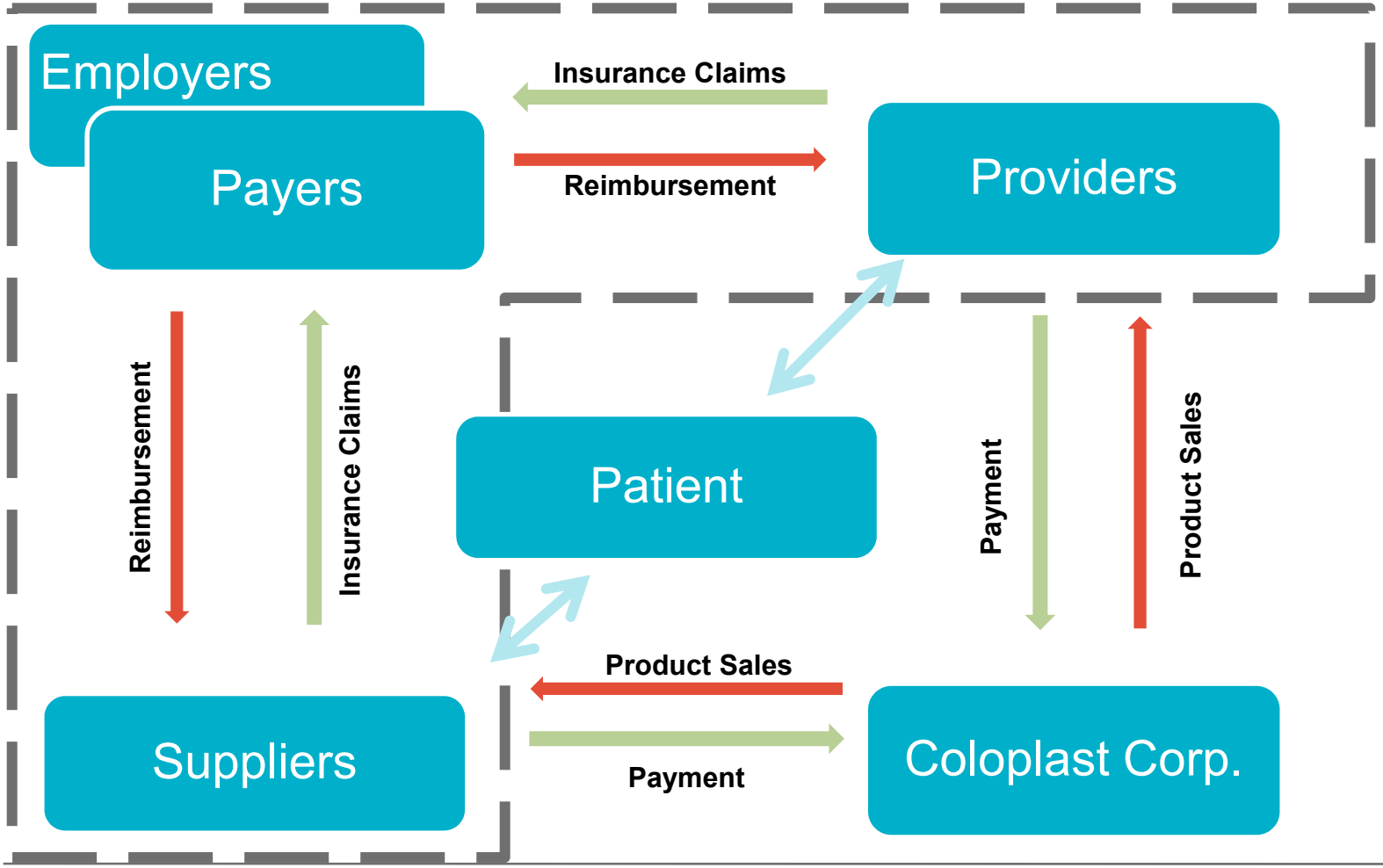
How Healthcare is Paid in the US

Coloplast Capital Market Day 2009

Russ Miller, Director of Reimbursement

The U.S. Health Insurance Environment and its Applicability to Coloplast Products

How Healthcare is paid in the U.S.



