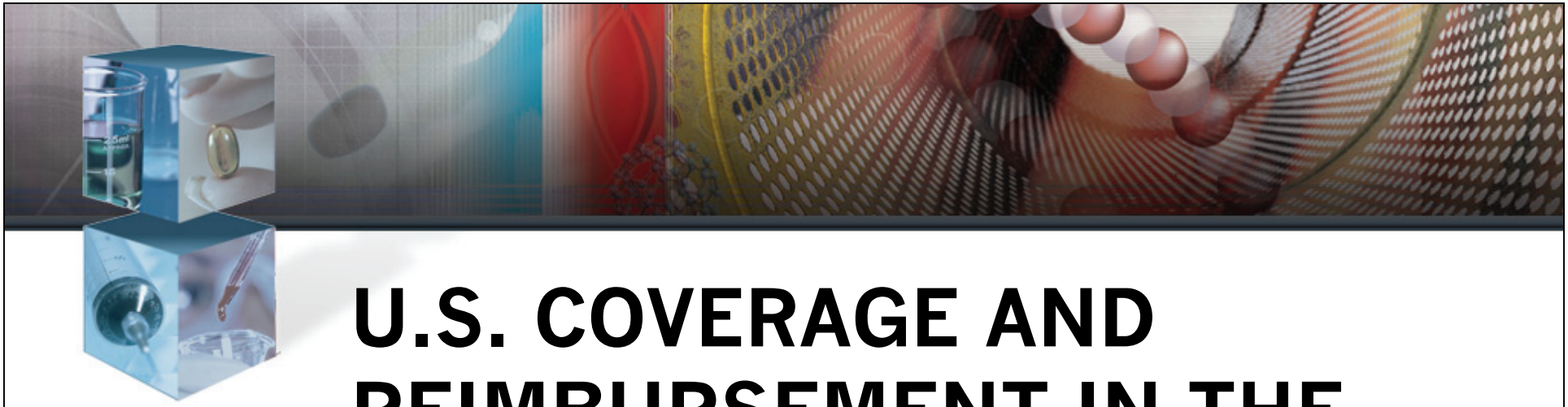

U.S. COVERAGE AND REIMBURSEMENT IN THE BIOMED FIELD

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U.S. Payers

- Government
  - Federal
    - Medicare
    - Veterans Administration
    - Department of Defense
  - State
    - Medicaid
- Private – Top plans include:
  - Blue Cross Blue Shield
  - United Healthcare
  - WellPoint/Anthem
  - Aetna
  - Kaiser

Types of U.S. Payers

- Fee-for-Service Plans
- Managed Care
  - Health Maintenance Organization (HMO)
  - Preferred Provider Organization (PPO)
  - Point-of-Service Plan (POS)

Who Makes Coverage and Reimbursement Decisions?

- Government
- Private insurance
- Physician specialty societies

Medicare Basics

- Largest health insurance program in the world
- Administered by Centers for Medicare & Medicaid Services (CMS)
- For individuals age 65 and older, and disabled

Medicare Basics

- Part A – Inpatient hospital care, post-hospital skilled nursing care, some home health services and hospice care
  - Prospective Payment Systems
- Part B – Physician services, outpatient hospital department care, laboratory services, some home health services, physical and occupational therapy, covered durable medical equipment and supplies, and some drugs
  - Fee Schedules
- Part D – Voluntary outpatient prescription drug benefit

Medicaid Basics

- Joint Federal/State program
- Administered by individual States with Federal oversight
- Program for categorically needy and medically needy
- State Children's Health Insurance Program (SCHIP)
  - Federal/State program to provide expanded coverage for children

Medicare Coverage: Relationship to FDA Approval

- FDA is a regulatory body
  - Is the product safe and effective?
- CMS is both regulator *and* purchaser
  - How does the technology compare with other existing alternatives?
- Historically, CMS coverage approval process follows FDA approval
  - Pending attempts to streamline
- CMS process is more public

