HealthIL

BOSTON MEDTECH ADVISORS
More Experience ▶ Better Results

PRICING OF DIGITAL HEALTH TECHNOLOGIES

CONSIDERATIONS, PITFALLS AND OPPORTUNITIES

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Founded in 2004,
Boston MedTech Advisors
has worked with more than 400
medical technologies and life
sciences companies.

Our Focus

- Support companies introducing new technologies
- Help increase the likelihood that the technology will be adopted

Experience *(partial list)*

Aesthetic Medicine	*Allergy*	*Ambulatory Monitoring*	*Anesthesiology*	*Biologics*	*Biomarkers*	*Brain / Neurosurgery*	*Cancer Therapies*
Cardiology	*Cellular Therapies*	*Critical Care*	*Cryosurgery*	*Dermatology*	*Diabetes*	*Digital Health*	*Drug Delivery*
Drug / Device Combinations	*Durable Medical Equipment*	*Emergency Medicine*	*Endoscopy*	*Gastroenterology*	*General Surgery*	*Health IT*	*Healthcare Services*
Hematology	*Hepatology*	*Home Care*	*Hypertension*	*Hyperthermia*	*Interventional Cardiology*	*In-Vitro Diagnosis*	*Interventional Radiology*
Light-Based Therapies	*Neurology*	*NICU*	*Ophthalmology*	*Orthopedic*	*Pain*	*Patient Monitoring*	*Pathology*
Pulmonary	*Radiology / Imaging*	*Rehabilitation Medicine*	*Renal*	*Robotics / Navigation Systems*	*Sleep Medicine*	*Speech Therapy*	*Spine Surgery*
Surgical Simulation	*Telemedicine*	*Transfusion Medicine*	*Urology*	*Vascular Medicine*	*Wearable Devices*	*Wellness / mHealth*	*Wound Care*

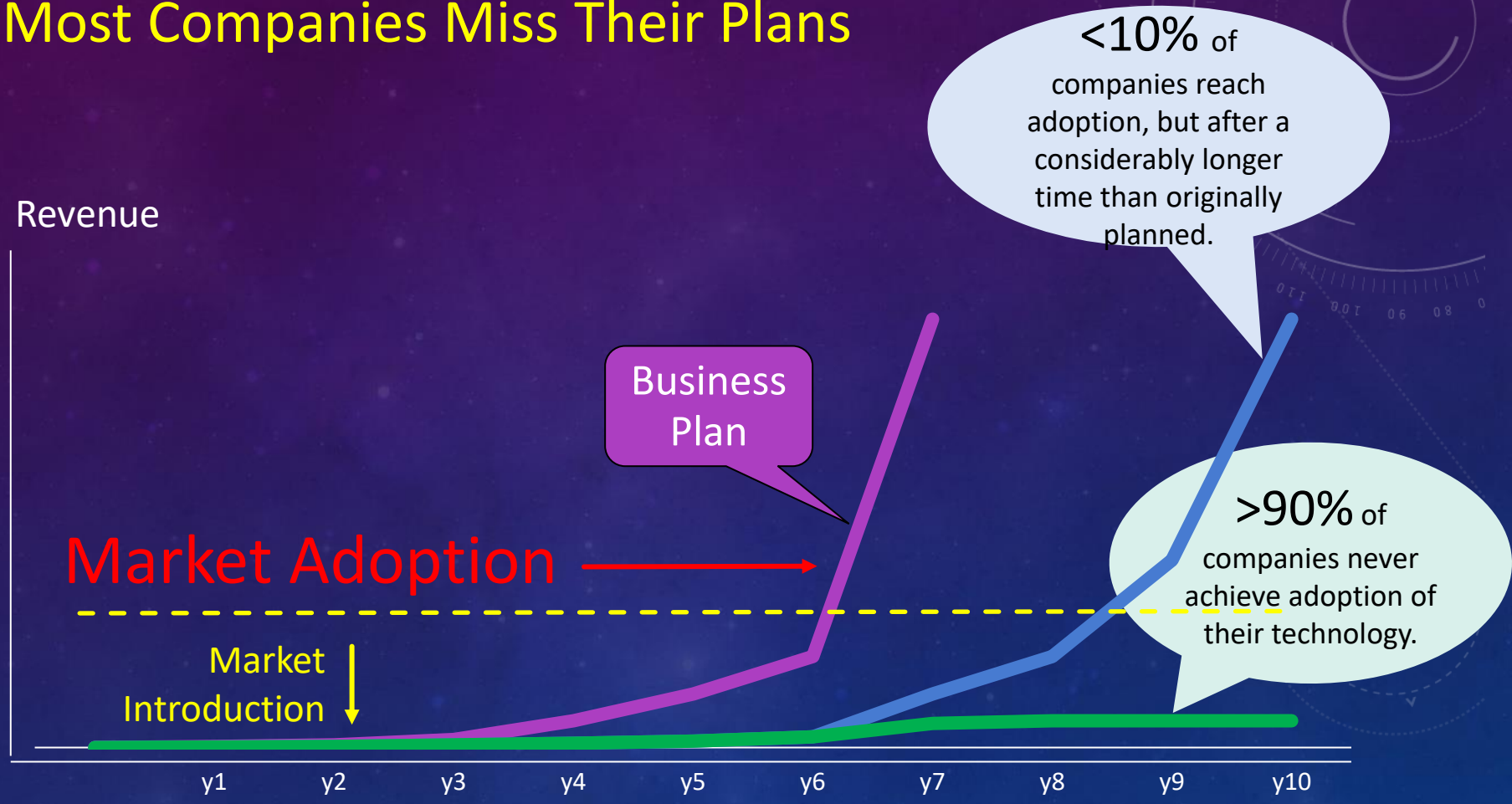
AGENDA

- Why ‘Pricing’ is important?
- The U.S. healthcare system
- Codes and Coverage
- The changing landscape
- Digital Technologies - Considerations and Decisions
- Case studies
- So, what do we need to do?

