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Pre-Conference II:
How to Explain Device Reimbursement to Your CEO
Harvard University
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Hospitals, doctors & patients
use **the products,**
but ***someone else pays*****.**

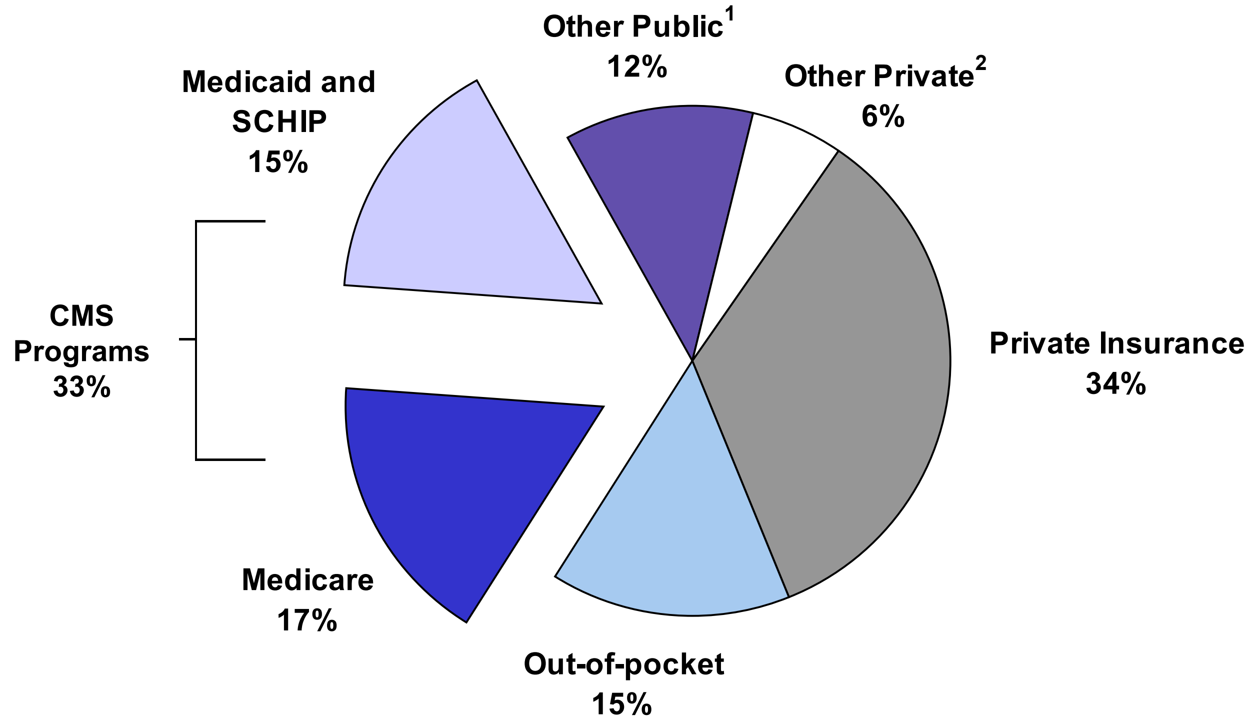
The third-party payers set the rules.

Third Party Payers/Insurers

- **Private/Commercial: BC/BS, PPOs, HMOs**
- **Medicare: 65+ & disabled**
  - **Part A: Hospital Inpatient**
  - **Part B: Outpatient, Physician, Diagnostics, Home Health, Administered Drugs**
  - **Part C: Managed Care**
  - **Part D: New Drug program**
- **Medicaid: State-run/matching $, for poor, includes long term nursing home care**

The Nation's Health Dollar, CY 2000

Medicare, Medicaid, and SCHIP account for one-third of national health spending.



Total National Health Spending = $1.3 Trillion

[1] Other public includes programs such as workers' compensation, public health activity, Department of Defense, Department of Veterans Affairs, Indian Health Service, and State and local hospital subsidies and school health.
[2] Other private includes industrial in-plant, privately funded construction, and non-patient revenues, including philanthropy.