Three Prerequisites for Medicare Coverage

- Number One
  - Must fall within one of 55 Medicare benefit categories
    - *E.g.*, physician, outpatient, DME, occupational therapy, etc.
  - Until 1996, no benefit category for prescription drugs
- Number Two
  - Must not be excluded from coverage
  - Examples of excluded items:
    - Immunizations
    - Hearing aids
    - Eyeglasses

Three Prerequisites for Medicare Coverage

- Number Three
  - Must be “reasonable and necessary”
    - For the diagnosis or treatment of illness or injury, or
    - To improve the functioning of a “malformed body member”
  - Excludes most preventative items
    - Exceptions: mammography, pap smears, prostate, colorectal and other screening tests

Medicare Coverage Process

- Two ways to obtain Medicare approval
  - Local contractor decisions
  - National Coverage Determinations issued by CMS
    - New technology or significant advance
    - Resolve inconsistent local decisions
    - Can be requested by any party (including manufacturer)
    - Certain requirements must be followed

Commercial Payers Coverage Process

- Many similarities in how commercial payers make decisions regarding new technologies and devices
- In most cases, process is under the direction of committee chaired by corporate Medical Director
- Decision-making process is based on clinical issues; what to pay is a separate analysis addressed after the coverage decision is made by a separate committee

Generic Components of the Commercial Payers Coverage Process

- Virtually all payers require FDA approval before consideration of a new technology or device
- All payers require that there be literature documenting the safety and efficacy of the technology
- Most payers use outside assessment companies as part of their process

Medicare Drug Coverage: Overview

- Part D
- Part B
- Off-Label
- Medicaid Drug Coverage
- Federal Price/Rebate Systems

Medicare Coverage of Drugs and Biologicals – Part B

- Part B covers "drugs and biologicals which are not usually self-administered by the patient"
- Includes drugs and biologicals listed in Medicare compendia (*e.g.*, United States Pharmacopoeia), drugs approved by hospital P&T or equivalent committee, and drugs used for anti-cancer chemotherapeutic regimen if use is for a "medically accepted indication"
  - Hospital outpatient setting
  - Physician office setting

Medicare Coverage of Prescription Drugs – Part D

- Medicare Modernization Act of 2003 created first comprehensive voluntary prescription drug benefit under Medicare program
- Known as “Medicare Part D”
- Largest expansion of Medicare program since its inception in 1965

Medicare Coverage of Prescription Drugs – Part D

- Part D covers majority of prescription drugs (excludes weight loss/gain, prescription vitamins as nutritional supplements)
  - Covered drugs are those covered by particular Part D plan
  - Decided through formulary placement and P&T Committee
  - CMS establishes certain standards
- CMS recognized in final Part D rule that off-label use is important, but does not have authority to require Part D plans to cover off-label use

Medicare Coverage of Off-Label Uses

- Part B Carrier has discretion to determine whether it will cover a drug off-label or off-compendia. Carrier must specifically "take into consideration" whether the use is on-compendia or discussed in authoritative medical literature or an accepted standard of medical practice
  - Must be FDA-approved drug
  - Other Medicare requirements must be met (*e.g.*, in physician office setting, "incident to" requirements)
  - Must be "reasonable and necessary"

Medicare Coverage of Medical Devices

- Depends on setting (*e.g.*, inpatient, outpatient, physician office)
- Setting determines reimbursement
  - Inpatient = Inpatient Prospective Payment System
  - Outpatient = Outpatient Prospective Payment System
    - Drugs over $50 assigned to own APC
    - Pass Through Payment for Drugs and Devices
  - Physician office = Physician Fee Schedule

Medicaid Coverage of Outpatient Drugs

- All Medicaid State plans must provide, at a minimum, certain services
  - Within this category, States may offer coverage of "covered outpatient drugs"
  - Defined as FDA approved for safety and effectiveness, drug that may only be dispensed upon prescription, and expressly excludes any drug used for a medical indication that is not medically accepted
- All 50 States and D.C. provide prescription drug benefit