Why ‘Pricing’ is Important?

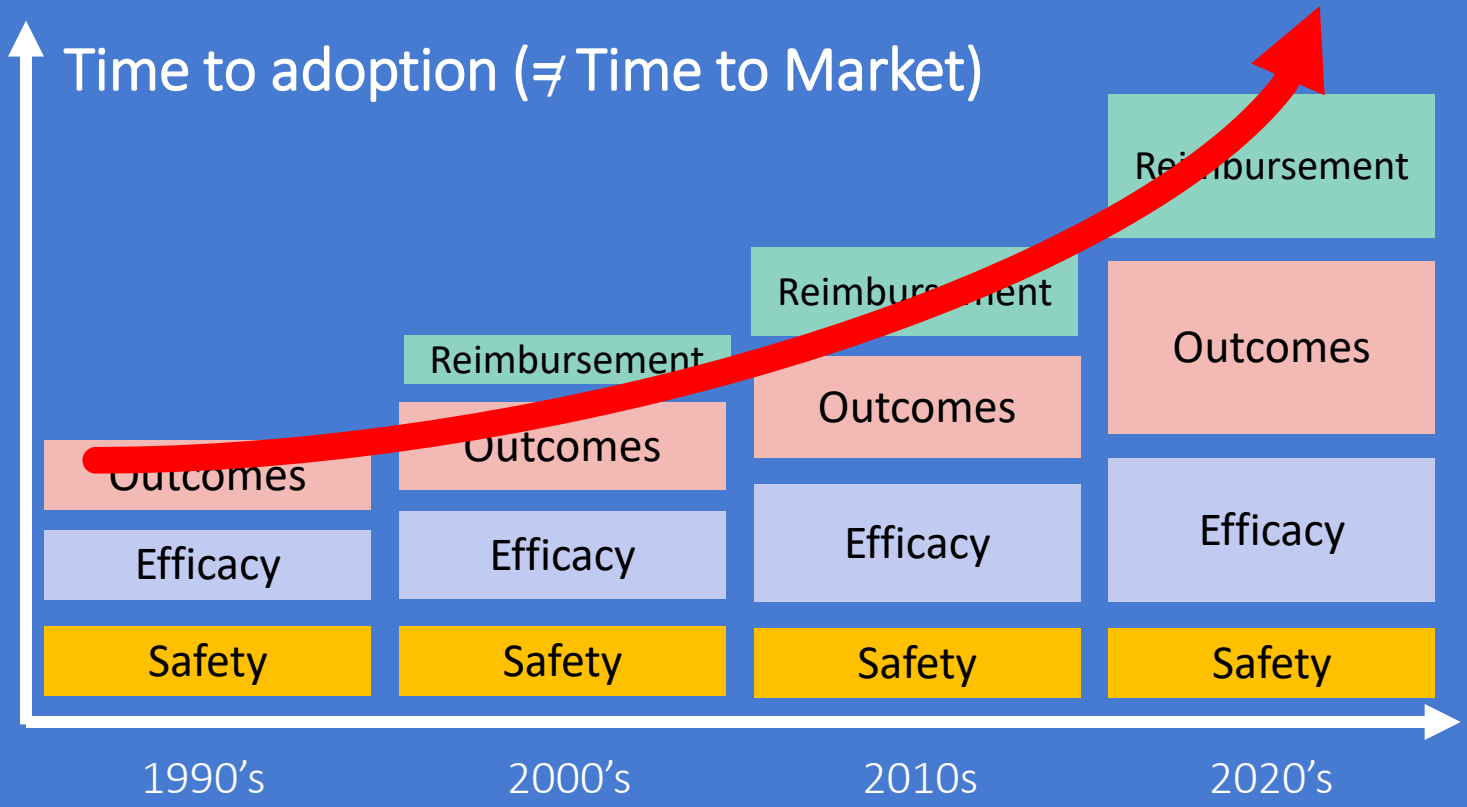
FACT #1:

