment Mechanisms for New Technology

- Medicare can establish new codes to facilitate special Medicare payment mechanisms for new technology meeting certain criteria
  - New Technology Add-on Payment (Inpatient setting)
  - New Technology Pass-through Payment (implantable devices and biologicals – outpatient/ASC settings)
  - New Technology Ambulatory Payment Class Designation (new technology services/procedures – outpatient/ASC settings)

Reimbursement

Reimbursement is a Marathon Not a Sprint



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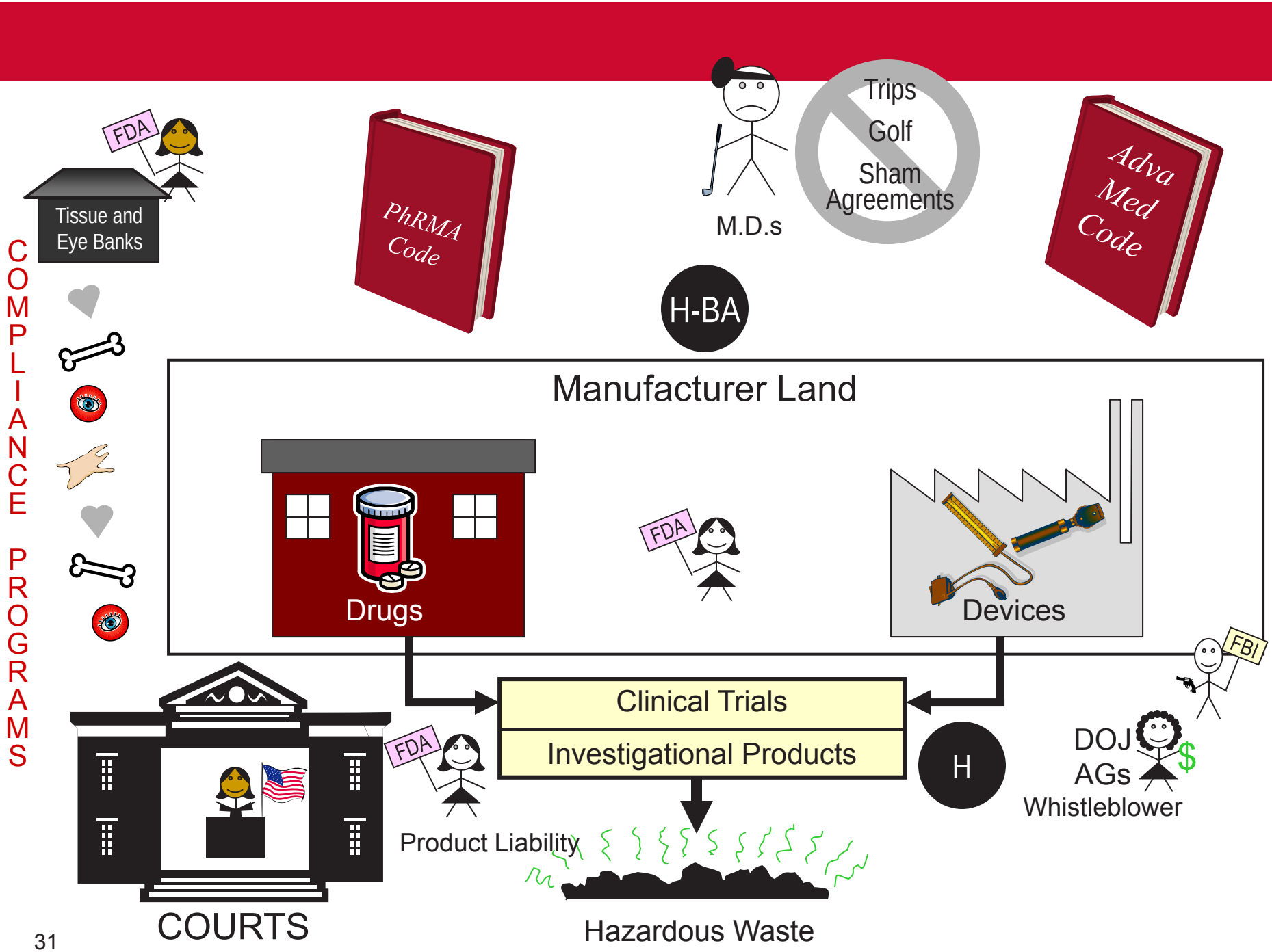
Preparing for Transactions: Compliance and Fraud and Abuse