Medicaid Coverage of Outpatient Drugs

- To receive federal financial participation for covered outpatient drugs, HHS Secretary must enter into national Medicaid Rebate Agreement with drug manufacturers
- Nothing in Medicaid statute prohibits States from covering off-label uses. States have authority to extend coverage for covered outpatient drugs beyond minimum federal floor coverage including coverage for off-label uses
- State Medicaid programs also have authority to implement variety of drug access restriction measure
  - *e.g.*, exclusion, prior authorization, formularies, prescription limitations

Drug Reimbursement: Federal Price/Rebate Systems

- Medicare Part B
- Medicaid
- Federal Supply Schedule/Federal Ceiling Price (negotiated prices for Veterans Administration/Department of Defense)

Key Pricing Concepts

CONCEPT	RELEVANCE
Average Manufacturer Price (AMP)	Medicaid Drug Rebate Program
Average Sales Price (ASP)	Medicare Part B
Average Wholesale Price	State Medicaid Programs, Commercial
Best Price (BP)	Medicaid Drug Rebate Program
Estimated Acquisition Cost (EAC)	State Medicaid Programs
Non-Federal Average Manufacturer Price (Non-FAMP)	Federal Ceiling Price
Wholesale Acquisition Cost (WAC)	Medicare Part B; State Medicaid Programs
Wholesale List Price (WLP)	Commercial; Government Programs Indirectly
Widely Available Market Price (WAMP)	Medicare Part B

Medicare Part B

- Medicare reimburses physicians and pharmacies for Part B drugs based on ASP as reported by manufacturer. Replaced AWP effective in 2005. AWP was perceived as "sticker price" vs. ASP based on actual sales
- ASP is average for drug taking into account all sales to all purchasers in U.S. (with limited exceptions) and taking into account price concessions. Calculated each calendar quarter for each 11-digit NDC number
  - Single source drug ASP = lower of 106% of volume-weighted average of all manufacturer ASPs for all NDCs of drug or 106% of WAC
  - Multiple source drug ASP = 106% of volume-weighted ASP for all manufacturer ASPs for all drugs within same multiple-source drug billing and payment code

Medicare Part B

- If OIG determines ASP exceeds WAMP by 5% or more, payment may be limited to WAMP or 103% of ASP in quarter. CMS has not yet acted on OIG WAMP reports
- Manufacturers report ASP prices within 30 days of close of calendar quarter to CMS. Rebates and price concessions may not be know when prices reported. "Lagged" price concessions are estimated based on 12-month rolling average

Medicaid Drug Rebate Program

- Manufacturers enter into national rebate agreement with HHS Secretary to provide rebates in exchange for outpatient prescription drug coverage under State Medicaid programs
- Manufactures pay quarterly rebate to State Medicaid programs on each unit of covered drug dispensed to Medicaid recipients

Medicaid Drug Rebate Program

- Rebates for branded drugs and generic drugs are calculated differently
  - Brand name drug rebate is currently greater of 15.1% of AMP or AMP minus BP
    - Possible legislation would increase the percentage to 20%
  - Generic rebate is 11% of AMP

Medicaid Drug Rebate Program

- AMP is the average price paid to a manufacturer for drug in the U.S. by wholesalers for drugs distributed to the retail pharmacy class of trade taking into account prompt pay discounts and other price concessions (other than Medicaid rebates).
- BP is lowest price available from the manufacturer to any purchaser (with limited exceptions) within the U.S. taking into account price concessions but not taking into account special packaging or labeling
- AMP and BP reported 30 days after last day of each calendar quarter to CMS. AMP to move to monthly reporting