Agenda

- **Payers**
- Providers and Suppliers
- Insurance Transactions (Coverage, Coding and Payment)
- Insurance Reimbursement for the Surgical Urology Patient
- Reimbursement for the Ostomy, Wound or Continence Patient
- Reimbursement for Med Tech Innovation

Health Insurance by Payer Segment

	Lives (millions)
Medicare	40.2
Employment-based insurance (Private Payers)	174.8
Directly purchased/Individual market (Private Payers)	26.8
Medicaid	38.1
Military healthcare coverage	11.2
Uninsured	46.6
Total Coverage Arrangements	**337.7**

2008 US Population: 304,000,000

Source: United States Census Bureau, Current Population Reports, August 2006, Table C-1; Income Poverty and Health Insurance Coverage in the U.S.; 2005, p.60.

Payer Mix for Product Categories

	Medicare	Medicaid	Private Payers	Self Pay
Surgical Urology ▪ Men ▪ Women	 68% 40%		 30% 60%	 2%
Continence Care	63%	----------	37%	----------
Ostomy Care	70%	----------	30%	----------
Wound Care	40%	25%	25%	10%

CMS Centers for Medicare & Medicaid Services

The Medicare Program:

For people age 65+ or with certain disabilities.

Types of Medicare Insurance:

- ***Part A*** – Inpatient Hospital Care, Skilled Nursing Facilities, Home Health Care
- ***Part B*** – Physician Services, Outpatient Hospital, Medical Supplies, Ambulatory Surgery Centers
- ***Part C*** – Medicare Advantage Plans (HMOs and PPOs)

Primary Sites-of Service (SOS) for Coloplast Corp.

22% of Medicare beneficiaries.

The World of **Private Payers**

Private sector companies who administer health plans that utilize governmental or private sector dollars

- Approximately 1500 – 1700 private health insurance companies

Private Payers in the U.S.

Private health insurance companies operate as:

- Health Insurance Companies (for individuals or groups)
- Third Party Administrators (for employers or unions)

- Government Contractors (for the Medicare program)

Medicaid

A state-administered insurance program for low-income persons:

- Who are aged, blind, disabled or low-income families with dependent children
- Who receive public assistance
- Other low income disabled groups with high medical expenses.