Most Companies Miss Their Plans



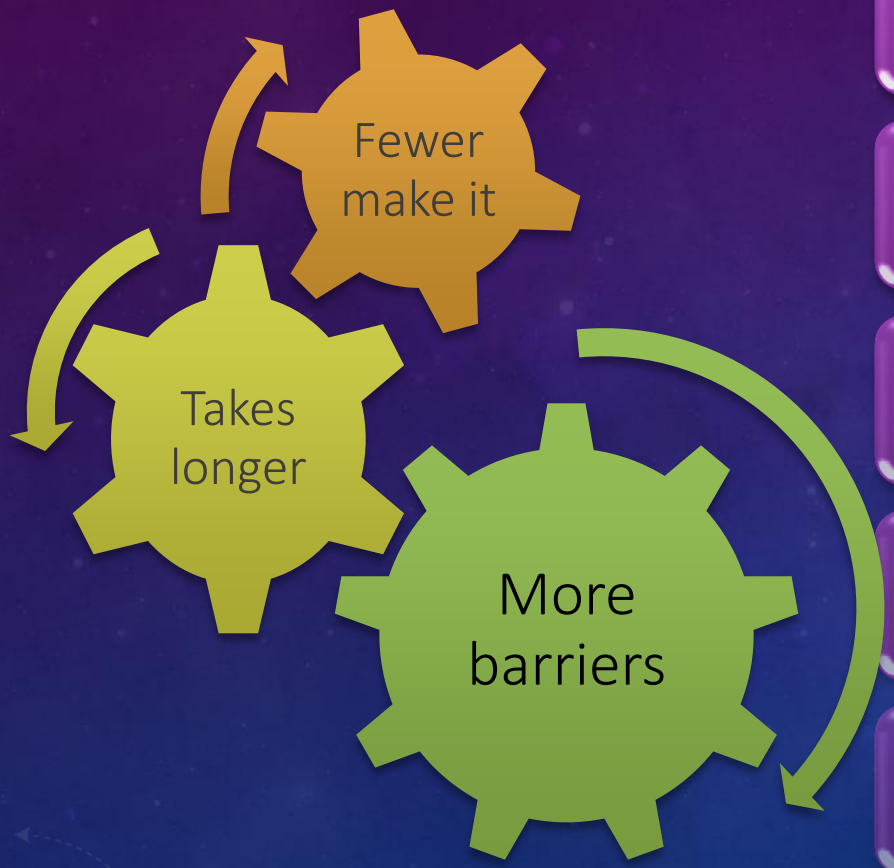
FACT #2

Time to Clinical and Market Adoption Continues to Increase



FACT #3:

Longer **Time-to-adoption** Has Considerable Implications



- Delayed revenue
- Need for more funding
- Valuations are negatively impacted
- Business development initiatives are delayed
- Increased risk of new competitors

Proper Pricing and Reimbursement are Key Requirements for Adoption of NEW Technologies

Pricing model and even favorable reimbursement do not guarantee utilization of the technology…

But,

Inappropriate pricing and lack of reimbursement adversely impact utilization.

What does it mean to 'have reimbursement'?

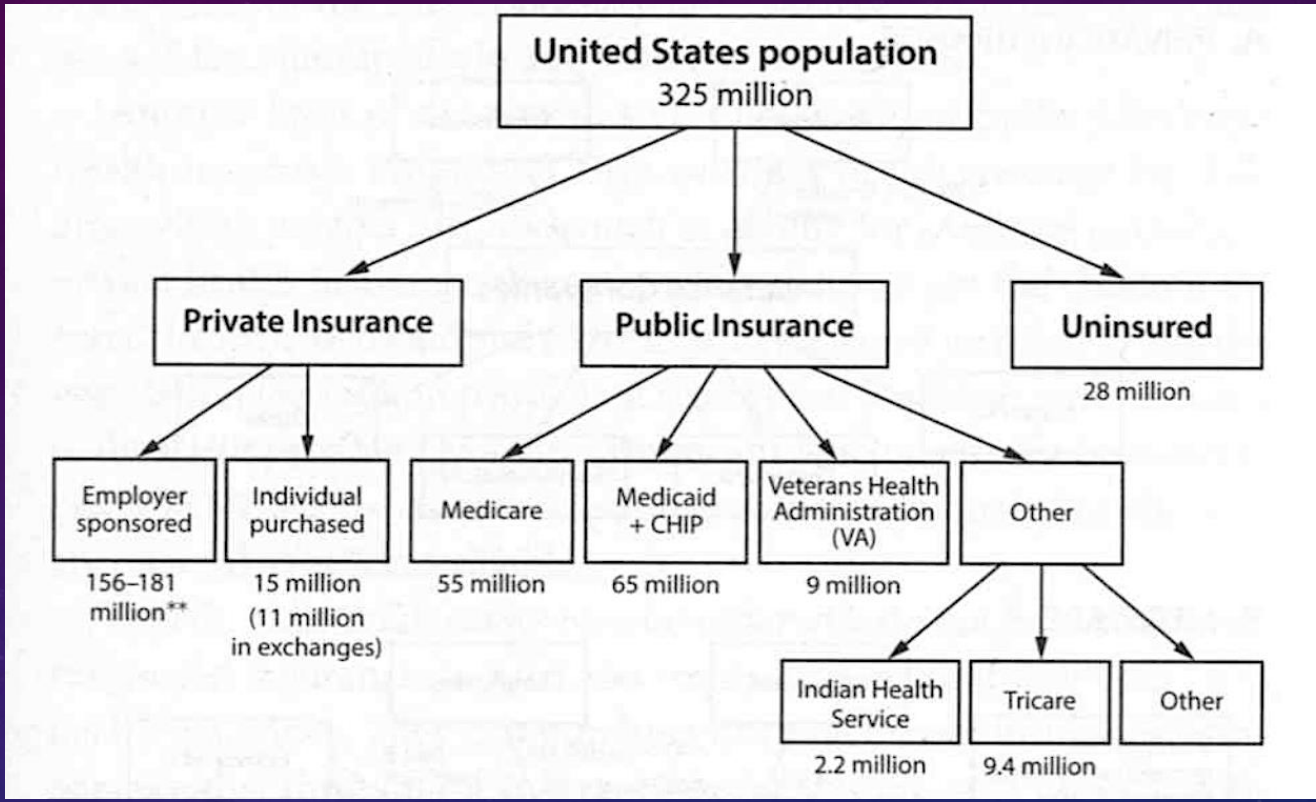
- ✓ The technology or procedure is **covered**…
- ✓ The coverage is **sufficiently broad**…
- ✓ The **payment is appropriate** - covering the costs of physicians, hospitals, distributors and manufacturers

The U.S. Healthcare System

"The American healthcare system is a patchwork of different arrangements and is very confusing to navigate…"

Dr. Ezekiel Emanuel

Healthcare Coverage in the U.S.



