BOSTON MEDTECH ADVISORS
More Experience ▶ Better Results

THE US HEALTH INSURANCE MARKETPLACE

WHY PLANNING YOUR REIMBURSEMENT STRATEGY IS CRITICAL FOR YOUR COMPANY'S SUCCESS

July 14, 2021

DAVID BARONE

BOSTON | GERMANY | ISRAEL

www.bmtadvisors.com
www.bmtCROgroup.com

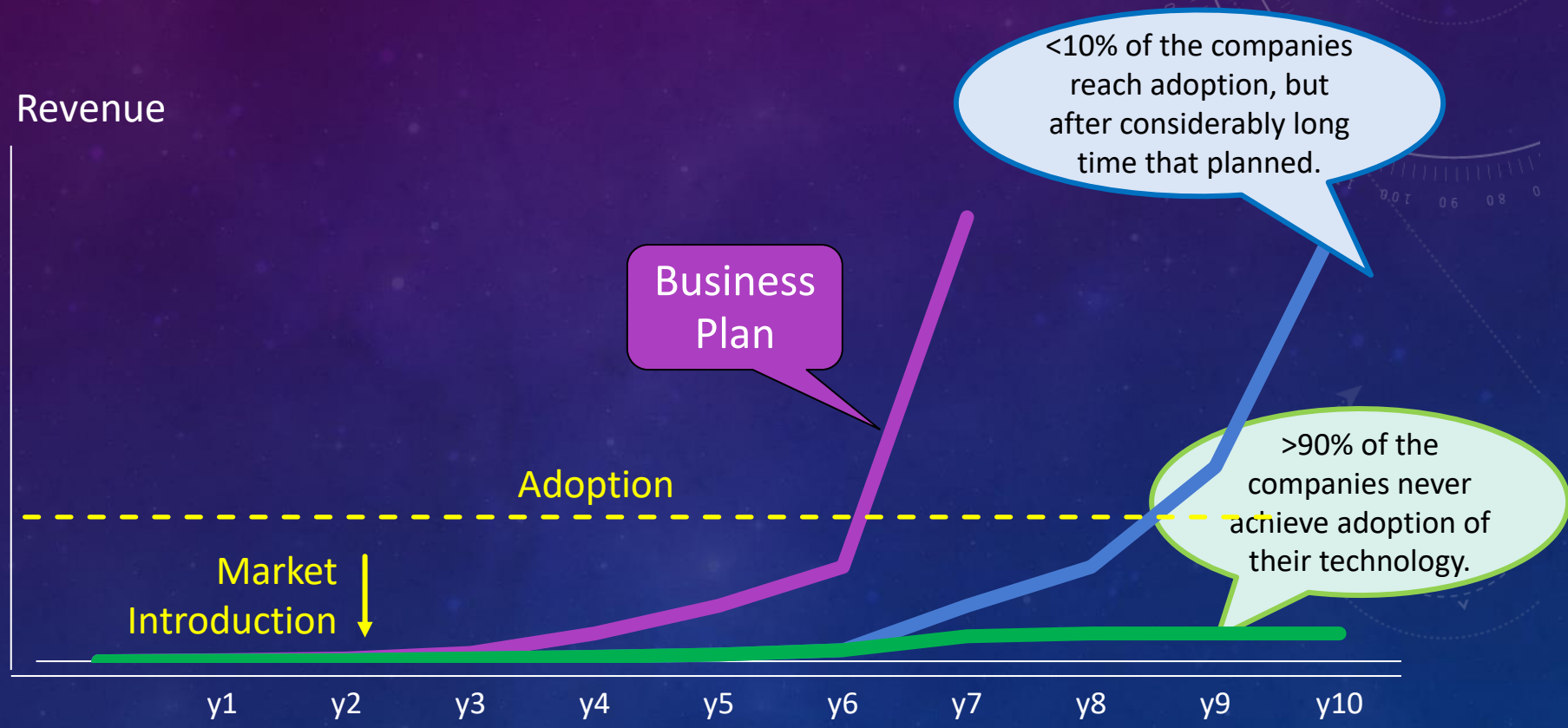
dbarone@bmtadvisors.com

Topics

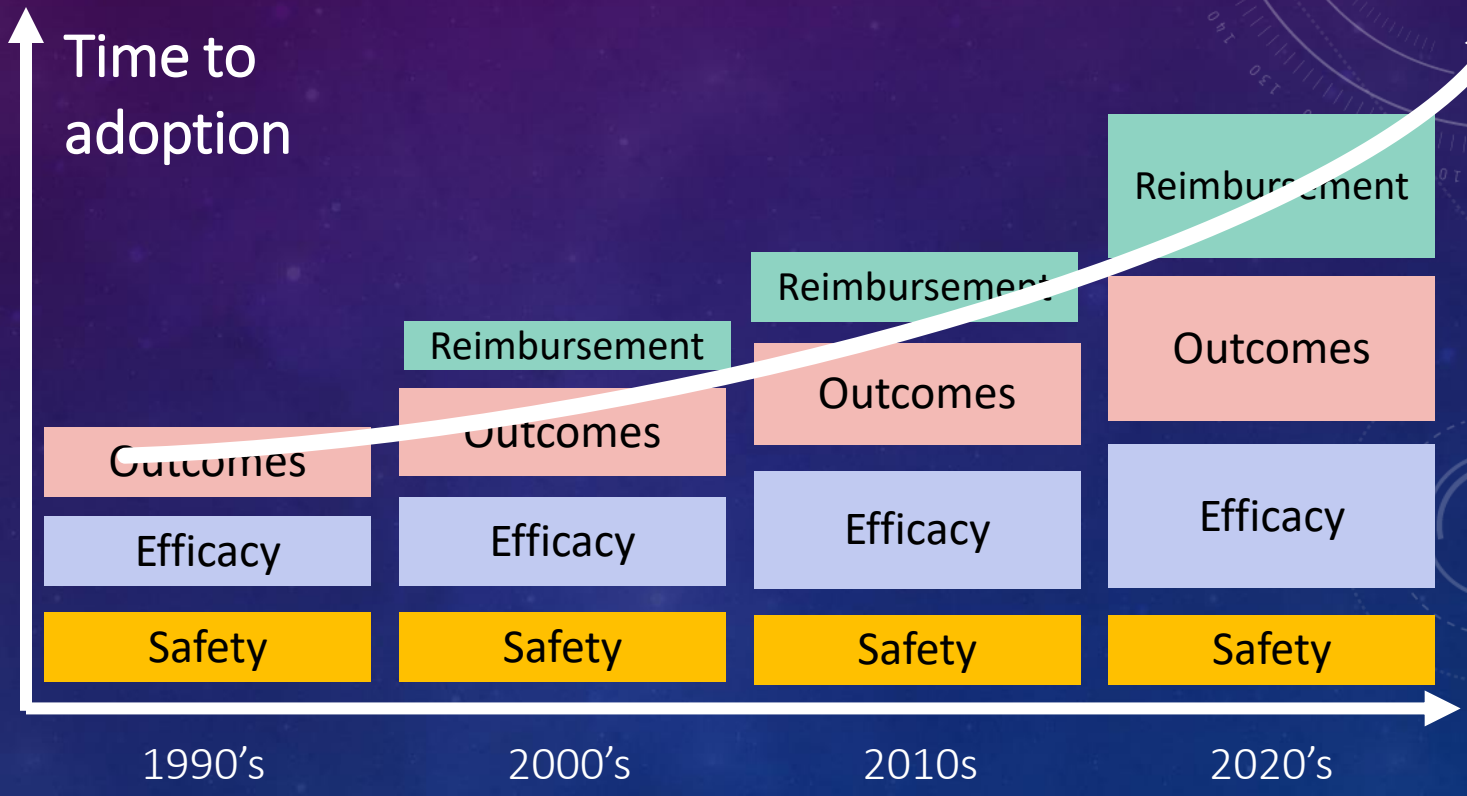
1. Why ‘Reimbursement’ is important?
2. The US healthcare system (overview)
3. Codes and Coverage 101
4. The changing landscape
5. So, what do we need to do?

Why ‘Reimbursement’ is Important?