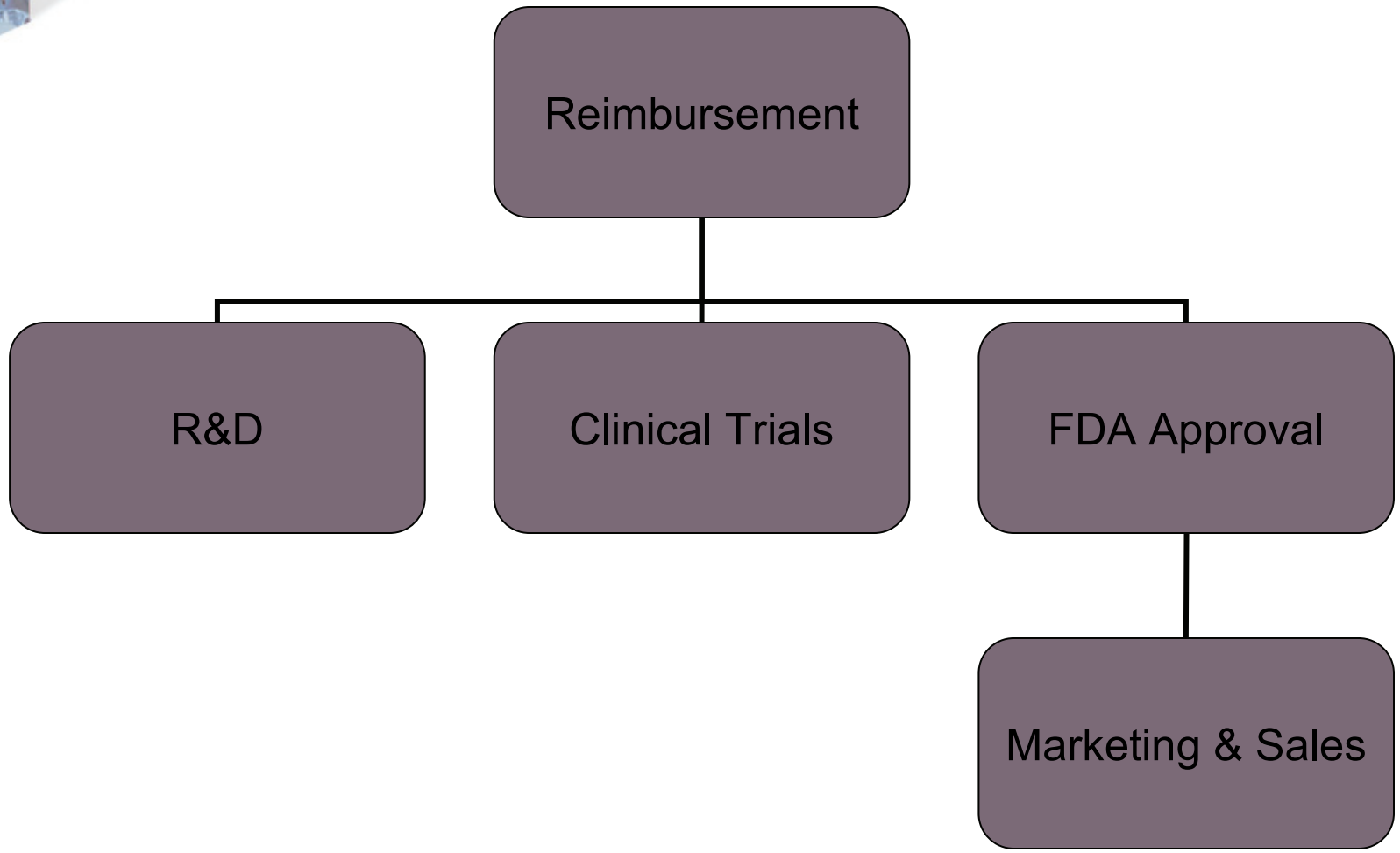
Federal Supply Schedule/Federal Ceiling Price

- Federal Supply Schedule (FSS) lists drug prices available to all direct federal purchasers. Manufacturers must list drugs on Federal Supply Schedule (FSS) for all government purchasers and agree to charge no more than the Federal Ceiling Price (FCP) to certain government agencies in order to receive payment from Medicaid and other government purchasers.
- FCP is statutory cap on branded drug prices paid by 4 largest federal drug purchases ("Big Four"). VA, DOD, Coast Guard, and PHS
- Price available to Big Four is lower of FSS or FCP.
  - FCP = Basic Discount plus Additional Discount subject to FSS cap
  - Basic Discount = 76% of Non-FAMP for prior year