Medicare

- Federal program, ages >65 and permanently disabled;
- ~35% - Medicare Advantage

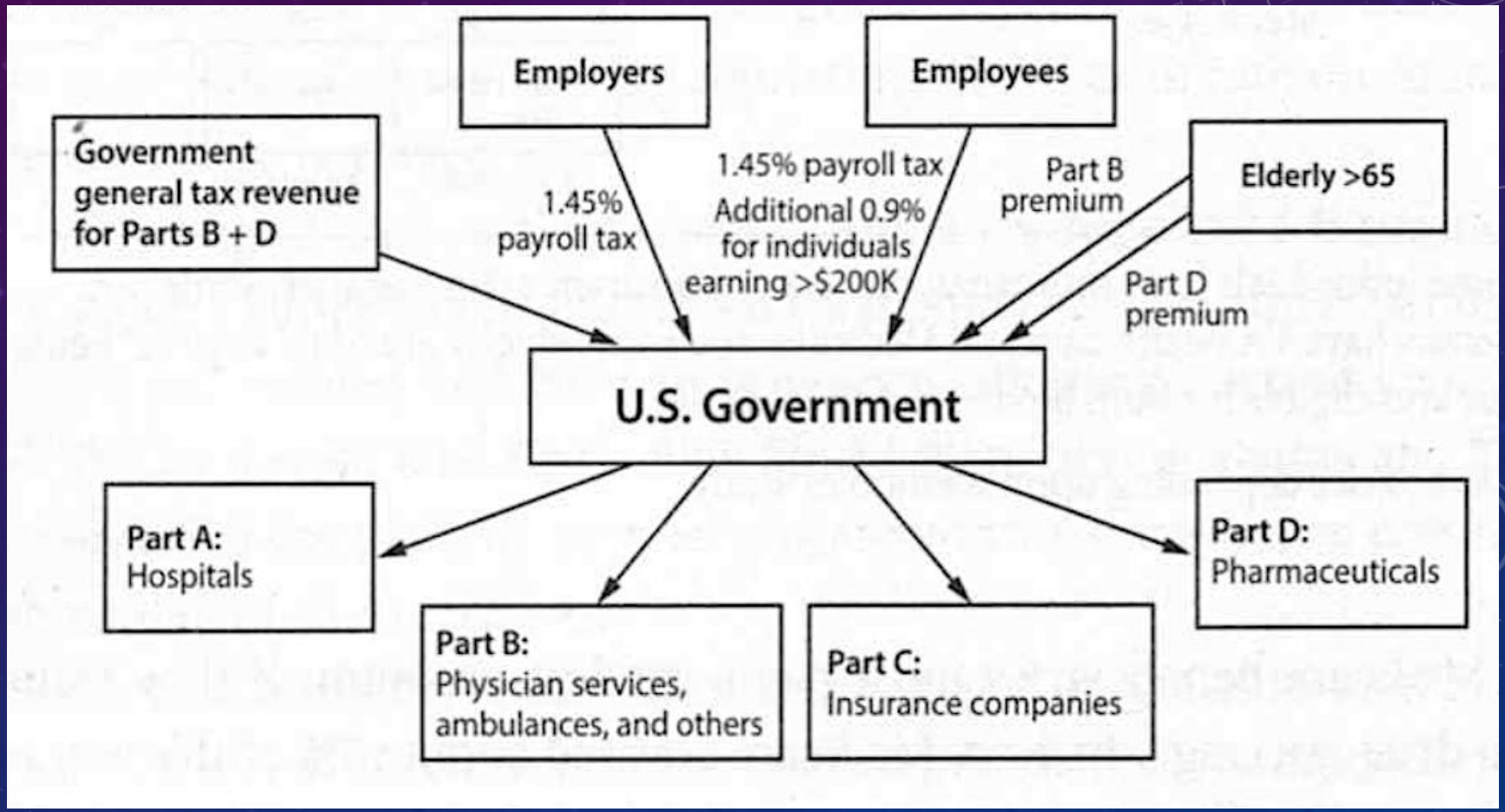
Medicaid

- Lower income (administered by states)
- **CHIP** (Children's Health Insurance Program): children not covered by parents' insurance