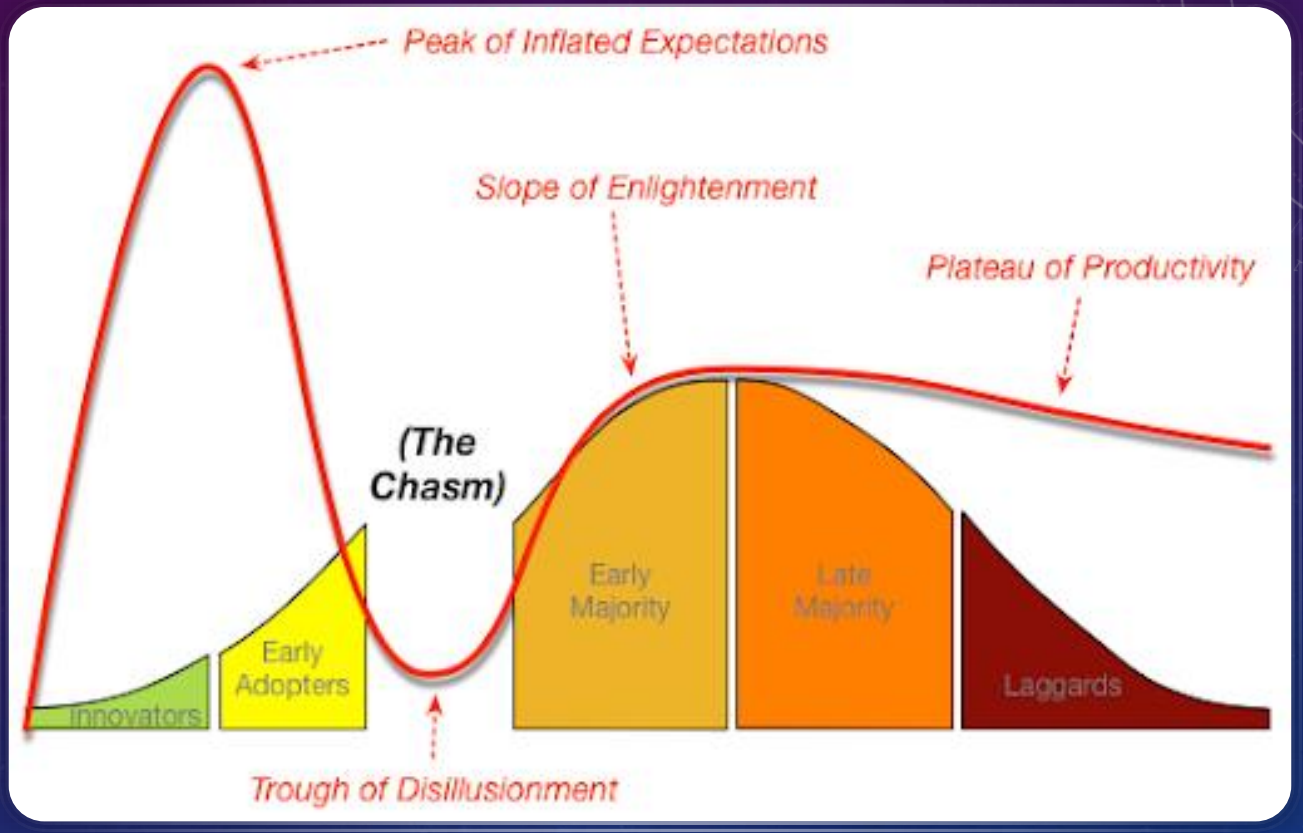
Reality Check - Most Companies Miss Their Plans



While Healthcare Markets Continue to Expand, Time To Market Adoption Continues to Increase

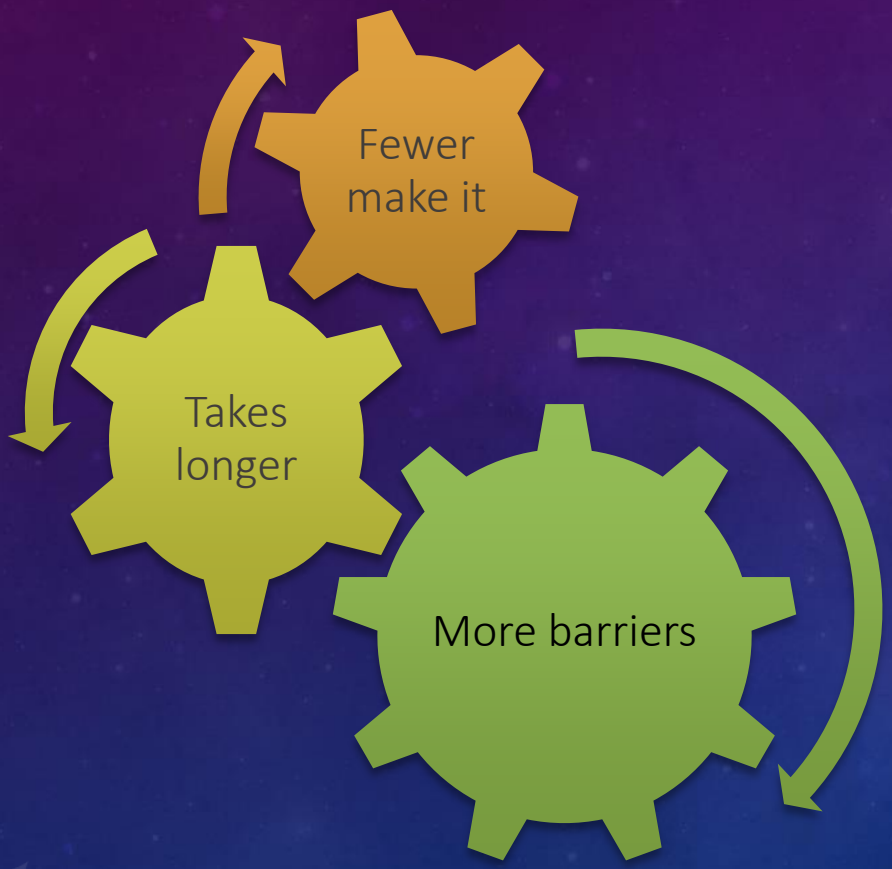


Moore's Technology Adoption Life Cycle



Success with 'early adopters' is not necessarily a predictor for broader market adoption

Considerable Implications to Longer Time-To-Adoption



- Delayed revenue
- Need for additional funds and financing rounds
- Valuations are negatively impacted
- Business development initiatives are delayed
- Increased risk of new competitors

Reimbursement - a Key Requirement for Adoption of the Technology

Lack of reimbursement can adversely impact utilization

Yet, reimbursement does not ensure utilization of the technology…

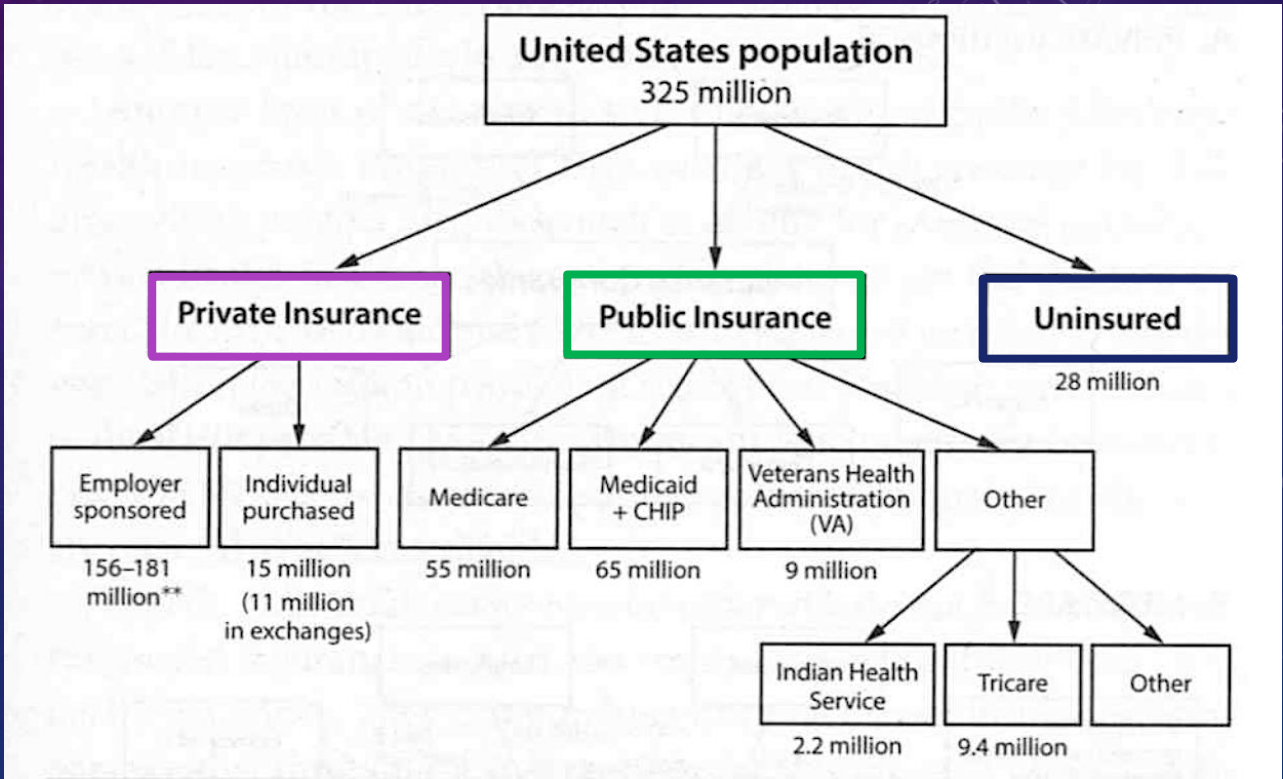
What Does It Mean to 'Have Reimbursement'?

- ✓ The technology or procedure is covered…
- ✓ The coverage is sufficiently broad…
- ✓ The **payment is** appropriate -
  covering the costs of physicians, hospitals, distributors and manufacturer

The US Healthcare System

Healthcare Coverage in the U.S.