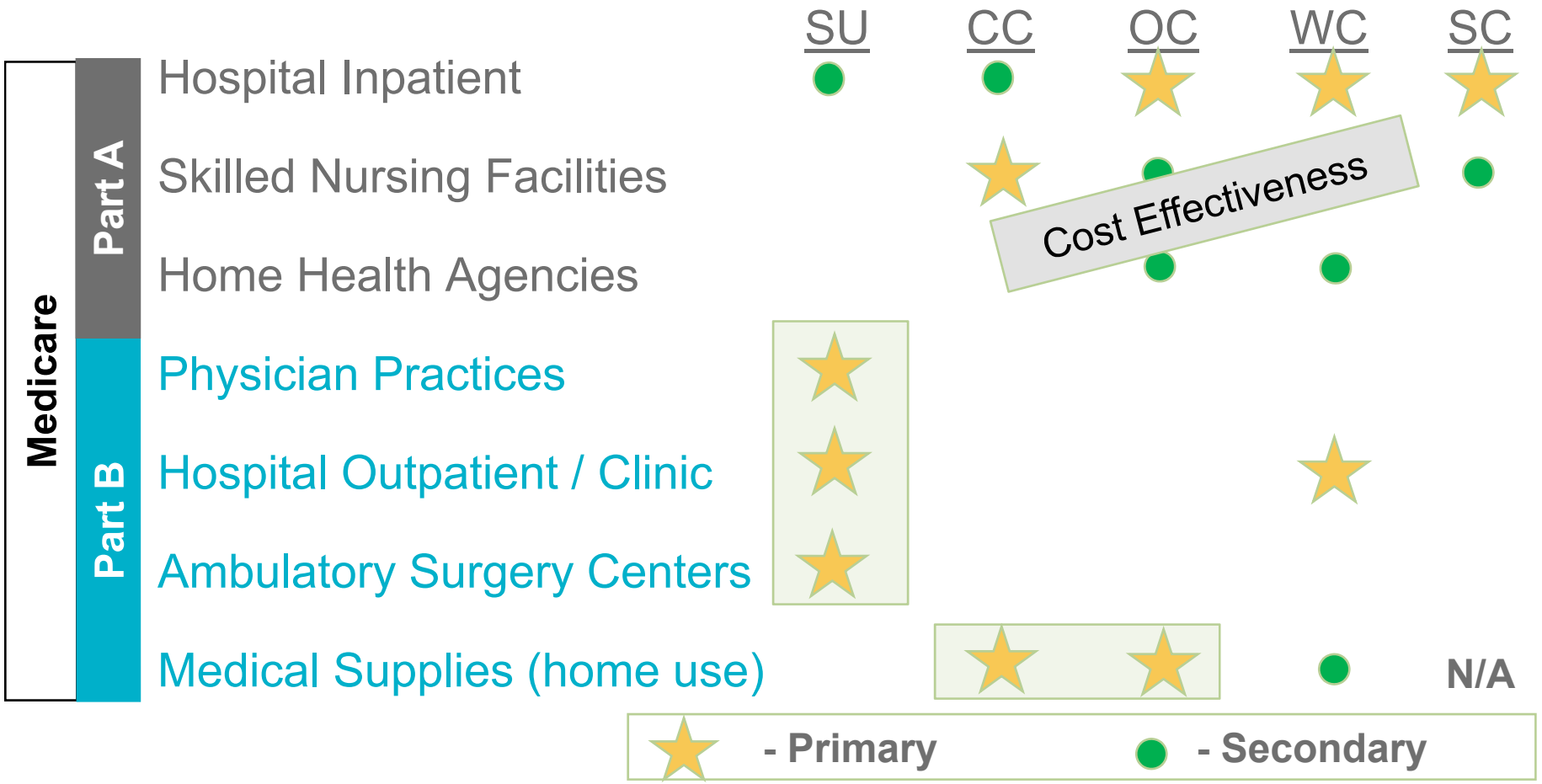
Eligibility is determined by federal and state law.

Medicaid programs are jointly funded by federal & state government.

Agenda

- Payers
- **Providers and Suppliers**
- Insurance Transactions (Coverage, Coding and Payment)
- Insurance Reimbursement for the Surgical Urology Patient
- Reimbursement for the Ostomy, Wound or Continence Patient
- Reimbursement for Med Tech Innovation

Product Categories by Provider/Supplier Type



Providers and Suppliers

 Integrated Delivery Network	A healthcare system of multidisciplinary providers owned or affiliated under common management. May include several hospitals, physician groups, rehabilitation centers, home health agencies, long-term care facilities and providers of Durable Medical Equipment and Supplies. There are approximately 300 IDNs in the US. Examples include: UCLA, Baylor and Mayo System.
 Hospital	An acute care facility that may or may not be part of an Integrated Delivery Network.
 Local Dealers	Regional and local providers of medical equipment and supplies to local healthcare facilities and patients. There are approximately 64,000 dealers in the US.
 GPO	For profit companies, usually corporations, that engage in contract negotiations on behalf of their member IDNs. The GPO retains an “admin fee” paid by the supplier, in exchange for the GPOs services. There are 6 national GPOs. Examples include MedAssets, Premier and Novation.
 National Distributors	Distribute large volumes of products to multiple healthcare entities, including hospitals, Durable Medical Equipment companies, and home healthcare organizations. Examples include: McKesson, Cardinal Health, Invacare Supply Group, Owens & Minor, Gulf South.

Agenda

- Payers
- Providers and Suppliers
- **Insurance Transactions (Coverage, Coding and Payment)**
- Insurance Reimbursement for the Surgical Urology Patient
- Reimbursement for the Ostomy, Wound or Continence Patient
- Reimbursement for Med Tech Innovation

The Building Blocks of Reimbursement

- **Coverage:** Defines the clinical conditions of a service or technology.
- **Coding:** The nomenclature used to classify medical services, supplies and diagnostic categories. Required for filing insurance claims with payers.
- **Payment**: Payments are made via defined payment systems and contracts. Payment assignment is driven by the coding on the insurance claim.