Note: Numbers shown may not sum due to rounding.

Source: CMS, Office of the Actuary, National Health Statistics Group.

Medicare/Medicaid $ Facts

- **45% of the Nation's healthcare dollars are spent by Centers for Medicare & Medicaid Services (CMS) and state agencies for Medicare, Medicaid & State Children's Health Insurance Program**
- **20% of the federal government's dollars are spent by CMS**

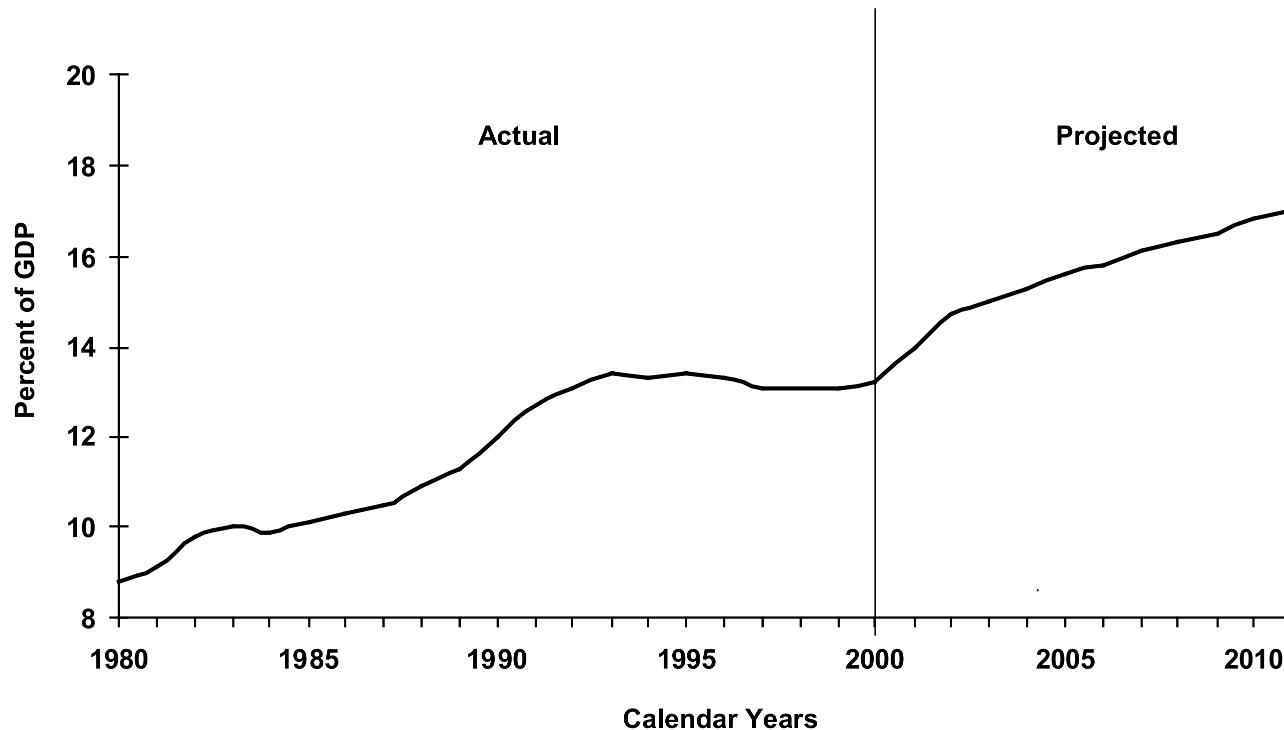
Medicare/Medicaid $ Facts

- **$519 billion was spent by CMS in FY 2005**

Program	Population	% of $	$ Spent
Medicare	42 million	63%	$327 bil
Medicaid	43 million	35%	$181 bil
SCHIP	6 million	1%	$5 bil

National Health Expenditures as a Share of Gross Domestic Product (GDP)

Between 2001 and 2011, health spending is projected to grow 2.5 percent per year faster than GDP, so that by 2011 it will constitute 17 percent of GDP.