FDA
Tissue and Eye Banks
COMPLIANCE PROGRAMS
PhRMA Code
M.D.s
Trips
Golf
Sham Agreements
Adva Med Code
H-BA
Manufacturer Land
Drugs
FDA
Devices
FBI
Clinical Trials
Investigational Products
H
DOJ
AGs
Whistleblower
$
FDA
Product Liability
COURTS
Hazardous Waste

Third Party Payment Programs

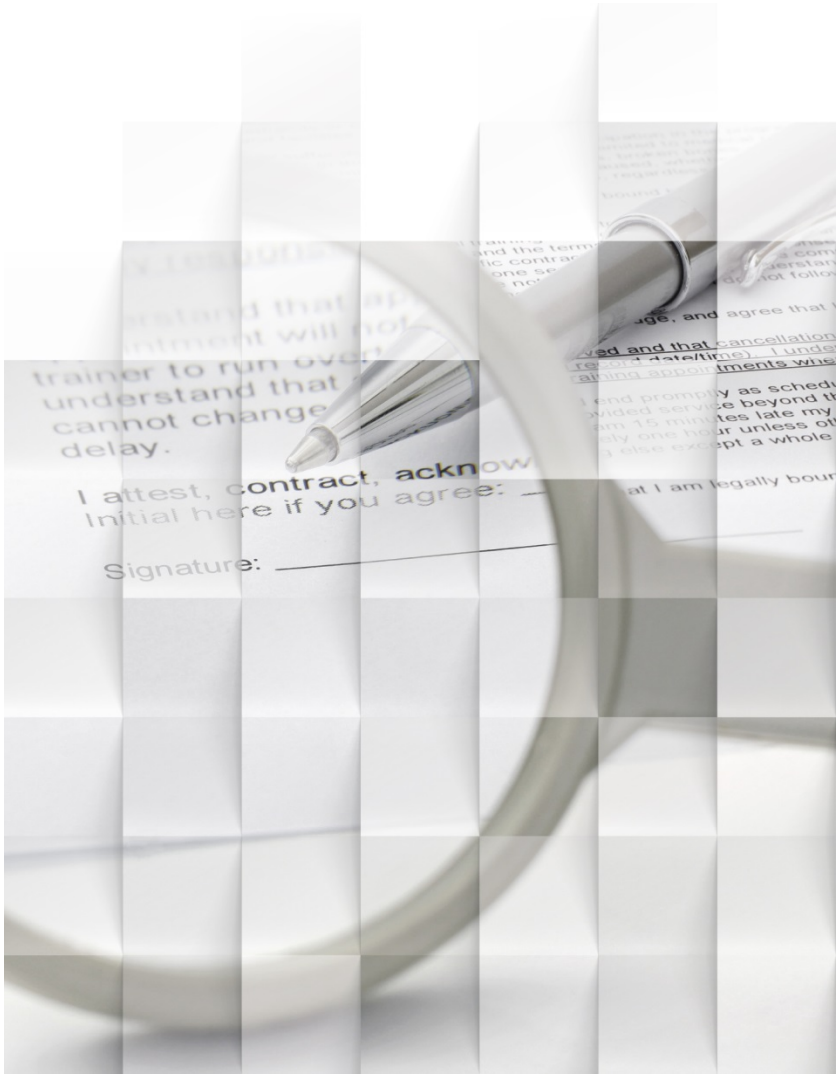
- If you participate in federal health care programs such as Medicare or Medicaid, you will be subject to many fraud and abuse laws, including:
    - Federal Anti-Kickback Statute
    - Stark Law
    - False Claims Act
    - Prohibitions on utilizing excluded personnel
- Why should we care?
    - The prohibitions are multiple and confusing
    - The statutes are broad
    - The case law is broader
    - Health care fraud is hot
    - The fines to providers and manufacturers are staggering.