- **Compliance:** Providers, suppliers and manufacturers are subject to government oversight and audits. Applicable statutes include:
  - False Claims Act,
  - Anti-Kickback statutes
  - FDA prohibitions on off-label promotion.

The Building Blocks of Reimbursement

	Medicare	Private Payers
Coverage Policies	National / Local	Made by each entity
Coding Systems	Universal	
Payment Systems	Defined system for each site-of-service	Often adopt Medicare site-of-service structure / pay rates set by contracts

Coding – The Language of Reimbursement

CPT ® Coding (Current Procedural Terminology) – used for reporting procedures and services performed by physicians.
HCPCS Coding (Level II) – identification of devices, drugs, and supplies.

ICD-9-CM Procedure Coding – identification of inpatient hospital services.
ICD-9-CM Diagnostic Coding – identification of the reason for the encounter.

® CPT is a registered trademark of the American Medical Association.

Coding drives Payment

XX = payment 'driver' **x** = required, but not a payment driver

	Coding				
Site-of-Service	CPT	ICD-9 ** Diagnosis	HCPCS	ICD-9 Procedure	Payment
Medical Supplies		x	**XX**		Fee Schedule

** Critical for meeting payer coverage requirements

Coding drives Payment

XX = payment 'driver' **x** = required, but not a payment driver

	Coding				
Site-of-Service	CPT	ICD-9 ** Diagnosis	HCPCS	ICD-9 Procedure	Payment
Hospital Outpatient	XX	x	x		→ APC Group (PPS)
Hospital Inpatient		XX		XX	→ MS-DRG (PPS)
Physician Practice	XX	x	x		→ Fee Schedule
Amb Surg Center	XX	x	x		→ Fee Schedule
Medical Supplies		x	XX		→ Fee Schedule

** Critical for meeting payer coverage requirements.
PPS – Prospective Payment System.

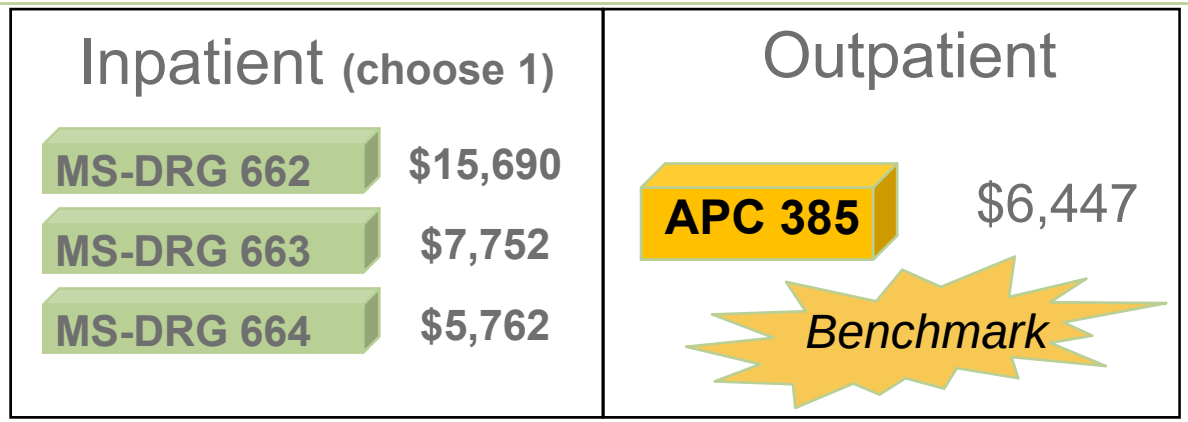
Agenda

- Payers
- Providers and Suppliers
- Insurance Transactions (Coverage, Coding and Payment)
- **Insurance Reimbursement for the Surgical Urology Patient**
- Reimbursement for the Ostomy, Wound or Continence Patient
- Reimbursement for Med Tech Innovation