Different insurance arrangements



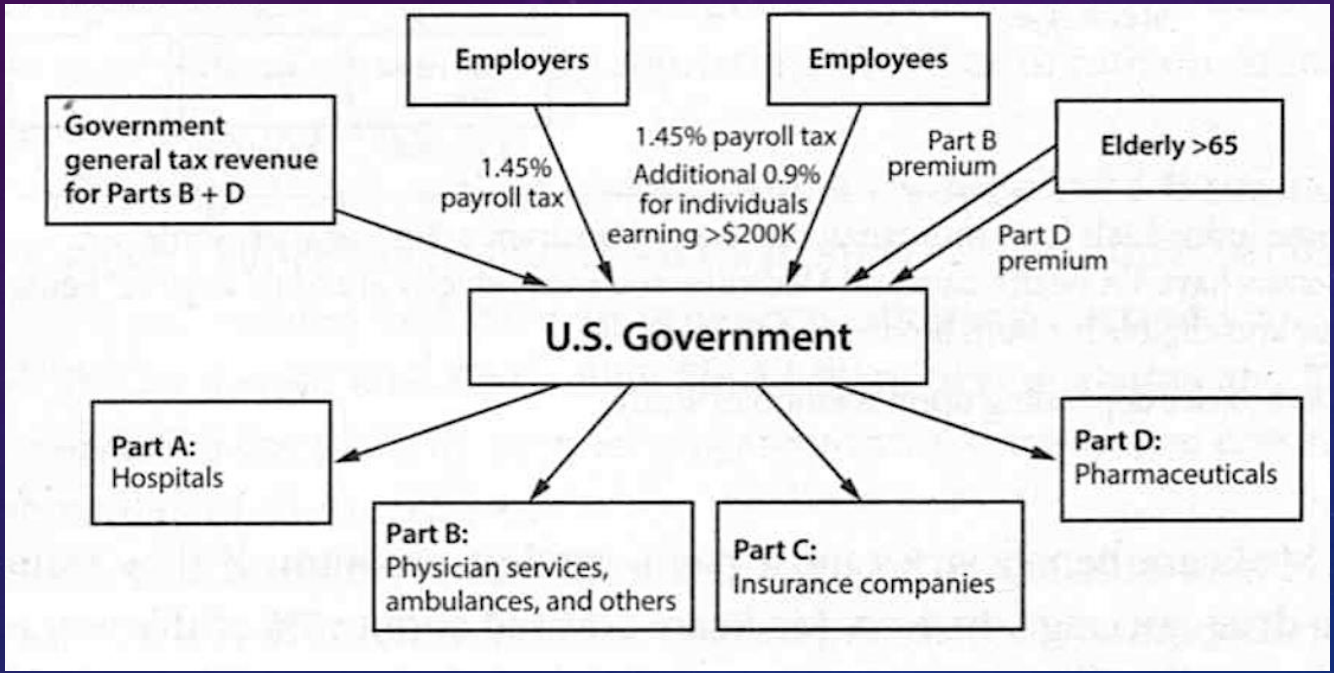
Financing Healthcare

$3.8 trillion / >$11,000 per person

Government	Federal	28%*	45%
	State and local	17%	
Private	Business	20%	55%
	Individuals	28%	
	Other sources	7%	

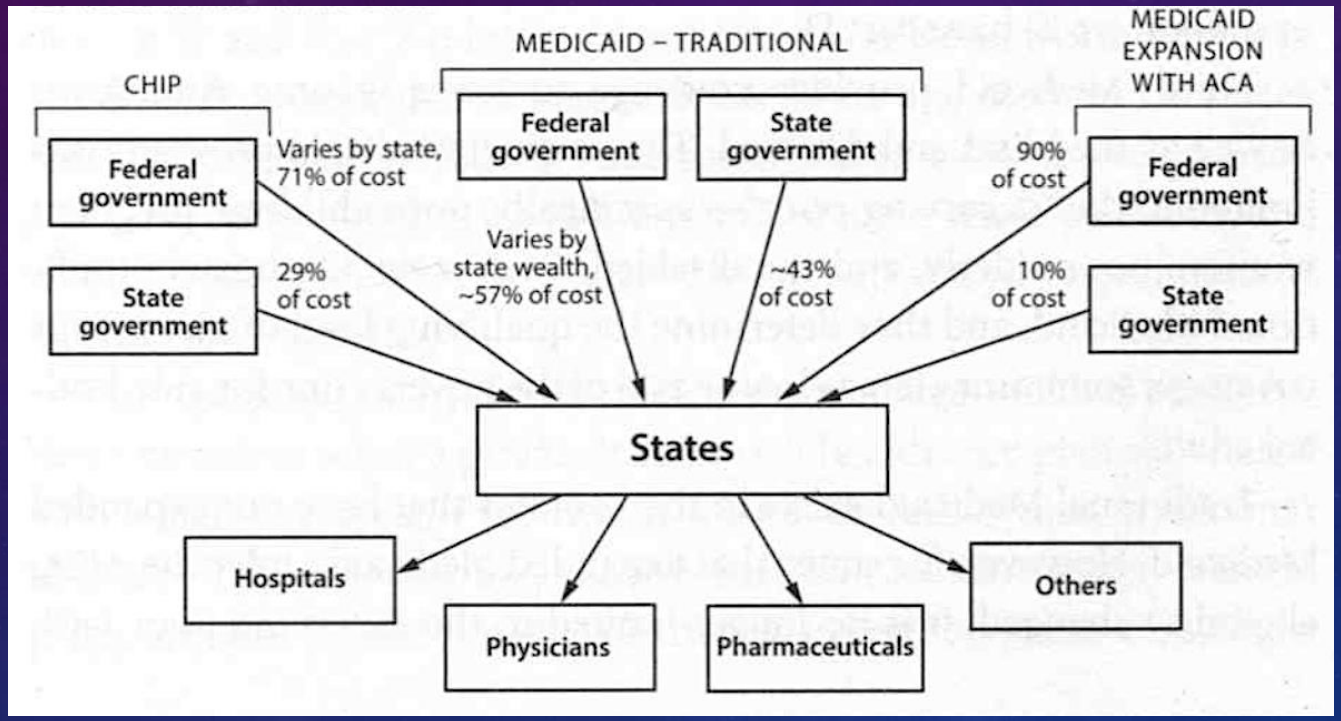
** including military, Veterans Administration and DoD*

Medicare



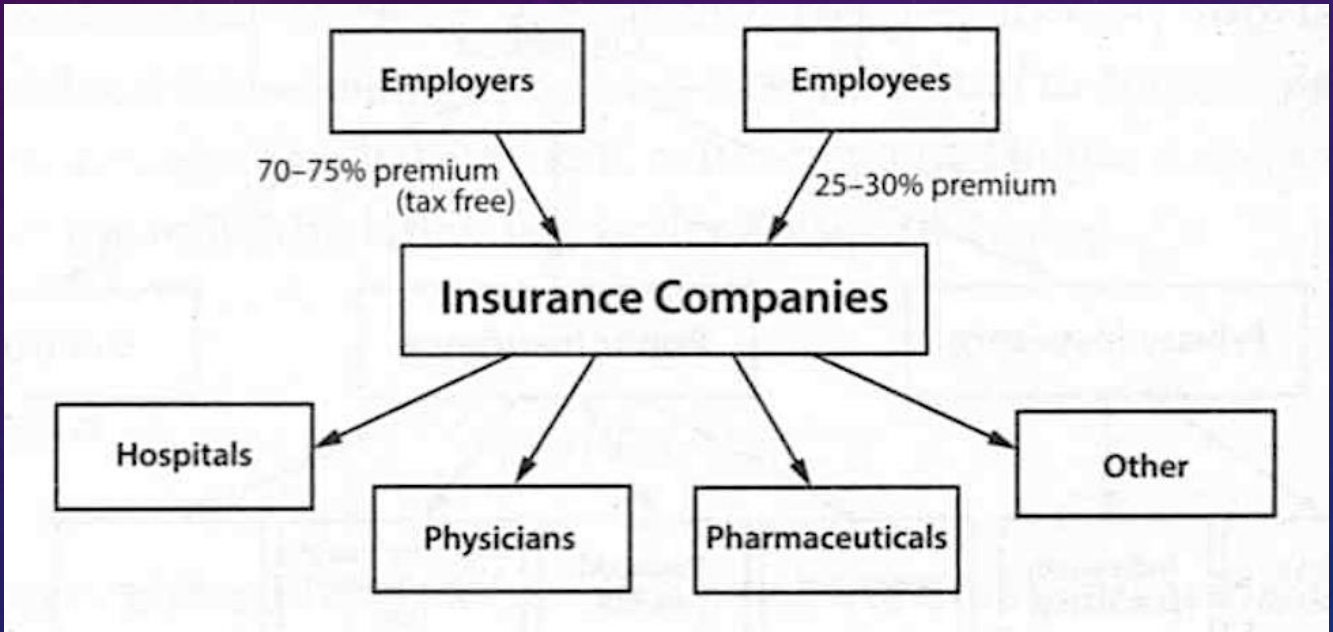
- Federal program
- Covering ~60 million people (18% of the population)
- All people ages >65; 65< with permanent disabilities; end-stage renal disease or Lou Gehrig's disease

Medicaid and CHIP



- A joint federal and state program
- ~62 million (19% of the population)
- People with low income
- Incl. benefits not normally covered by Medicare, like nursing home care and personal care services.