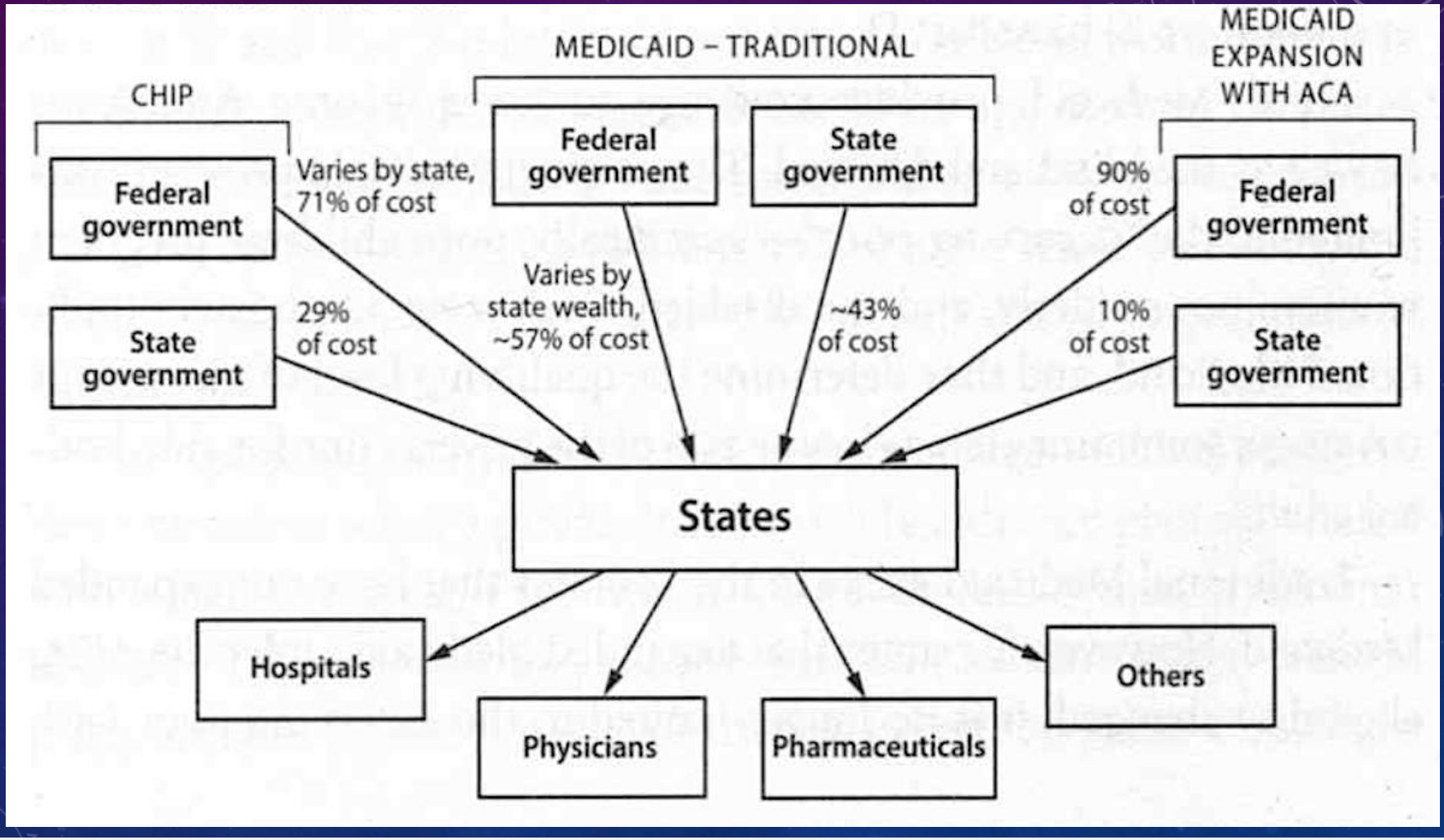
Private insurance

- Hundreds of plans
- Most covered through employers.

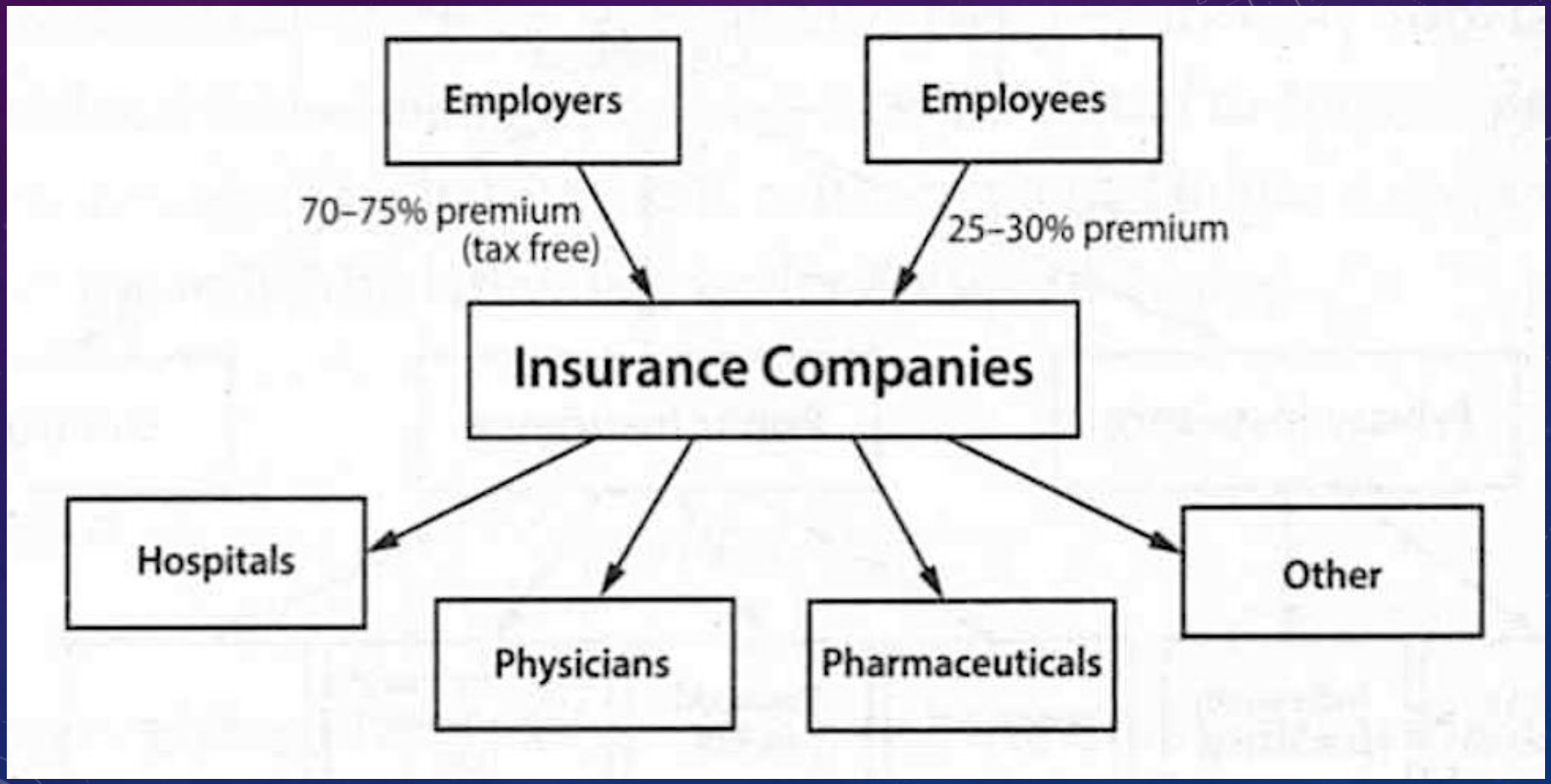
Medicare -
pays through 4 major programs to statutory mandated services