Source: CMS, Office of the Actuary, National Health Statistics Group.

Reimbursement Planning:

Begin early in product development cycle to anticipate these rules and requirements.

1. **Coverage**
2. **Coding**
3. **Payment**

1. Coverage

- **Will Medicare or the insurer pay for this product or service?**
- **What are the limits or restrictions on the types of patients, indications, or conditions?**
- **Can you prove the *value* of a new product: clinical/peer-reviewed?**

Medicare Coverage

Statutory Authority: Section XVIII of the Social Security Act

- **Defined benefit categories**
- **Exclusions**
- **Treatment must be "reasonable and necessary" for the care of the patient**
  - **Source of national and local authority to establish additional coverage and non-coverage policies**

Medicare Benefit Categories Examples:

- Acute care for diseases, conditions, injuries
- Diagnostic, medical and surgical care, and rehabilitation in:
  - Inpatient hospital
  - Outpatient hospital
  - Physician offices
  - Ambulatory surgical centers

Medicare Benefit Categories Examples:

- Post-acute care in
  - Skilled nursing facilities
  - Patient’s home
- Hospice care
- Durable medical equipment, prosthetics & orthotics
- Other specified care (eg, ESRD; mental health, etc.)

Screening & Preventive Care

- Limited to Congressional mandates written into statute:
  - Cancer: Breast, Prostate, Colorectal
  - Cholesterol
  - High Risk Diabetes
  - “Welcome to Medicare” Physical
- Not covered:
  - Cosmetic items & services
  - Eyeglasses & hearing aids