Medicare Prospective Payment Systems

➢ Hospital Inpatient and Outpatient

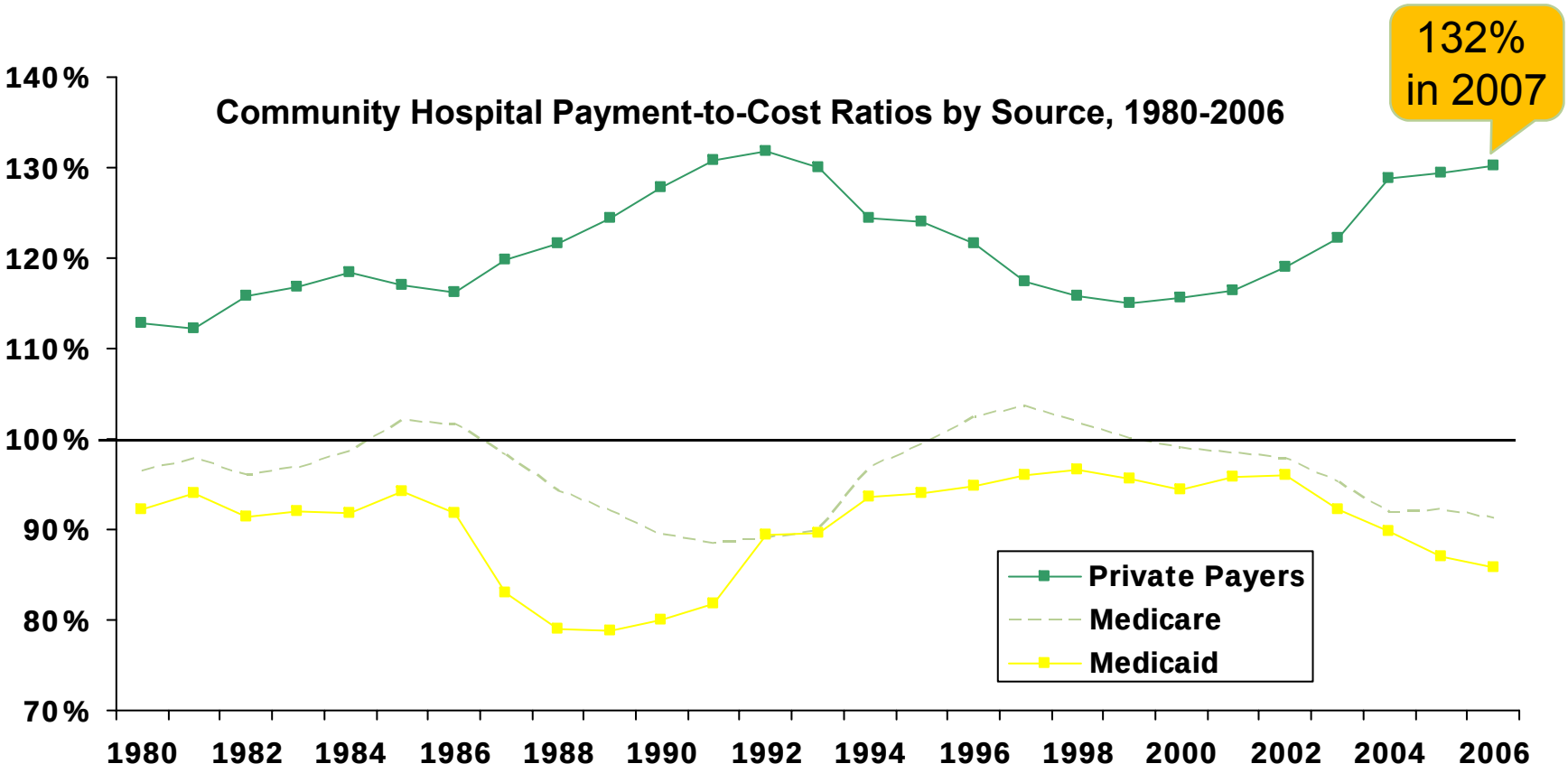
Example: Virtue Male Sling System



- > 24 hour stay (patient in bed).
- Based on diagnosis and procedure.
- Subdivided by Severity.
- Data-driven Payment (Claims data).
- Geographic adjustment.

- < 24 hour stay (observation room).
- Based on procedures only.
- Data-driven Payment (Claims data).
- Geographic adjustment.