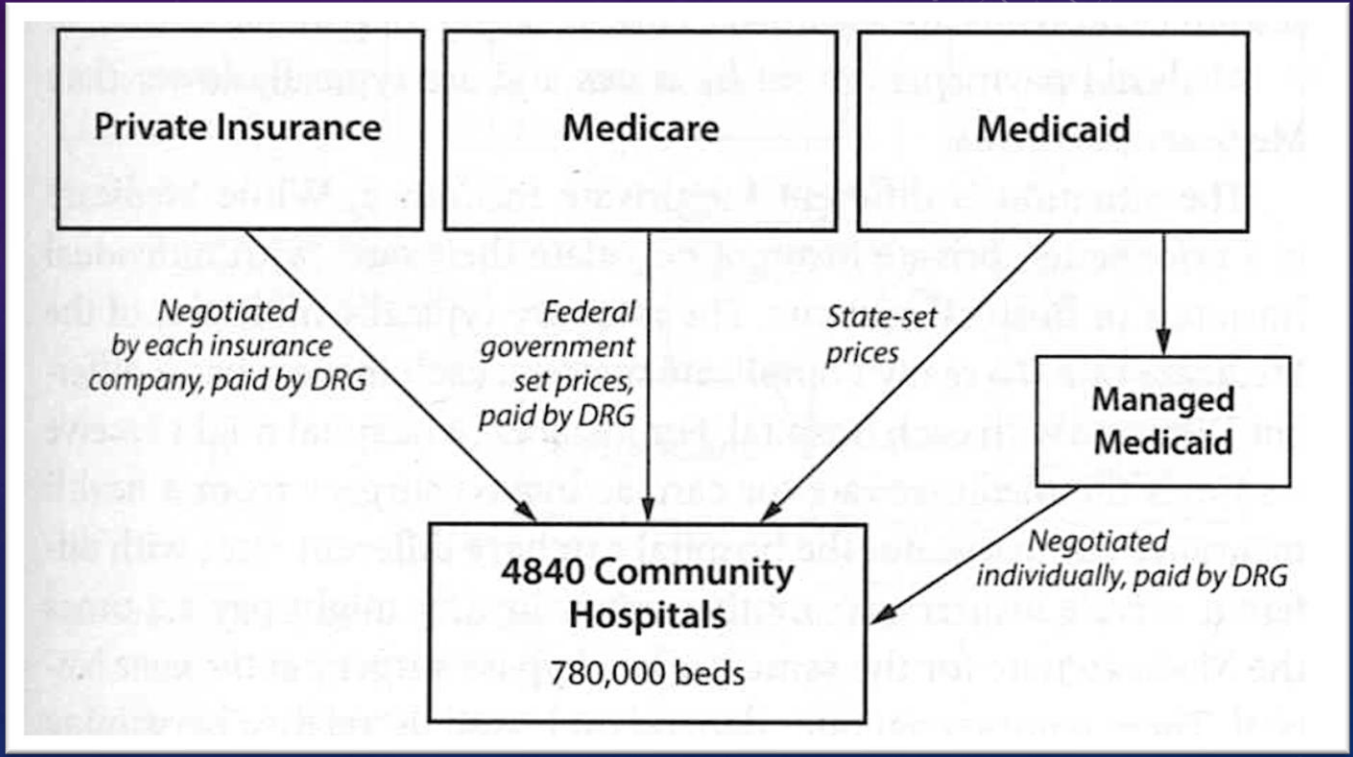
Private Insurance



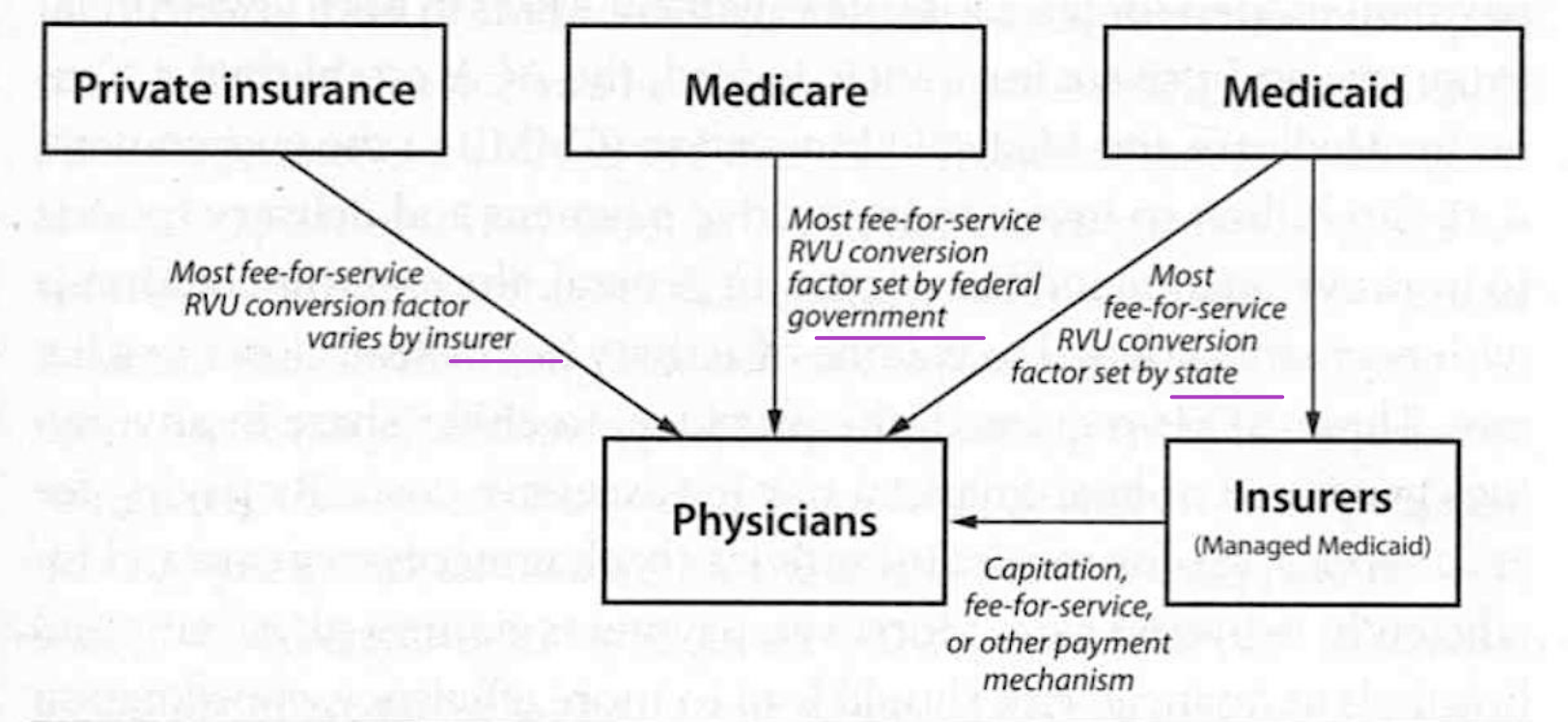
- Employer sponsored: ~153 million people (49% of the population)
- ~19 million (6%) non-group insurance.
- Coverage vary considerably, as each plan sets its own policies
- No insurance: ~33 million people (10% of the population). Out-of-pocket pay or ER / emergency care

Payments to Hospitals

- $1.1 trillion (~33% of total health care spending)
- Most payments are based on DRGs
- >750 MS-DRGs
- DRG payments exclude:
  - Physician services
  - Outpatient care