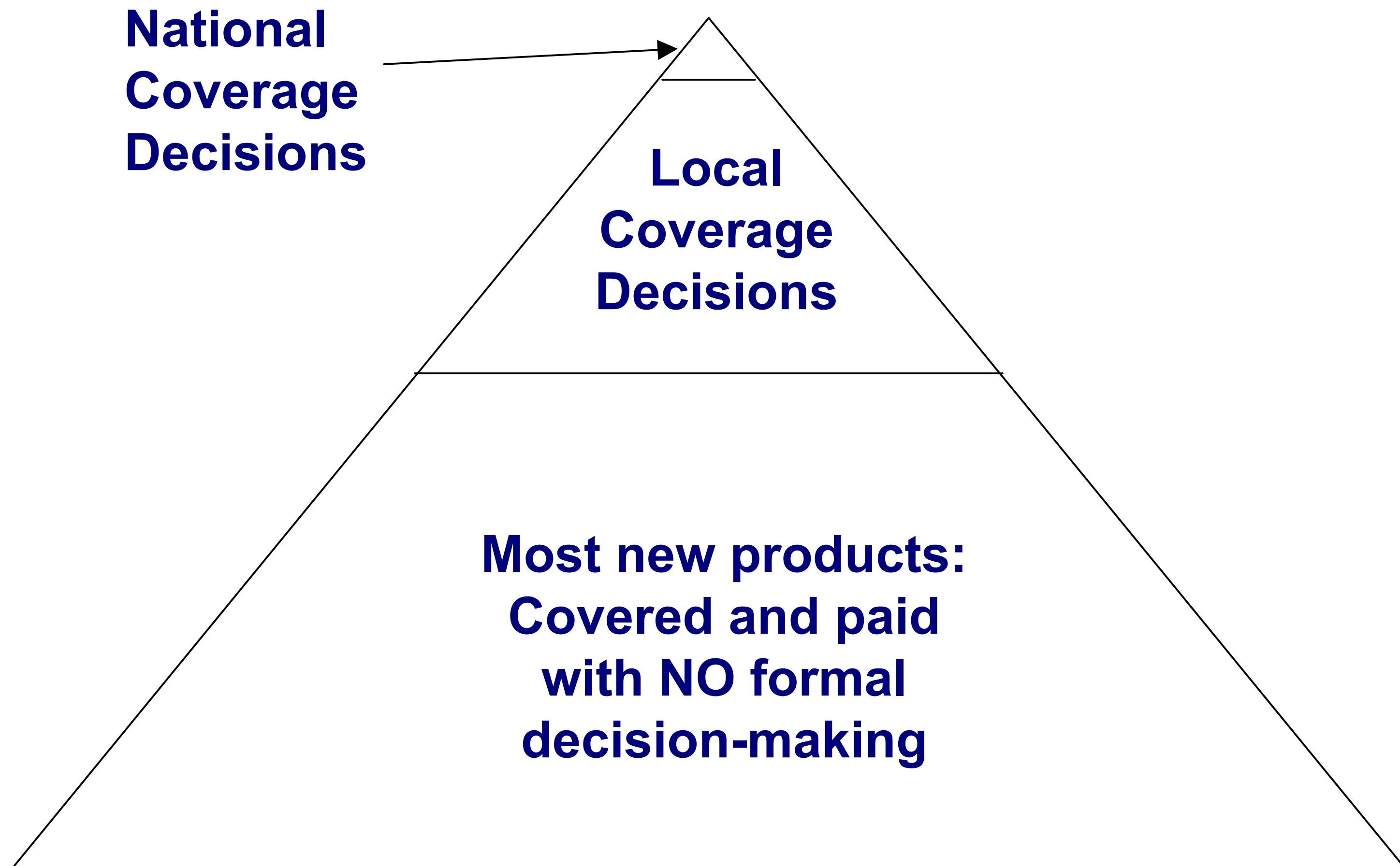
Medicare Coverage Planning

- Identify your product's benefit category:
  - How will it be used?
  - Where? If used in more than one setting, which is predominant?
  - Who and where were your clinical trials conducted?
  - Focus on diagnosis and treatment; avoid preventive & screening services

Medicare Coverage Planning

- **Coverage decisions are broad: By <u>type</u> of product, <u>not</u> by individual company's brand**
- **Most new products & services: Covered & paid <u>without</u> formal decision-making**

Medicare Coverage Planning



Local Coverage Process

- Decisions can vary by area
- Local medical community involvement
- Allows pay earlier in diffusion cycle
- Often relates to local “Program Integrity”
- Applies to:
  - New products: significantly different by clinical aspects or by cost
  - Existing items: “over-utilization” or high-cost (per item or volume used)

Criteria for National Process

- Requests for NCDs:
  - By manufacturers, providers, other stakeholders
  - Special “aggrieved parties”
  - Internally by CMS staff
  - Program integrity issues

Criteria for National Process

- To answer questions needing national attention:
  - Safety, effectiveness
  - Appropriateness compared to other available treatment,
  - Obsolescence
  - New information or evidence to change policies
- To resolve inconsistent or conflicting local policies

Criteria for National Process

- To address Program Integrity issues:
  - Significant increase in utilization
  - Fraud & abuse
  - Established products, as well as new
- Product represents millions $$ to Medicare program

New National Coverage Process

- **Coverage determination with conditions:**
  - **Specific type of patient**
  - **Specific indications**
  - **Specific providers or facilities**
  - **Coverage with Evidence Development - part of a data collection or study protocol**

New National Coverage Process

- Non-coverage determination:
  - Medicare will not cover or pay nationally or locally
- Coverage without conditions:
  - Very unlikely to issue unconditional decisions again

Example of a National Coverage Decision

Non-Implantable Pelvic Floor Electrical Stimulator

"Pelvic floor electrical stimulation with a non-implantable stimulator is covered for the treatment of stress and/or urge urinary incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training. A failed trial of PME training is defined as no clinically significant improvement in urinary continence after completing 4 weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength."