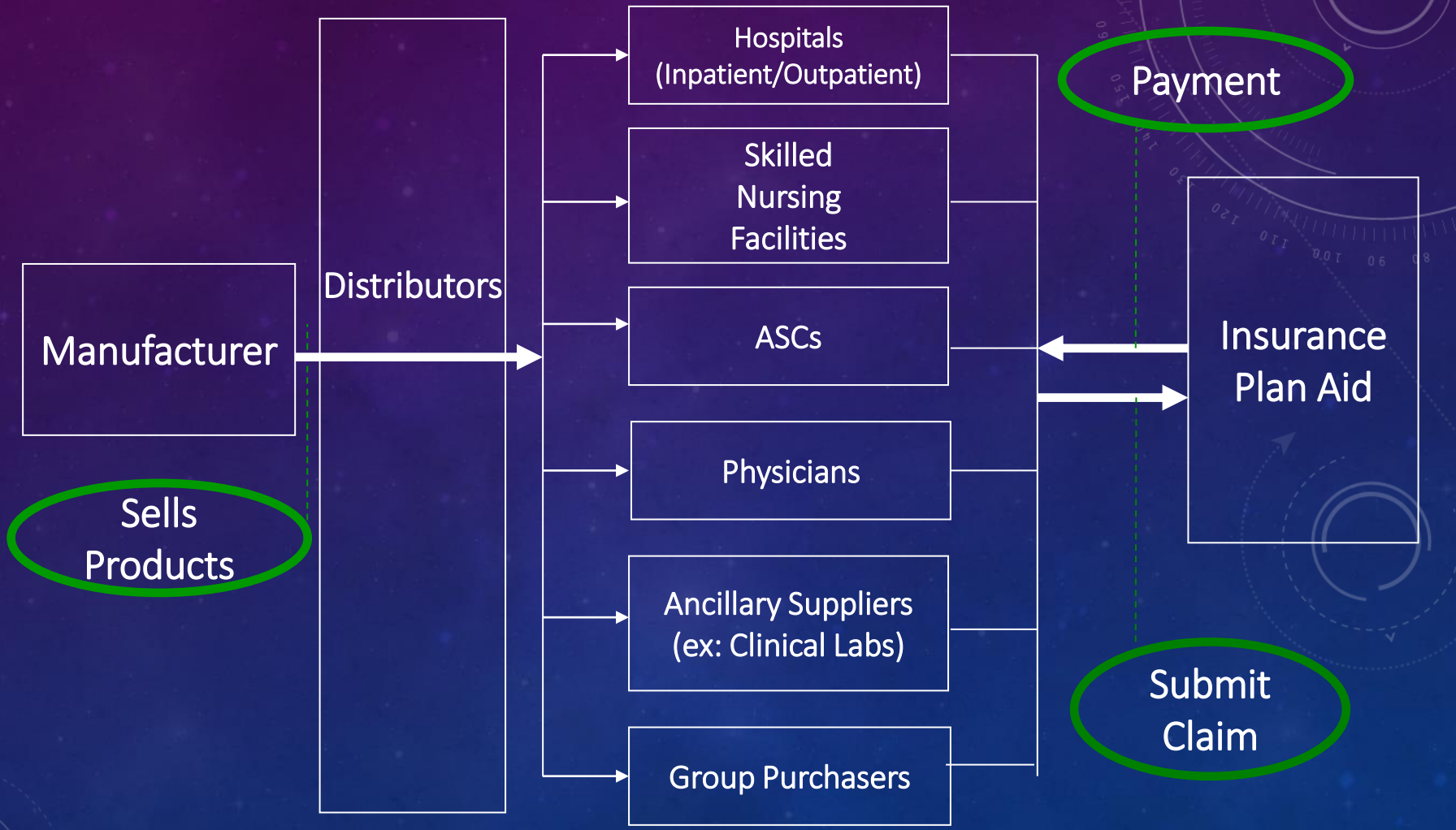
Medicaid -
each state runs its program, determines coverage and payments