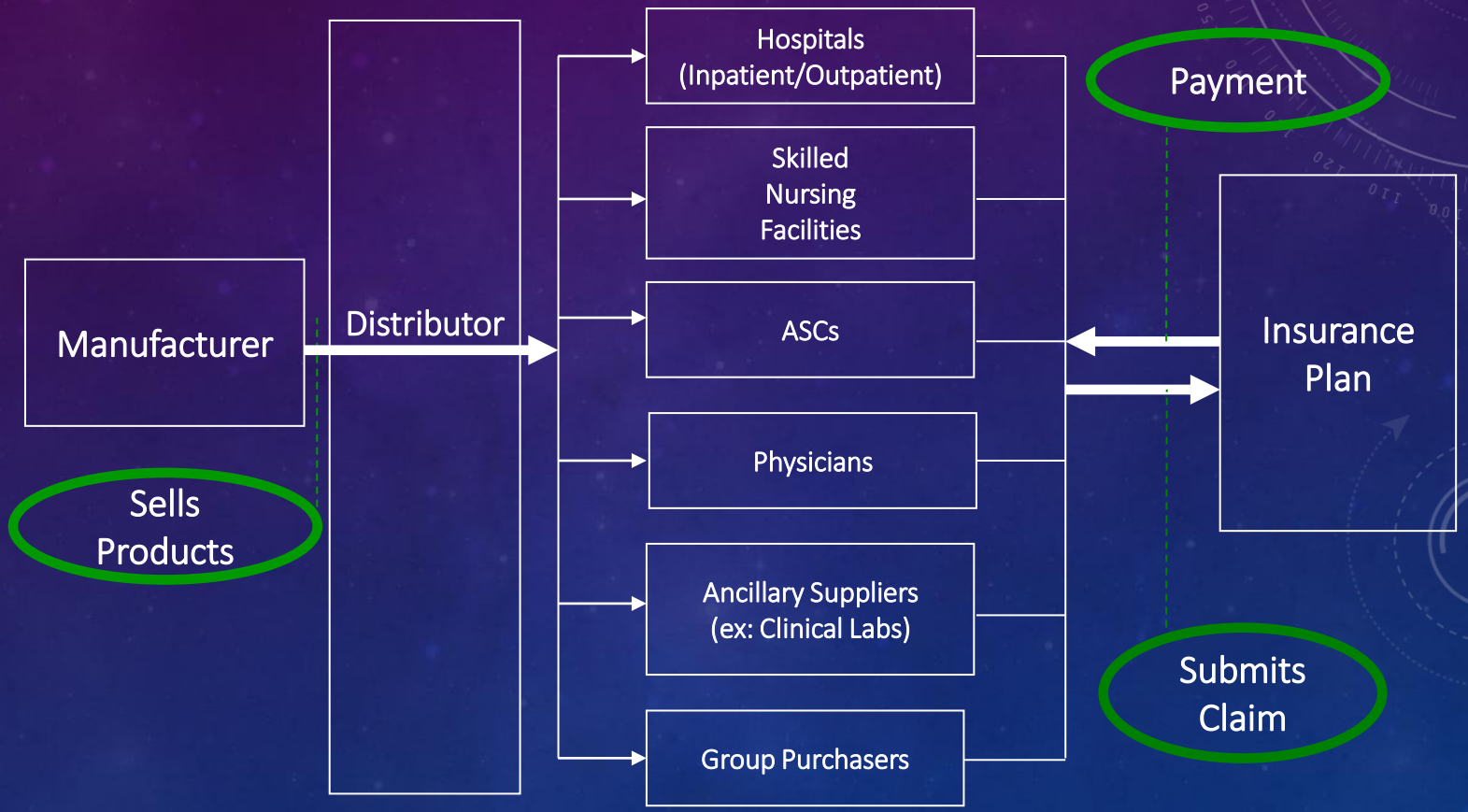


Payments to Physicians

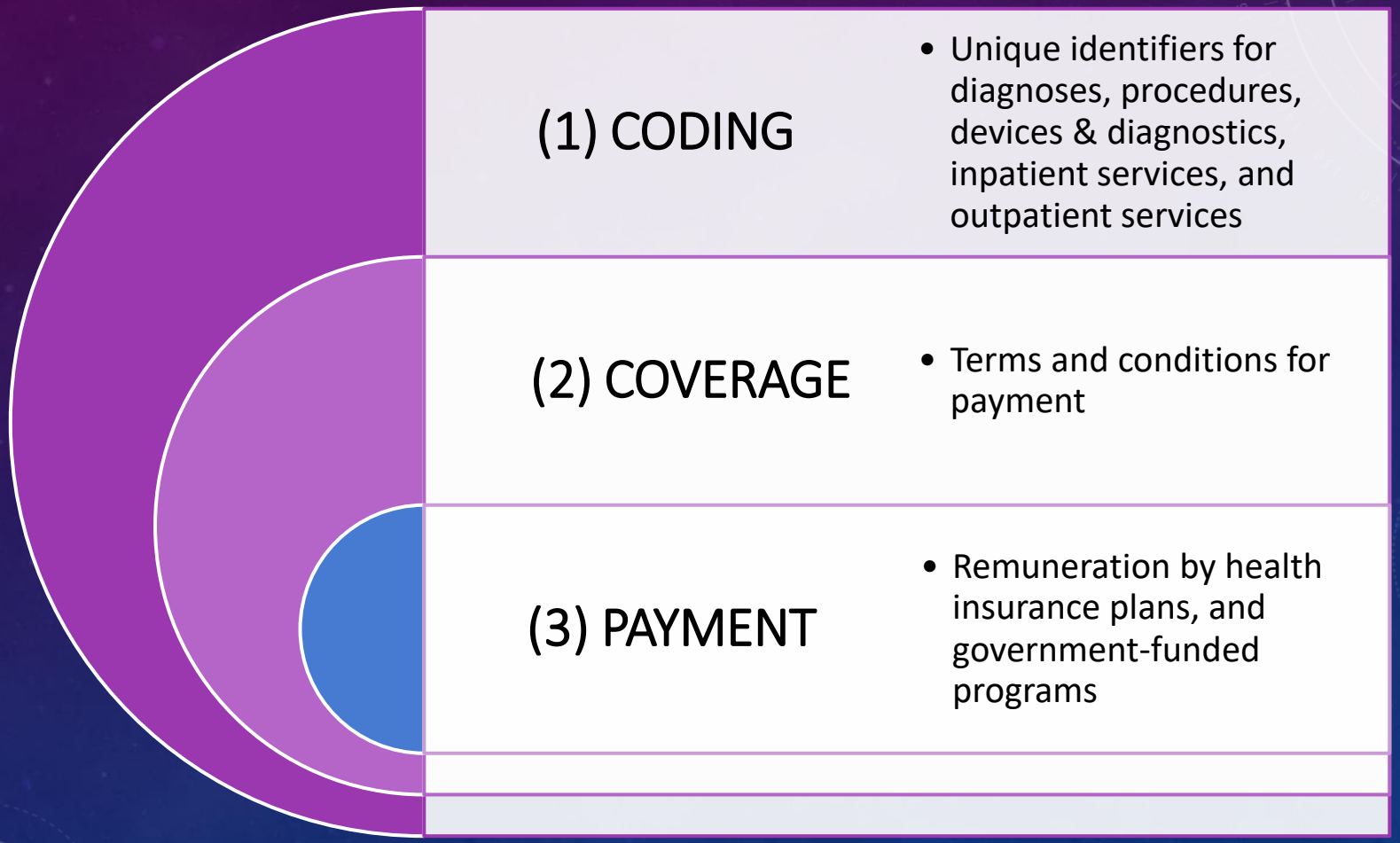


Codes and Coverage 101

How Does a New Medical Device Fit Into the Payment System?



Reimbursement - Three Distinct Components



Standardized

Plan-specific

Negotiated with each provider

Coding Basics

- A reimbursement code is an identifier for a diagnosis, drug, device, or procedure
- Codes allow for rapid claims processing

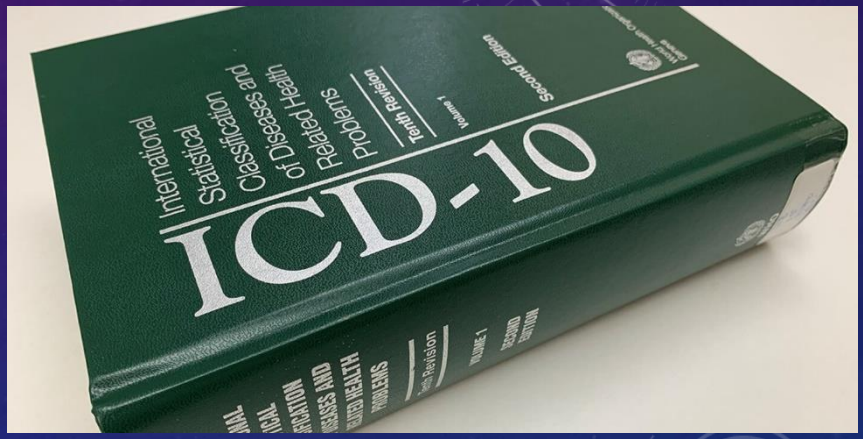
Code ≠ Coverage

ICD -
The International Classification of Diseases (10th Edition)

- Published by The World Health Organization (WHO)
- ~70,000 ICD-10-CM diagnosis codes and ~70,000 ICD-10-PCS procedure codes
- Updated annually

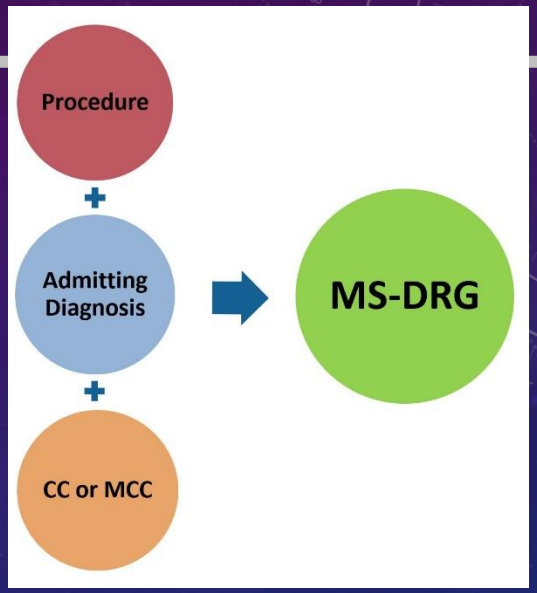
PCS - procedural classification system

CM - morbidity classification



DRG - Diagnosis Related Groups

- Classify hospital cases deemed to have a similar clinical condition and expected similar use of hospital resources.
- An **MS-DRG is determined** by the principal diagnosis, the principal procedure, and certain **comorbidities and complications.**
- **~740 DRG** categories, defined CMS
- Payment **rates** are based on the ”average” **cost** to deliver care to a patient with a particular disease.



DRG payments cover all charges associated with an inpatient stay from the admission to discharge, including nursing services, room and board, diagnostic and all ancillary services.