Medicare Coverage Planning

- Assess current local & national coverage decisions relating to product
- Seek local support
- Build reimbursement evidence & data:
  - Cost
  - Utilization
  - Risks & benefits for aged 65+
  - Comparative effectiveness & value
  - Quality of life, long term health outcomes

Medicare Coverage Planning

- **Join with competitors & other stakeholders to initiate or respond to a local or national coverage decision**

2. Coding

- Defines the condition, product, service
- Uses a uniform nationally-recognized number under HIPAA
- Systems maintained by AMA, HHS, and others

Why plan for coding?

- Used for billing & payment purposes
- Describes medical care provided and why
- Most encompass a range of services, products, conditions
- Edited, added, deleted, based on advances in clinical practice

Types of Codes

Type	Coding System	Provider Using Code
Diagnosis	ICD-9-CM, Diagnoses, Volumes 1 & 2	All providers indicate patient's diagnosis
Procedure or Service	ICD-9-CM, Procedures, Volume 3	Hospitals for <u>in</u>patient services
Procedure or Service	CPT-4 (HCPCS Level 1)	Physicians, hospital <u>out</u>patient, ASCs, labs
Products & Non-MD Services	HCPCS (Level 2)	Durable medical equipment, prosthetics, orthotics, supplies, administered drugs

Diagnostic Coding

- ICD-9-CM: International Classification of Diseases, 9th Revision, Clinical Modification
- 3-5 digits specifying the disease, condition, or reason for the patient's visit
- Volumes I & II:
  - I: Disease index
  - II: Tabular list

Diagnostic Code Example: “Itch”

Index of Diseases	Tabular list	Code
Itch: grocers’	Acariasis, other (eg, chiggers)	133.8
Itch: jock	Dermatophytosis, of groin	110.3
Itch: 7 year	Counseling for marital problems, unspecified	V61.10
Itch: swimmers’	Schistosomiasis, cutaneous	120.3

How Specific?

ICD-9 code: ***133.8 [Itch: grocers']***
Acariasis, other (eg, chiggers)

- **Does the product treat a very specific strain or stage of disease?**
- **If yes, it may be appropriate to establish a more detailed diagnostic description**

Inpatient Hospital Procedures

- ICD-9-CM Volume III:
  - Index to Procedures
  - Tabular list
- Used to code the service performed on inpatient hospital patients (24+ hour stay)
- Example: 47.0 Appendectomy
  - 47.01 Laparoscopic appendectomy

Outpatient & Physician Codes

- CPT: Current Procedural Terminology, 4th Edition, revised annually
  - 5 digits plus 2-digit modifiers
- Describes surgical, medical, diagnostic, therapeutic, clinical lab tests, and other services performed by physicians & other practitioners
- Outpatient & ambulatory facilities use these codes, instead of ICD-9 procedural codes

CPT Code Examples

- **44950 Appendectomy**
- **44970 Laparoscopy, surgical, appendectomy**

<u>Note</u>: "Surgical laparoscopy always includes diagnostic laparoscopy.
To report a diagnostic laparoscopy (peritoneoscopy) (separate procedure), use 49320."

Note on Coding New Technology

Using a laparoscope to perform surgery resulted in a series of new codes, based on the surgical procedure, not the device

- **60650 adrenal gland, excision**
- **47562 cholecystectomy (gall bladder)**
- **43645 gastric bypass**

CPT Category III Codes

- **Temporary codes for emerging technology, services & procedures**
- **Pros: Less stringent application requirements; semi-annual publication**
- **Cons: Medicare & other third-party payers <u>seldom pay</u>; non-specific coding alternatives <u>not</u> allowed**

HCPCS II Codes

- **CPT is Level I of Healthcare Common Procedure Coding System**
- **HCPCS Level II: For items & services not described by CPT codes**
- **5 digit alpha-numeric codes, with modifiers**
- **Product descriptions are generic, to cover more than one brand of product**