Include Reimbursement in Regulatory Planning

- Scope of clinical trials
  - If Medicare reimbursement is important (*e.g.*, patients 65 years of age or older), include them in the trial
  - Expand clinical endpoints to reach "improvement in net health outcomes"

Reimbursement Can Inform Product Management



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Recommendations

- Early in product development, ask key reimbursement questions
- Make sure:
  - Regulatory approval pathway (IDE/PMA or 510(k))
  - Data (improved outcomes and cost effectiveness)
  - Labeling (support reimbursement and ultimate product management goals)

Recommendations

- Start reimbursement plan early in product development
- Partner with physicians and hospitals on developing and implementing reimbursement strategy
- Integrate reimbursement with R&D, clinical and regulatory affairs, and product management

Compliance:
Recent Drug and Device Settlements

Abbott/Ross	$615 million
Abbott/TAP	$875 million
Pfizer/Parke-Davis	$430 million
Guidant/EVT	$100 million
AstraZeneca	$355 million
Bayer	$257 million
GlaxoSmithKline	$88 million
Serono	$704 million
Medtronic	$40 million
Multiple investigations pending	

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Anti-Kickback Statute

- Anti-Kickback Statute prohibits the payment or receipt of anything of value, in cash or kind, as an inducement for the referral or generation of business
- Statute may be violated if even "one purpose" of the remuneration is inducements

Safe Harbors

- Examples:
  - Employment
  - Personal services contracts
  - Space and equipment leases
  - Discounts and warranties, etc.
- Failure to fall in safe harbor does not make the arrangement illegal
- Advisory process is available for arrangements outside safe harbors

Dual Relationships Between Customers and Companies

- Physicians are customers but also...
  - Inventors
  - Consultants
  - Researchers
  - Clinical instructors
- Hospitals are customers but also...
  - Research sites
  - Charitable entities

Arrangements that Raise Kickback Issues

- Payments for consulting, speaking, research or other services to physicians
  - Post-marketing studies or data collection
- Royalty payments
- "Charitable" donations
- Trips and entertainment in connection with marketing and product training

Other Arrangements that Raise Kickback Issues

- Free samples or equipment loans
  - Permissible if physician does not charge for use with patients
- Volume discounts
  - Permitted if structured to fit within the Discount Safe Harbor
- Free goods bundled with paid for items
  - Discount safe harbor permits if both items are reimbursed under same methodology and other safe harbor conditions are met

Sources of Guidance

- OIG Compliance Program Guidance for Pharmaceutical Companies (2003)
  - Partially applicable to device companies
- AMA Code of Ethics (1990)
- PhRMA Code of Ethics (2002)
- AdvaMed Code of Ethics (2003)
- Other domestic and international codes

PhRMA and AdvaMed Codes

- Gifts
  - Must be related to professional practice or benefit patients and be modest in value (less than $100, with exceptions under AdvaMed for texts and anatomical models)
  - Branded items of minimal value related to patient care (no golf balls or shirts)

PhRMA and AdvaMed Codes

- Marketing Meetings and Product Training
  - May not be in resort locations
  - Any reception or similar activities must be modest and subordinate to primary purpose
  - Golf, sporting events or other
  - Spouses/others may not be invited at company expense

Off-Label Promotion

- FDCA *does prohibit* manufacturers from marketing or promoting a drug for off-label uses
- If the information was provided by a manufacturer, statement must be affixed to it stating the source of the information, that it concerns off-label use, and the medication in question has been approved by the FDA for other uses

Illegal Off-Label Promotion

- Billing for an off-label prescription submitted to a Federal health care program (Medicare or Medicaid) that does not pay for the use may be considered a false claim under the Federal False Claims Act
- Example: Intermune Settlement (2006)
  - Claims submitted to Medicare and Medicaid as a result of alleged illegal promotion and marketing of Actimmune (treatment chronic granulomatous disease) were alleged to be false claims
    - Settlement $36 million

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