Be Prepared: Health Care Compliance

- Compliance program/Code of Ethics
- Intense government scrutiny of health care providers and life science companies at the federal and state levels
- Subpoenas, audits, pre-payment reviews, terminations
- Even if you are not subject to an investigation, is the company in a “high risk” area (e.g., durable medical equipment? Specialty pharmacy? Pediatric dentistry?)?

What are appropriate provisions in the Purchase Agreement?

- Definitions key
- Tailor reps and warranties to business
- Litigation
- General compliance with laws
- Health care compliance with laws
- Conditions to closing
- Covenants/reporting obligations
- Events of default
- Indemnification
- Rep & warranty insurance



Developing an effective health care due diligence process

- Establish clear timeline and expectations
- Buyer's preparation of appropriate due diligence request list
    - Based on assessment of potential risk areas related to target's business
- Seller's provision of material's that are responsive to request list
    - Use of electronic data rooms
- Supplemental requests
- Review of materials furnished
- Use of clinical/billing consultants
- Interview Seller legal and compliance personnel
- Development of written or verbal due diligence report

Any proposed changes in laws/rules impacting your business?

- Home Infusion Case Study:
  - 21st Century Cures Act contained provision that shifted payments for Medicare Part B infusion drugs from average wholesale price model to an average sales price model.
    - Results in drastic reduction in reimbursement.
  - The Cures Act adds Medicare coverage of home infusion therapy, effective January 1, 2021.
  - Ramifications for pending and future transactions.

Tel Aviv: Best food city in the world?

The Biggest Regulatory Weapon….

- The Civil False Claims Act
  - Knowingly submitting or causing submission of false/fraudulent claim for payment or approval
  - Making/using false record material to payment or approval of a claim
  - Reverse false claims/Implied False Claims
- Penalties:
  - Qui tam provisions: relator can receive up to 30% of recovery
  - Treble damages + ($10,781.40-$21,562.80/claim)
  - Exclusion/Civil Money Penalties
- Example:
  - $100K damages x 3 = $300,000
  - 2000 claims x $21,562.80/claim = $43,125,600
  - Total liability = $43,425,600

FCA Liability is Expanding

- Off-label promotion
- Improper coding advice
- Kickbacks = false claims
- Quality and manufacturing issues (e.g., adulterated devices into interstate commerce)
- Implied False Claims

Anti-Kickback Statute: Basic Prohibition

- Knowingly and willfully
- Offer, pay, solicit or receive
- Any remuneration
- To induce or in return for
- Purchasing, ordering, or recommending or arranging for purchasing or ordering
- Items or services covered under federal health care programs

Penalties

- Criminal statute
- Five years in jail
- Criminal fines of $25K, potentially more
- Civil fines up to $50K and three times amount claimed, per violation
- Exclusion (civil or criminal)

Interpretive Guidance

- OIG Compliance Program Guidance for Pharmaceutical Manufacturers – made applicable via footnote 5 to devices
- Advisory Opinions
- Settlements and Corporate Integrity Agreements

Device/Pharma Issues Potentially Implicating the Anti-Kickback Statute

- Discounts and rebates
- Distribution service and inventory management fees
- GPO arrangements
- Write-offs
- Meeting and event sponsorships
- Data purchases
- Value added services
- Service fees, grants, consulting, research
- Billing assistance and reimbursement support
- Disease education support
- Coupons and promotions, free goods
- Meals, gifts, travel and entertainment

Key Take Aways

- The entry into the US market is both rewarding and challenging
- Reed Smith assists innovators with securing market access

Questions?

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