MS - medical severity

CPT -
Current Procedural Terminology Codes

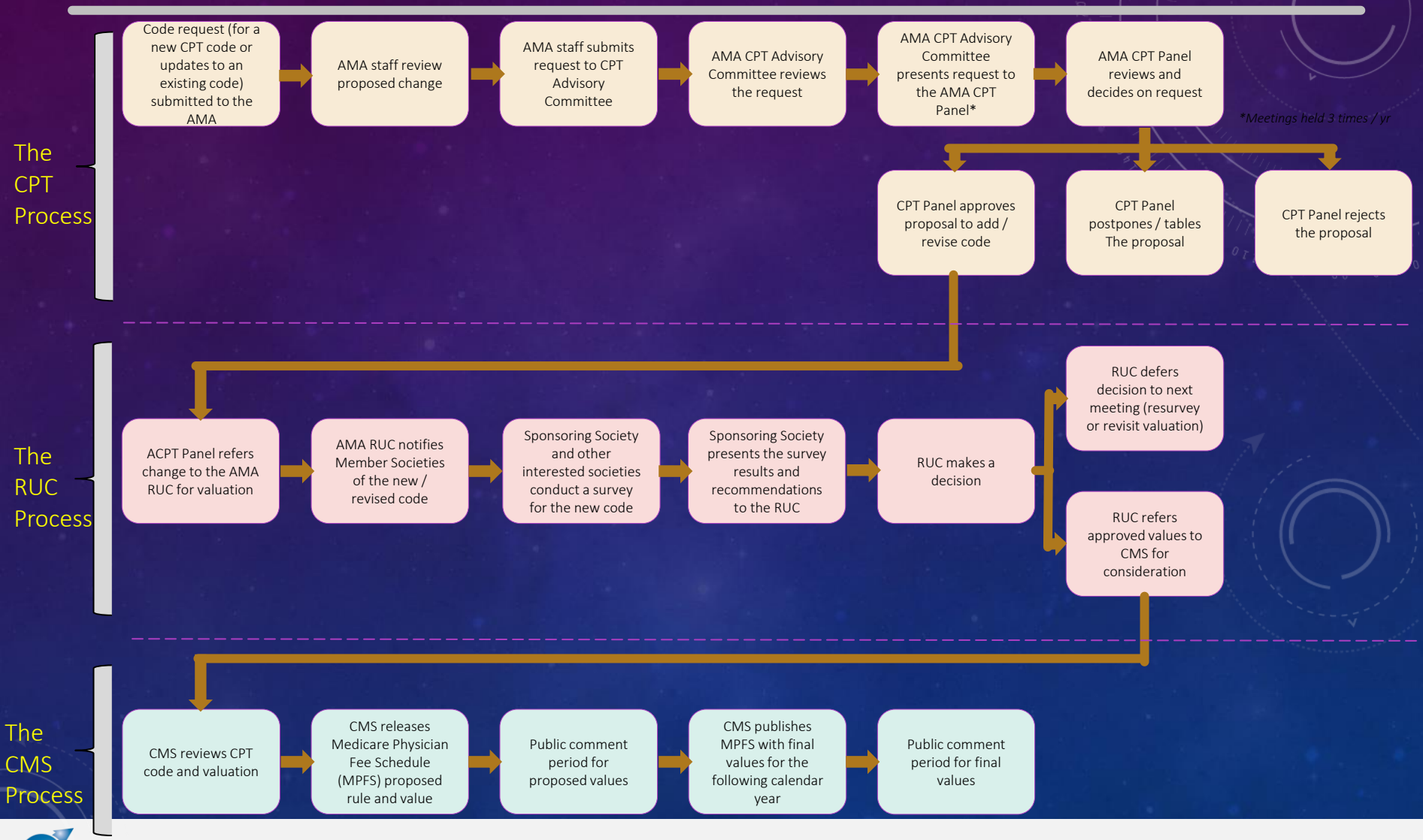
- Used to report medical, surgical, and diagnostic procedures and services to health insurance companies.
- >10,000 codes
- Maintained by AMA

cpt®

Requirements for a new code *(partial)*

- The device used in providing the service received approval from the FDA for the specific purpose described in the proposed CPT code.
- The service is performed routinely across the US at the time of application
- The clinical efficacy of the service is well-established and documented in peer review literature (at least one report with U.S. patients).
- **Supported by the relevant medical professional society(ies).**

Development of a New CPT Category I Code



CPT Category III

Assigned to emerging technologies, for services that do not meet requirements for Category I code.

Requirements

- The procedure is currently performed in humans
- At least one of the following:
  1. Support by at least one professional society
  2. Peer reviewed literature documents clinical efficacy
  3. There is

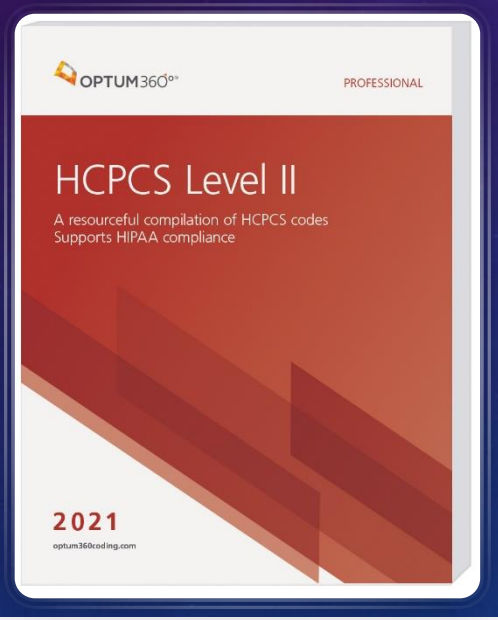
     a) at least one IRB approved protocol of an efficacy study of the procedure in the U.S.

     or

     b) other evidence of evolving clinical utilization in the U.S.

HCPCS - Healthcare Common Procedure Coding System

- Primarily for non-physician services - supplies and non-physician services
- >6,000 codes
- Maintained by Medicare



A-codes	**Transportation, Medical & Surgical Supplies, Miscellaneous**
B-codes	Enteral and Parenteral Therapy
C-codes	**Temporary Hospital Outpatient Prospective Payment System**
D-codes	Dental Procedures
E-codes	**Durable Medical Equipment**
G-codes	**Temporary Procedures & Professional Services**
H-codes	Rehabilitative Services
J-codes	Drugs Administered Other than Oral Method, Chemotherapy Drugs

Also: K, L, M, P, Q, R, S, T, V codes

Requirements for Assigning a New HCPCS Code

- The item must be diagnostic or therapeutic in nature.
- Not used only in the inpatient setting.
- FDA approval
- Sufficient claims activity associated with the new item.

Standards for Coverage

Medicare*

"reasonable and necessary for the diagnosis or treatment of illness or injury"

- Improved outcomes
- Benefits outweigh risks
- Clinical evidence show outcomes in the relevant population

* Section 1862(a)(1)(A) of the Social Security Act

Private Plans**

- FDA approval
- Evidence - health outcomes
- The technology must improve net health outcomes
- Technology is beneficial as any established alternatives
- Improvement is attainable outside of investigational settings

** e.g., BCBS Evidence Street

Why is Coverage Denied?

- Does not meet FDA requirements
- Not within a defined benefit category (e.g., some preventive services)
- Insufficient or inconclusive evidence, even when FDA cleared (experimental / investigational)
- Evidence not available for target population (e.g., >65 for Medicare)
- Inconsistent with existing professional practice guidelines

FDA Approval Does Not Predict Reimbursement

- FDA approval of a device allows its marketing in the US. Payers decide whether to cover the device / procedure.
- The FDA process is a structured process, driven by well-defined guidelines. Coverage decisions are subjective, made separately by each payer.
- Clinical data supporting FDA approval (if required) - generally limited to a single pivotal study documenting safety and efficacy. Payers' decisions are based on multiple peer-review publications summarizing studies assessing clinical outcomes.