Types of HCPCS II Codes

A: Medical & surgical supplies & transport services

B: Enteral & parenteral therapy

C: Outpatient prospective payment codes – for new technology & radiopharms

D: Dental procedures, services & products

Types of HCPCS II Codes

- E & K: Durable Medical Equipment
- G & Q: Temporary procedures, services & products
- J: Administered drugs & chemotherapy drugs
- L: Orthotic & Prosthetic procedures

Types of HCPCS II Codes

P: Pathology & Lab services, including blood products

S & T: Codes for Medicaid & other payers

V: Vision services

Examples of HCPCS II Codes

- **A4253:** Blood glucose test or reagent strips for home blood glucose monitor, per 50
- **B4104:** Additive for enteral formula (eg fiber)
- **C1715:** brachytherapy needle
- **E0756:** implantable neurostimulator pulse generator
- **E0776:** IV pole

Examples of HCPCS II Codes

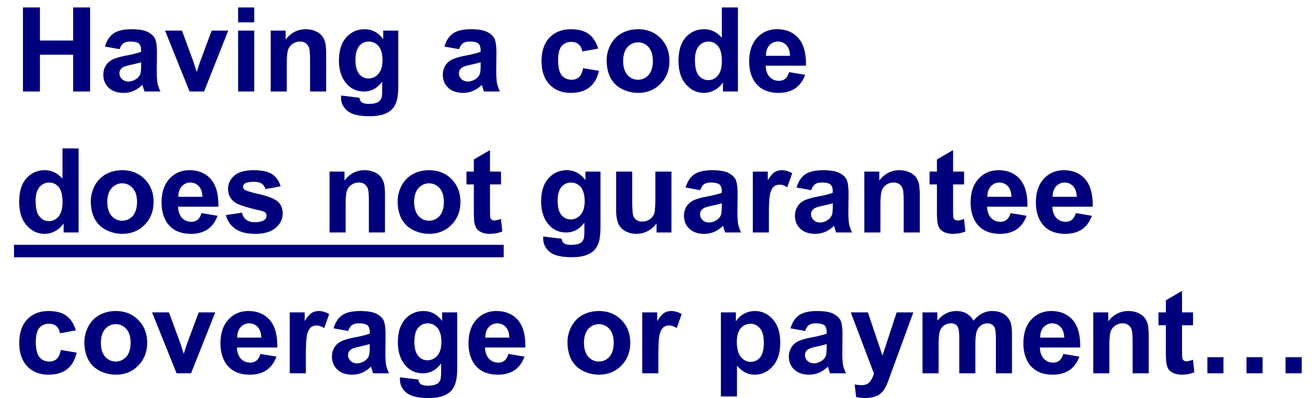
- **G0279: Extracorporal shock wave therapy; involving elbow epicondylitis**
- **J0585: botulinum toxin type A, per unit (Botox)**
- **L8030: breast prosthesis, silicone**

Planning for Coding

- What current diagnostic codes fit the indications for using the product?
- What procedural codes best describe how the physician will use the product?
- What codes will be used by the facility or provider to account for the use of the product?

Planning for Coding

- **If these codes are insufficient, what clinical data & which providers will support a new code?**


Having a code
does not guarantee
coverage or payment…

3. Payment

- How much will Medicare or the insurer pay?
- What are the rules controlling how they pay?
- What does the patient pay?

Medicare Payment Systems

Site of Service	Type of Payment	New Tech Program
Hospital Inpatient Acute Care	DRG bundle	Add-on pay or special DRG assignment
Hospital Outpatient Acute Care	APC bundle	Pass-thru category or New Tech APC
Physician	RBRVS Fee Schedule	Technical component calculation
Ambulatory Surgery Centers	Levels of Pay bundle	None

Medicare Payment Systems (cont.)