Private Payer Reimbursement is critical for Hospital Profitability

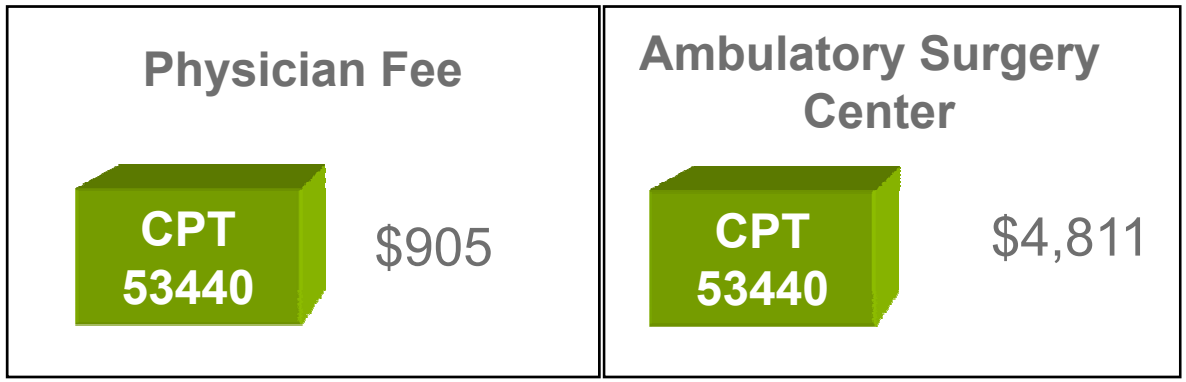


Source: American Hospital Association.

Medicare Fee Schedules

➢ Physician and Ambulatory Surgery Center

Example: Virtue Male Sling System



- Formula-driven Payment
  - Relative Value Units (RVUs)
  - Sustainable Growth Rate (SGR)
- Geographic adjustments

- Factored from the Hospital Outpatient Payment
- Geographic adjustments

Private Payers ≈ Medicare + 25%

Agenda

- Payers
- Providers and Suppliers
- Insurance Transactions (Coverage, Coding and Payment)
- Insurance Reimbursement for the Surgical Urology Patient
- **Reimbursement for the Ostomy, Wound or Continence Patient**
- Reimbursement for Med Tech Innovation

Insurance Reimbursement

Two Important Variables

- A Reimbursement Rate that allows for Supplier Margin
- A Utilization Rate that reflects Accepted Clinical Practice
  - Defined by Coverage Policies

Product	Medicare Rate	Medicare Utilization
One-Piece Ostomy Pouch (drainable, with filter)	$4.99	Max. 20 / month
Intermittent Urinary Catheter	$1.62 - $1.90	Max. 200 / month
Foam Dressing, ≤ 4” x 4”	$7.85	3 changes / week

Agenda

- Payers
- Providers and Suppliers
- Insurance Transactions (Coverage, Coding and Payment)
- Insurance Reimbursement for the Surgical Urology Patient
- Reimbursement for the Ostomy, Wound or Continence Patient
- **Reimbursement for Med Tech Innovation**