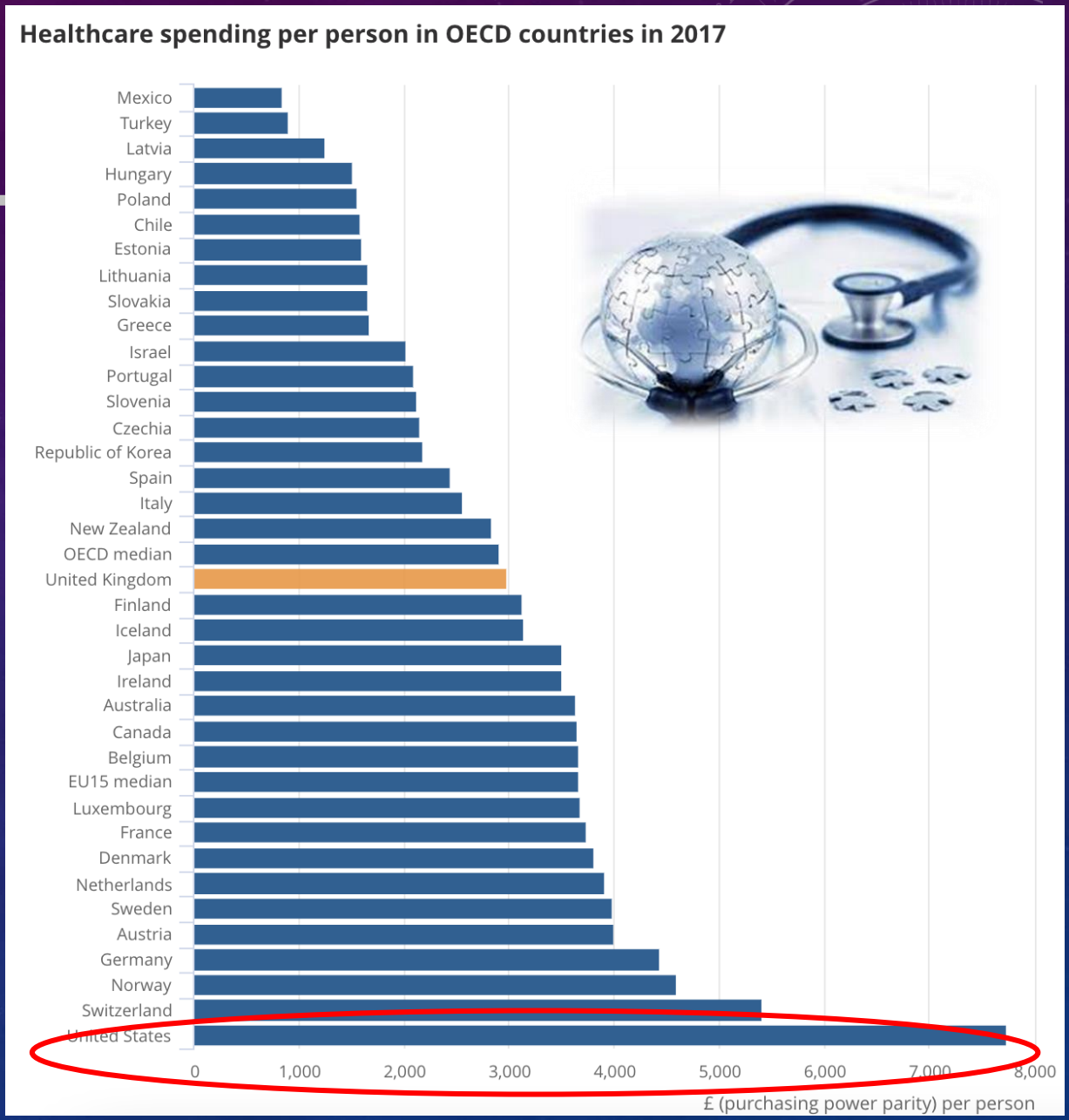
Setting Payments for Professional Services

- Medicare Physician Fee Schedule (PFS).
- Services paid under the PFS are divided into:
  - Physician work. Reflecting the physician's time, effort and technical skill required to render the specific service.
  - Practice expense. Including equipment, supplies and office overhead.
  - Malpractice insurance premiums.
- CMS - most services have a national rate (payments adjusted to reflect regional costs, type of facility, etc.).
- When a service does not have a national payment rate, each regional Medicare contractor determines the payment rate for its locality.
- CMS is prohibited from using differential payments based upon the specialty of the physician performing the service (commercial payers are not bound by this restriction).
- Most commercial payers use Medicare fee schedule as a benchmark.

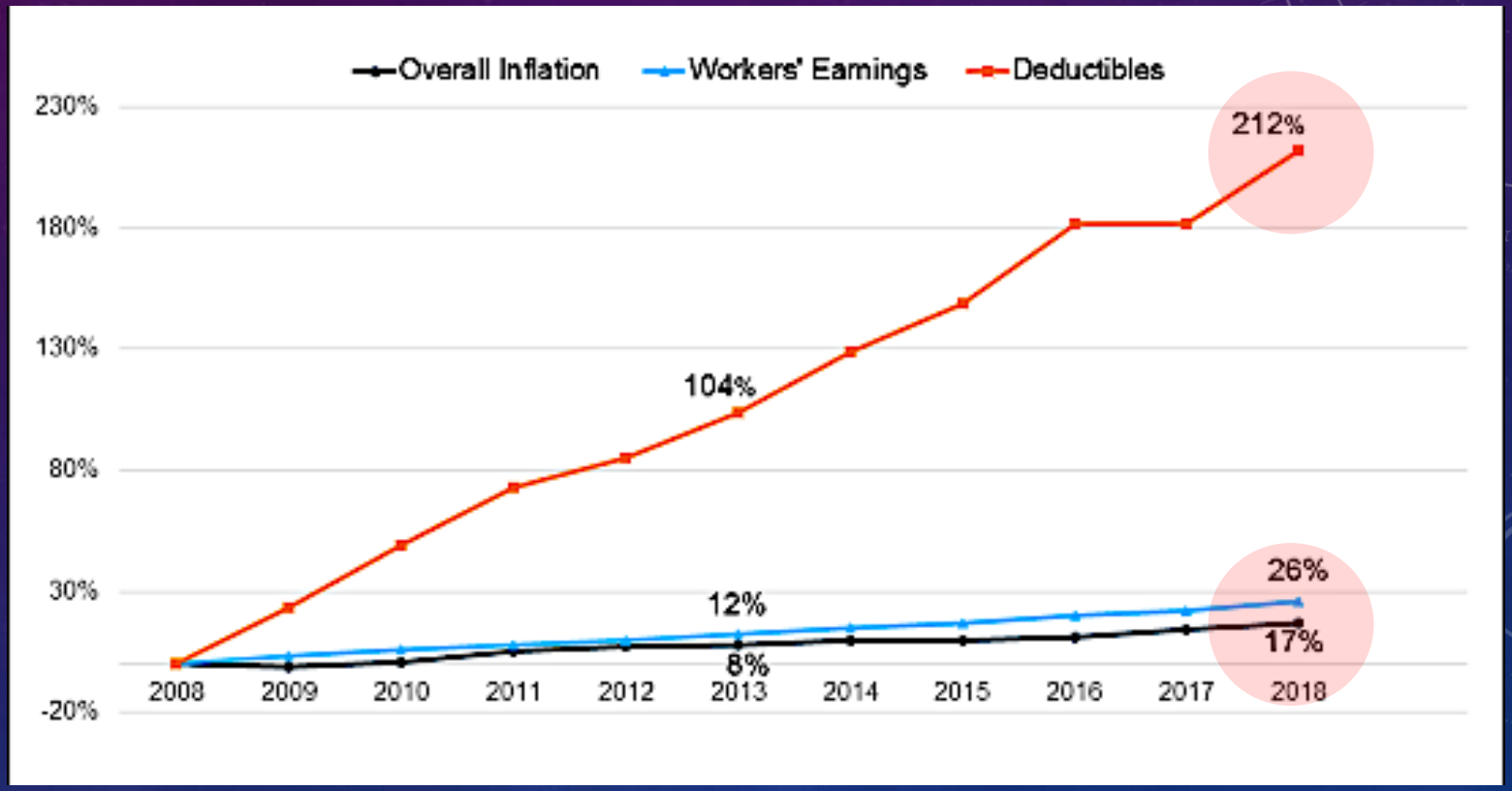
The Environment is Changing

Health spending in the U.S. accounts for 17.7% of GDP

Significant pressures (public, employers, politicians) to reduce rate of increase in cost of care.



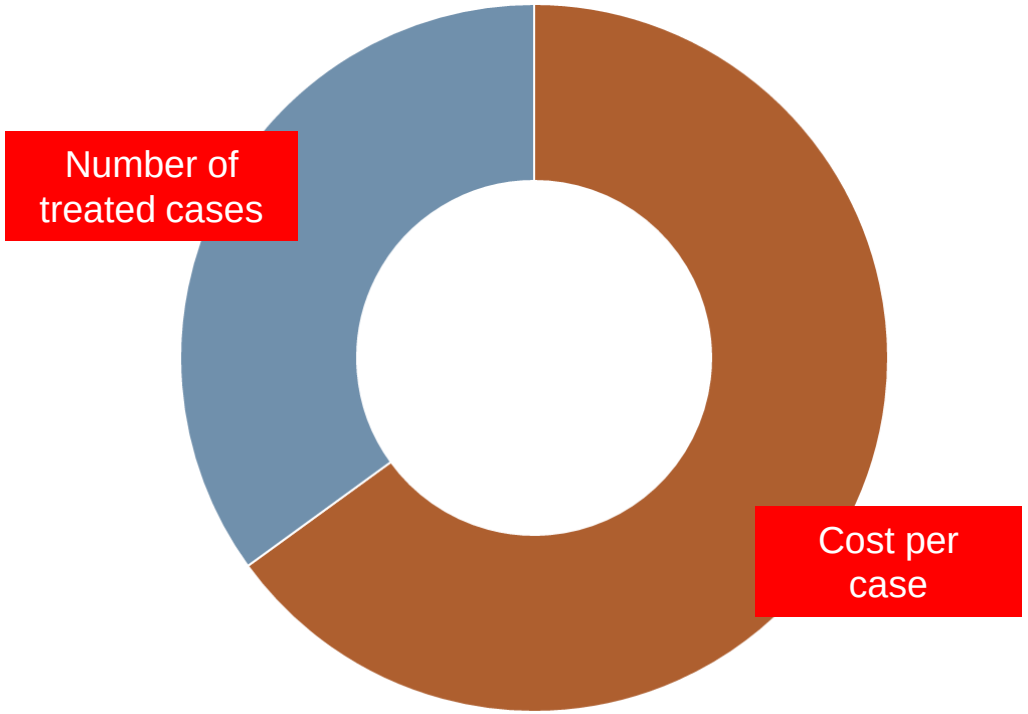
Annual Deductibles for Workers Have Increased 8 Times as Wages