Private Insurance - each plan determines what to cover; payments are negotiable

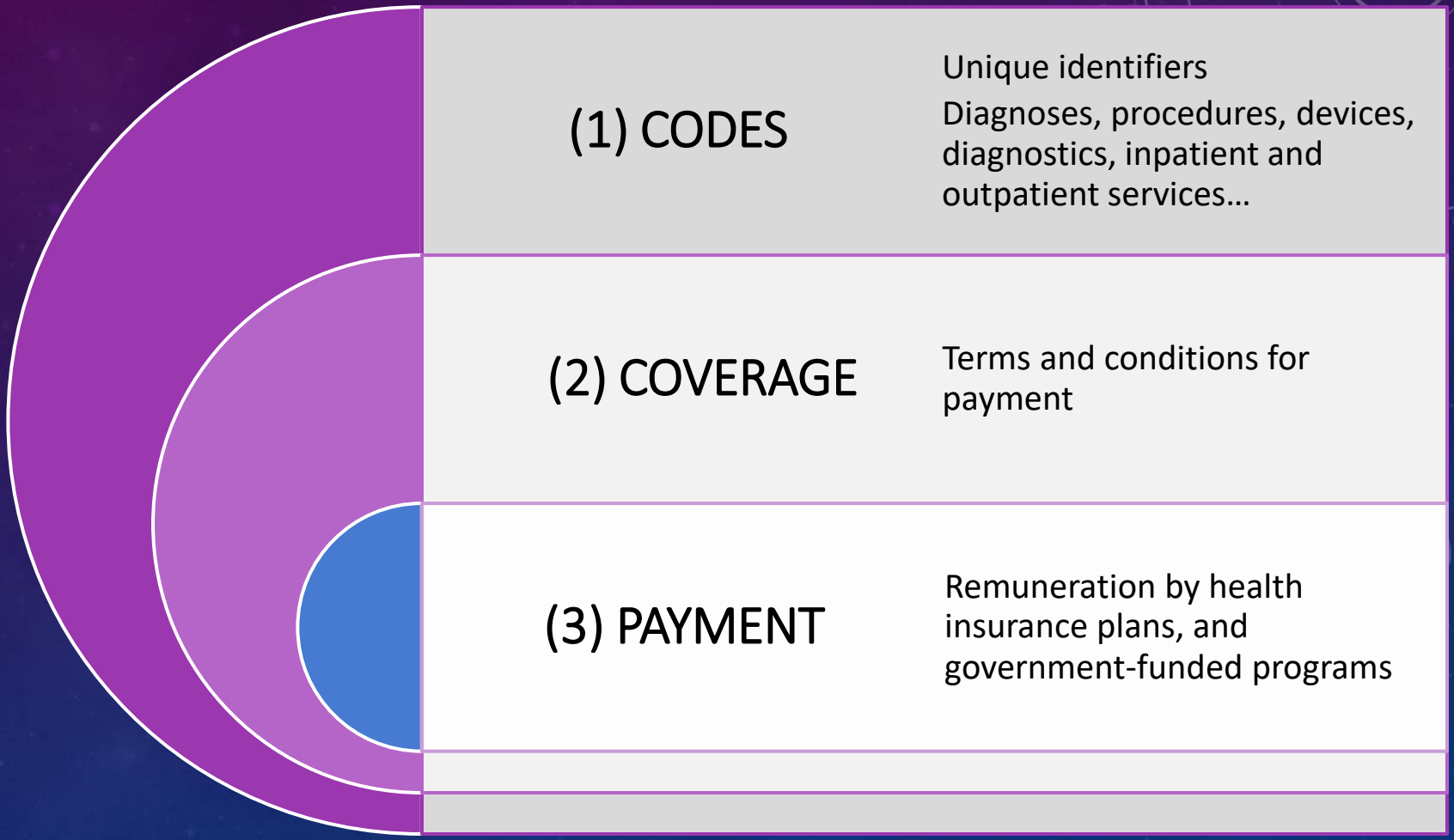


Payments by payers are Made To Providers, Not to Manufacturers of Technology



Codes and Coverage 101

THREE DISTINCT ELEMENTS



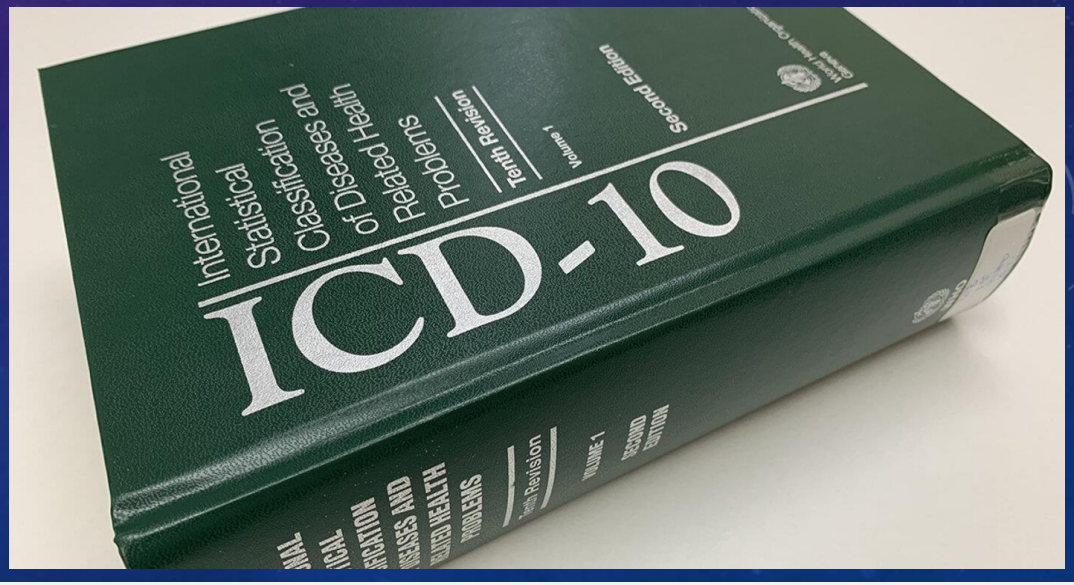
THE INTERNATIONAL CLASSIFICATION OF DISEASES Tenth Edition (ICD-10)