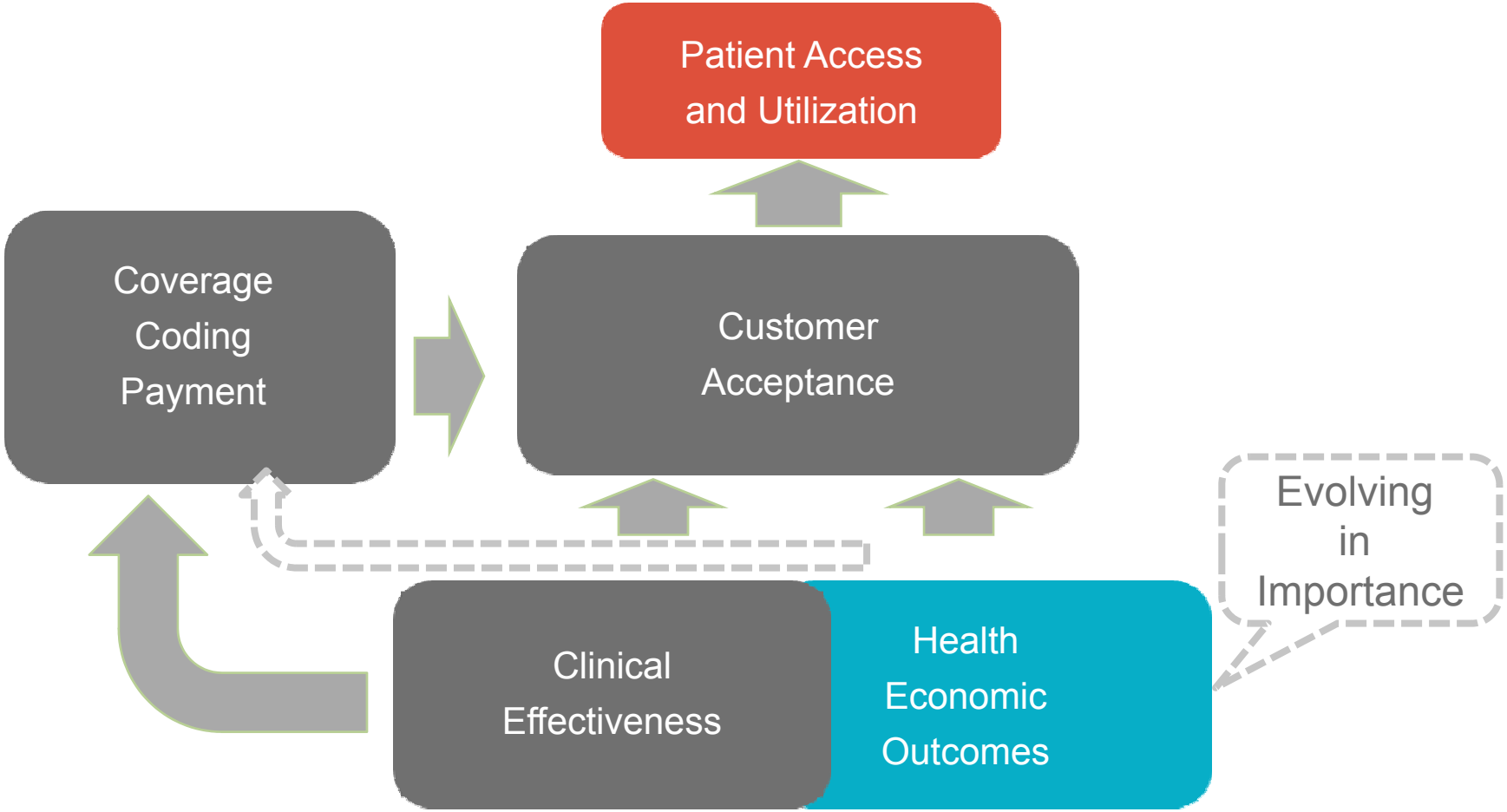
re'im·burse'ment *n. – a.) repayment for expenses incurred, b.) payments given to healthcare providers for services rendered or supplies provided, base on benefits covered under an insurance plan.*

…but more importantly…

It's a critical factor for:

- *Determining the speed of market acceptance for new technology,*
- *Providing the appropriate margin for product pricing.*
- *Creating the space for volume growth of existing technologies.*

From a Foundation of Clinical Effectiveness



How Medicare determines coverage

CMS Centers for Medicare & Medicaid Services

"No payment may be made under [Medicare] for any expenses incurred for items or services [that] **are not reasonable and necessary** for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."
Section 1862(a)(1)(A) of the SSA*

- The absence of formal criteria gives CMS discretion and results in **a "quasi-case law" approach** to establishing coverage policies.

- Generally, a technology is considered "reasonable and necessary" when it:
  1. Produces a **demonstrable clinical benefit** for the Medicare population, and
  2. Is supported by **methodologically sound evidence**.

How Private Payers determine coverage

- Few payers have published clinical criteria.