Site of Service	Type of Payment	New Tech Program
Skilled Nursing Facility	RUG bundle	None
Clinical Laboratory Tests & Services	Fee Schedule	None
Durable Medical Equipment, Prosthetics, Orthotics & Supplies	Fee Schedule (Competitive bidding in 2007)	None

Medicare Payment Systems

- **Every site of service has its own payment system**
- **Hospitals, ambulatory surgical centers, skilled nursing facilities, home health agencies paid with <u>bundled rates</u>**
- **Physicians paid by <u>each</u> procedure or service under a resource-based fee schedule**

Medicare Payment Systems

- Labs, durable medical equipment, prosthetics & orthotics paid under archaic fee schedules
- Most rates have geographic and other adjustments to the national amount

Payment System Examples

Inpatient Prospective Payment System: Diagnostic Related Groups (DRGs)

for Acute Inpatient Procedures

Annual Update: Proposed in May; Effective Oct

DRG	Description	Relative Weight*	Unadjust. Payment*	Avg. DaysI
164	Appendectomy with complications	2.2921	$10,400	8.2
167	Appendectomy without complication	0.8956	$4,060	2.3

Note: For illustration purposes only, based on 2005 rates.

Payment System Examples

Outpatient Prospective Payment System: Ambulatory Payment Classification (APC) Groups

Patient in hospital less than 24 hours

Annual Update: Proposed in Aug; Effective Jan

APC	Description	Relative Weight*	Unadjust. Payment*
131	Level II Laparoscopy (lap. appendectomy)	42.7526	$ 2,436
259	Level VI ENT proc. (cochlear implant)	444.1223	$ 25,307

**Note: For illustration purposes only, based on 2005 rates.*

Payment System Examples

Physician Resource-Based Relative Value Scale (RBRVS) Fee Schedule

Services by M.D. or under supervision

Annual Update: Proposed July; Effective Jan

CPT	Description	Relative Weight*	Unadjust. Payment*
44950	Appendectomy	15.60	$ 591
44970	Laparoscopic appendectomy	13.90	$ 526

**Note: For illustration purposes only, based on 2005 rates.*

Medicare Payment Systems

Special Consideration for New Tech:

- **Inpatient: Add-on payment or grouped to higher-paying DRG**
- **Outpatient: Pass-through category or grouped to a New Tech APC**
- **Physician: Technical component calculation**

Medicare Payment Systems

- **The <u>same device</u> is paid differently when used during an inpatient, outpatient, physician office, or home procedure**
- **Example: blood glucose monitoring**