Source: Kaiser Family Foundation

Increases in prices and service intensity have driven most of spending growth

Percent change from previous year for price indexes and real expenditures on medical services by disease, 2001 - 2012



Changes In Reimbursement are Under Way

"Value is measured by patients' health outcomes per dollar spent."

$$\text{Value} = \frac{\text{Quality (Outcomes, Safety, Service)}}{\text{Cost}}$$

Quality Improvements (examples)

- ✓ Prevention of illness
- ✓ Early detection
- ✓ Right diagnosis
- ✓ Right treatment to the right patient
- ✓ Rapid cycle time of diagnosis and treatment
- ✓ Fewer invasive treatments
- ✓ Fewer complications
- ✓ Fewer mistakes and repeat treatments
- ✓ Faster and more complete recovery
- ✓ Lees need for long-term care
- ✓ Fewer recurrences
- ✓ Reduced need for ER visits
- ✓ Slower disease progression

The Emerging Landscape

Past		Future
Volume based incentives	→	Value based / outcomes
Fee-for-service	→	Bundled care
Payers assume financial risk	→	Payers & providers share risk
Devices selected by physician [Clinical consideration]	→	System decisions [Clinical, operational, marketing, economics]

Many Reforms and Initiatives are in the Pipeline

CMS Vision

"We are moving to a system that rewards value over volume.

Start paying for value will foster innovation, as providers look for ways to compete for patients by providing the highest quality care at the lowest cost."

Accountable Care Organizations (ACO)
Shift from fragmented care to coordinated care and measured performance

Value-Based Purchasing (VBP) Program
Reward value and patient outcomes, instead of volume of services

Reduced Payments for Hospital Acquired Conditions
Stop paying for certain conditions developed while the patient is hospitalized

Hospitals Readmission Reduction Program
Reduce payments to acute care hospitals with excess readmission

Payment Reforms
Incentivize Quality, not Volume; pay-for-performance (value)

Payers Must Balance Conflicting Objectives

Maintain costs, address government, employers and patients' desire to keep costs down

Compensate providers for their costs of delivering required care

So, What Do We Need To Do?

	Addressing reimbursement early in the process changed from	Failure to address reimbursement early in the project life changed from
Past	• Not important	• Not a big deal
Yesterday	• Nice to do	• Bad practice
Today	• Important / critical	• Business malpractice

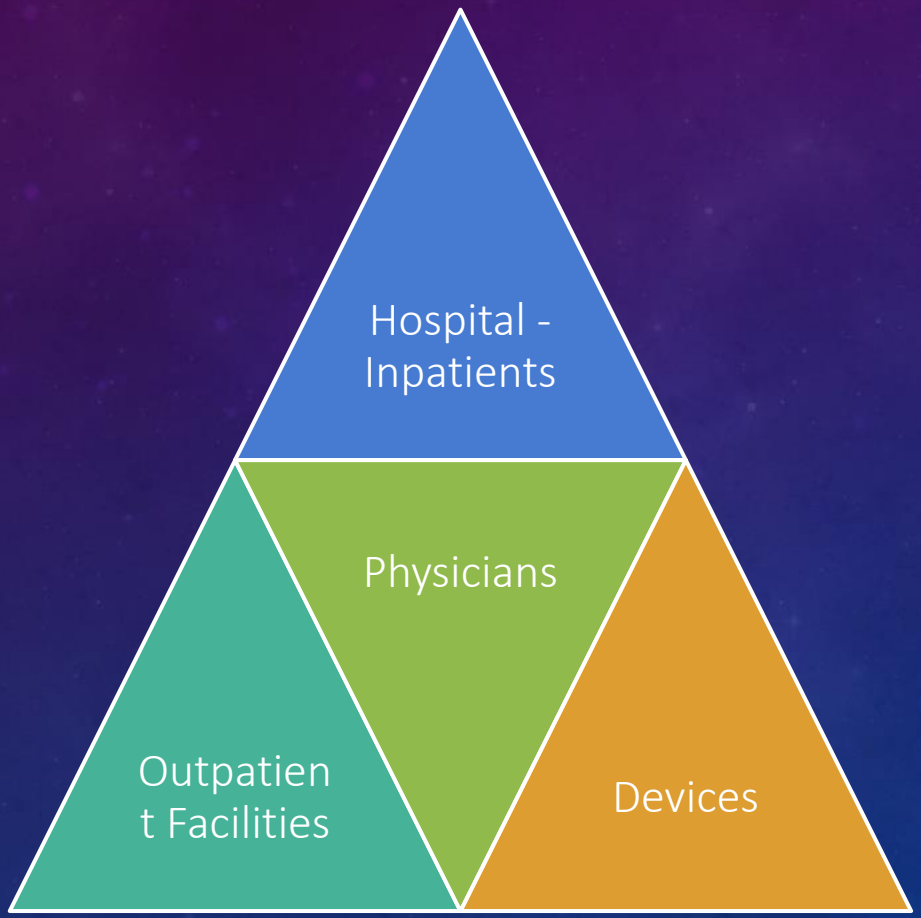
Reimbursement Affects Financial Success

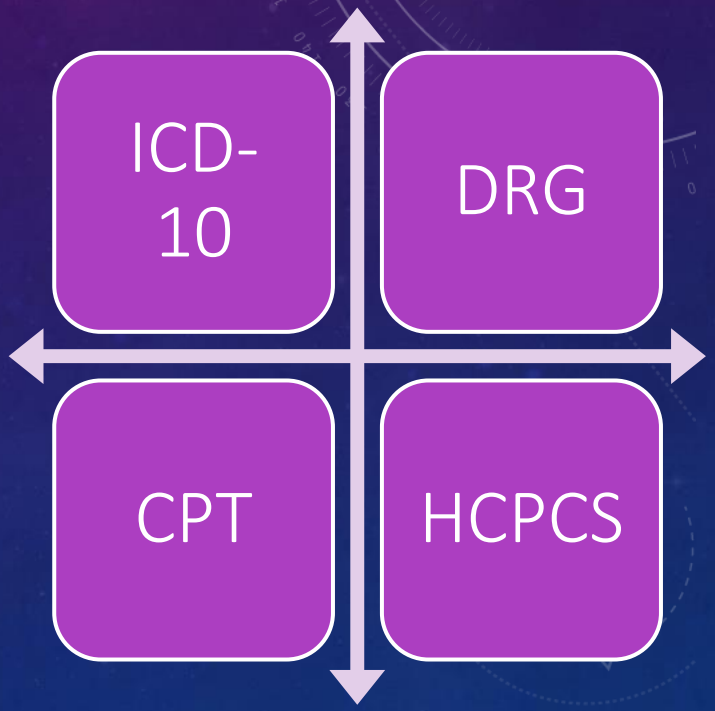
Investors want to know early on what it will take (time, funds) to obtain reimbursement

Sales are difficult to ramp-up until reimbursement is established

Marketing partners and acquirers hold off getting involved until reimbursement is established

First Step:
Understand Payment Mechanisms for Your Product / Service





The Initial Review

What will be reimbursed?

- Professional services
- Facility costs
- Device / product

Medical practice

- Established, modified or a new practice?
- Clinical protocol / workflow

Where will the product be used?

- Inpatient facility
  - Hospitals
  - Long term care
- Outpatient
  - Hospital-based
  - Ambulatory surgical centers
  - Physician offices / clinics
- Home

Who are the users?

- Physicians / specialties
- Nurses
- Licensed therapists
- Patients

Who will pay?

- Medicare
- Medicaid
- Commercial payers
- IDNs
- Government
- Employers
- Patients

Step Two:
Develop a Roadmap to Reimbursement

Integrate Coverage Supporting Data Into Clinical Trials Design

Evidence of improved outcomes, clinical efficiency, and cost effectiveness

Include gathering data comparing study device to existing treatments or technologies

- Well-established performance of the technology.
- Demonstrated clinical outcomes / improvement over the established practice
- Well-defined patient population.
- Economic rationale (preferably short-term benefits).

Step Three:
Integrate 'Reimbursement' into Your Business Plan

Selection of first application / indication / market segment	Product configuration / users' requirements	Regulatory strategy / IFU
Required clinical data to support regulatory + reimbursement + marketing	Go-to-market strategy	Pricing Strategy
Business and operating models	Identifying appropriate advisors	Required people, Skills & budgets

So, When Should We Start Reviewing Reimbursement?

Company valuation is predicated upon convincing investors and acquirers that the technology will gain adoption.

Adoption requires reimbursement

Gaining reimbursement requires a coherent strategy

Defining the business model and strategy requires an understanding the roadmap to reimbursement

Earlier the better!


thank you
شكرًا
danke
謝謝
ngiyabonga
teşekkür ederim
спасибо
dank je
gracias
tapadh leat
bedankt
dziękuję
mochchakkeram
go raibh maith agat
obrigado
sukriya
kop khun krap
arigatō
dakujem
grazie
terima kasih
мерси
תודה
감사합니다
ευχαριστώ
merci
Баярлалаа
рахмат
хвала
hvala
maururu
sagolun
takk
trugarez
ありがとう