Technology Evaluation Center Criteria

BlueCross BlueShield Association

1. The technology must have final approval from the appropriate governmental regulatory bodies
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes
3. The technology must improve the net health outcome
4. The technology must be as beneficial as any established alternatives
5. The improvement must be attainable outside the investigational settings

New Coding requires Clinical Evidence

Requirements

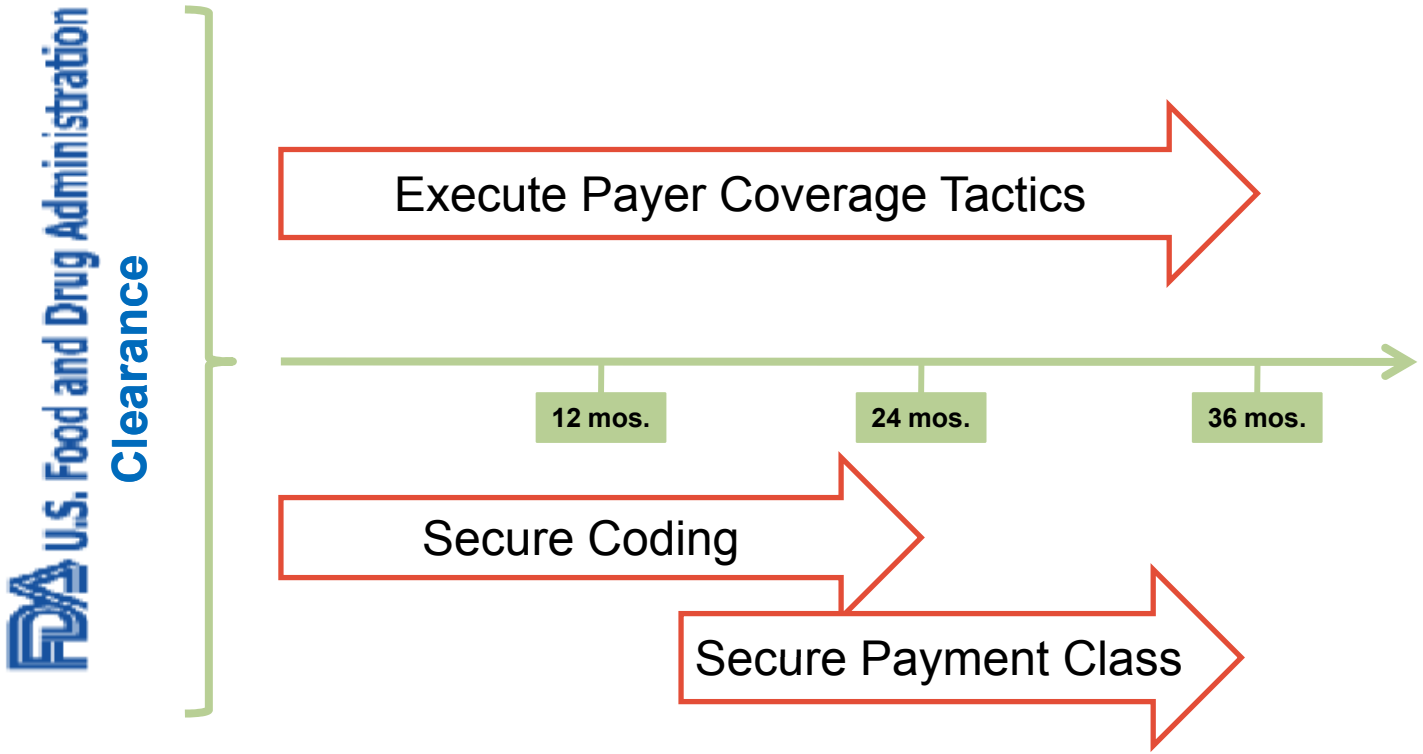
AMA Website – Requirement for **New CPT Coding:**

- ***"…the clinical evidence of the service/procedure is well-established and documented in U.S. peer-reviewed literature."***

CMS Requirements - **HCPCS Request Process**:

- Requires evidence for claims of ***"significant therapeutic distinction."***
- CMS Denial Letters often state – ***"Clinical information…does not demonstrate superior clinical outcomes."***

Successful Execution of Concurrent Pathways



Reimbursement / Health Economic Assessment Model