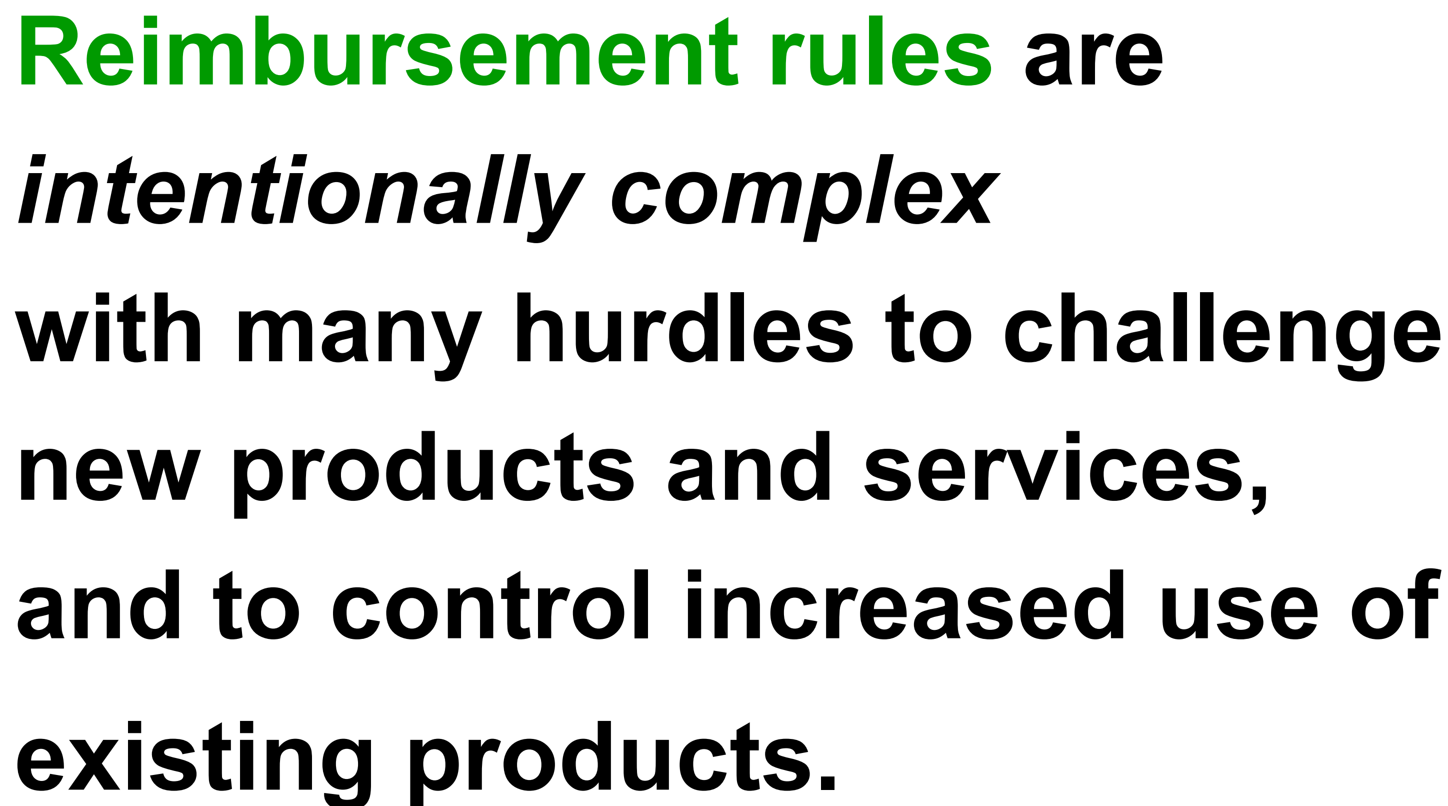
Medicare Payment Planning

- Assess product's use by site-of-service
- Determine payment rate for procedures using product & site differences
- Compare to rates for procedures using similar products
- Understand physician's rate for performing procedure
- Assess potential for special payment

Private Insurance

- Everything is negotiable – but negotiations favor the insurer
- Each insurer contracts separately with hospitals, physicians, labs, other providers
- Rates are proprietary & confidential
- Insurers both follow & lead Medicare

- Gain support from medical community for product
- Develop individual strategies for each insurer
- Join other stakeholders


Reimbursement rules are
intentionally complex
with many hurdles to challenge
new products and services,
and to control increased use of
existing products.

Reimbursement Planning Summary

- **Start early in product cycle to develop data & medical community support**
- **Understand how and where product will be used**
- **Assess Medicare coverage, coding, and payment policies**

Reimbursement Resources

- **Medicare Index:** **www.cms.hhs.gov/home/medicare.asp**
- **CMS Coverage:** **www.cms.hhs.gov/center/coverage.asp**
- **Coding**
  - **CMS resources**
    - **ICD-9: www.cms.hhs.gov/ICD9ProviderDiagnosticCodes/**
    - **HCPCS: www.cms.hhs.gov/MedHCPCSGenInfo/**
  - **AMA CPT resources**

    www.ama-assn.org/ama/pub/category/3113.html
  - **Ingenix: major publisher of coding & payment system reference books: www.ingenixonline.com**
- **Payment**
  - **Physician, DME, clinical lab fee schedules**

    www.cms.hhs.gov/FeeScheduleGenInfo/
  - **Hospitals and other facilities**

    www.cms.hhs.gov/ProspMedicareFeeSvcPmtGen/