~70,000 diagnosis codes and ~70,000 procedure codes

- Published by The World Health Organization (WHO)
- Updated annually

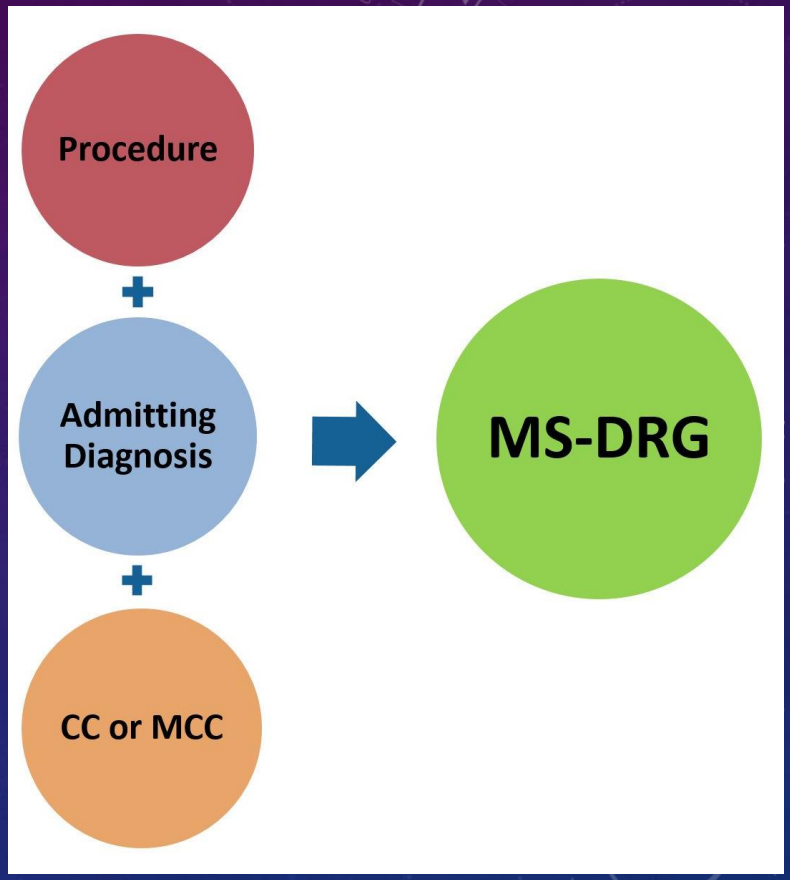
PCS - procedural classification system

CM - morbidity classification



DIAGNOSIS-RELATED GROUPS (DRG)

- **~740 DRG** categories.
- Enable **standardized prospective payments** to hospitals, based on the "average" **cost** to deliver care to a patient with a particular disease.
- The **DRG is determined** by the principal diagnosis and procedure, and patient's secondary **comorbidities and complications**.

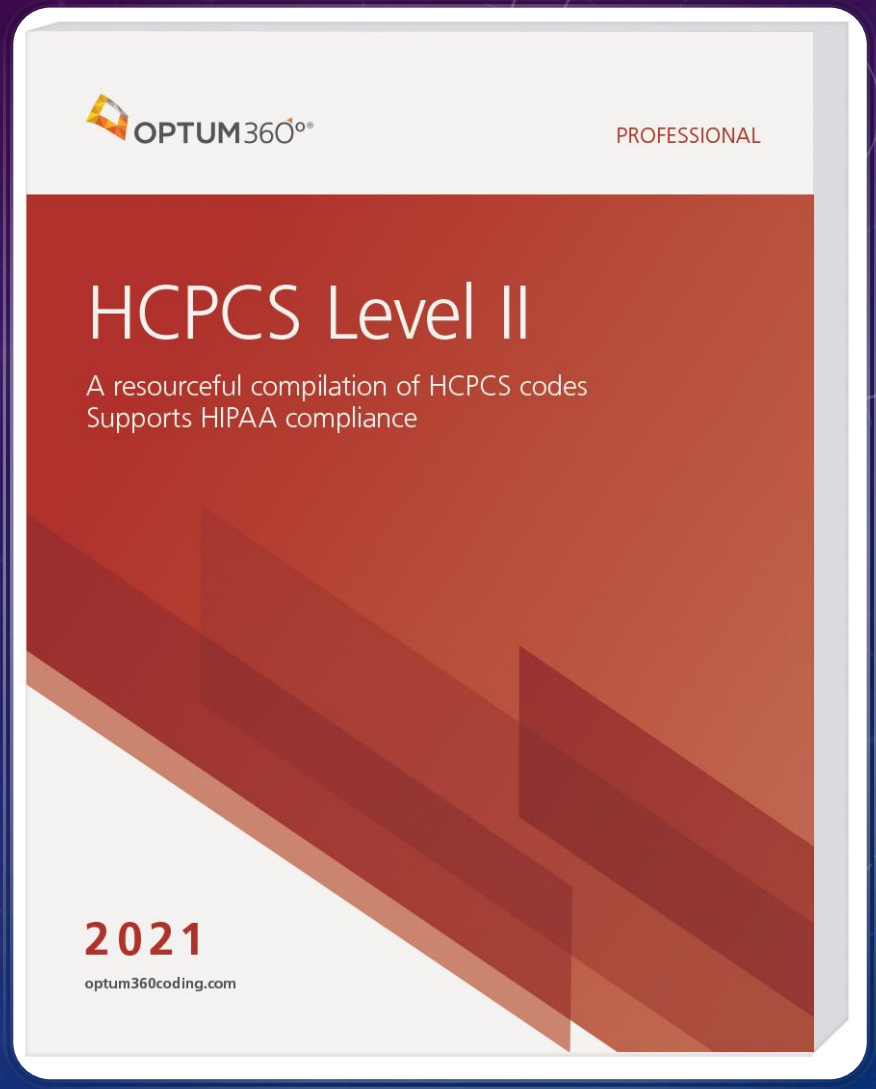


DRG payments cover all charges associated with an inpatient stay from the admission to discharge including nursing services, room and board, diagnostic and all ancillary services, **EXCEPT PAYEMNTS TO PHYSICIANS**.

HEALTHCARE COMMON PROCEDURE CODING SYSTEM (HCPCS LEVEL II)

Codes describing items, supplies and non-physician services not covered by payments for other services.

- Maintained by Medicare
- Updated quarterly



CPT (CURRENT PROCEDURAL TERMINOLOGY) CODES

Report medical, surgical, and diagnostic procedures and services.

- Over **10,000 codes**
- CPT codes are maintained by the AMA CPT Editorial Panel
- The Editorial Panel revises, updates, and modifies CPT codes, descriptors, rules and guidelines.

CPT CODES

Category I

- Approval requires meeting significant requirements, including multiple publications, installed / growing user base in the U.S. and support of relevant professional societies.

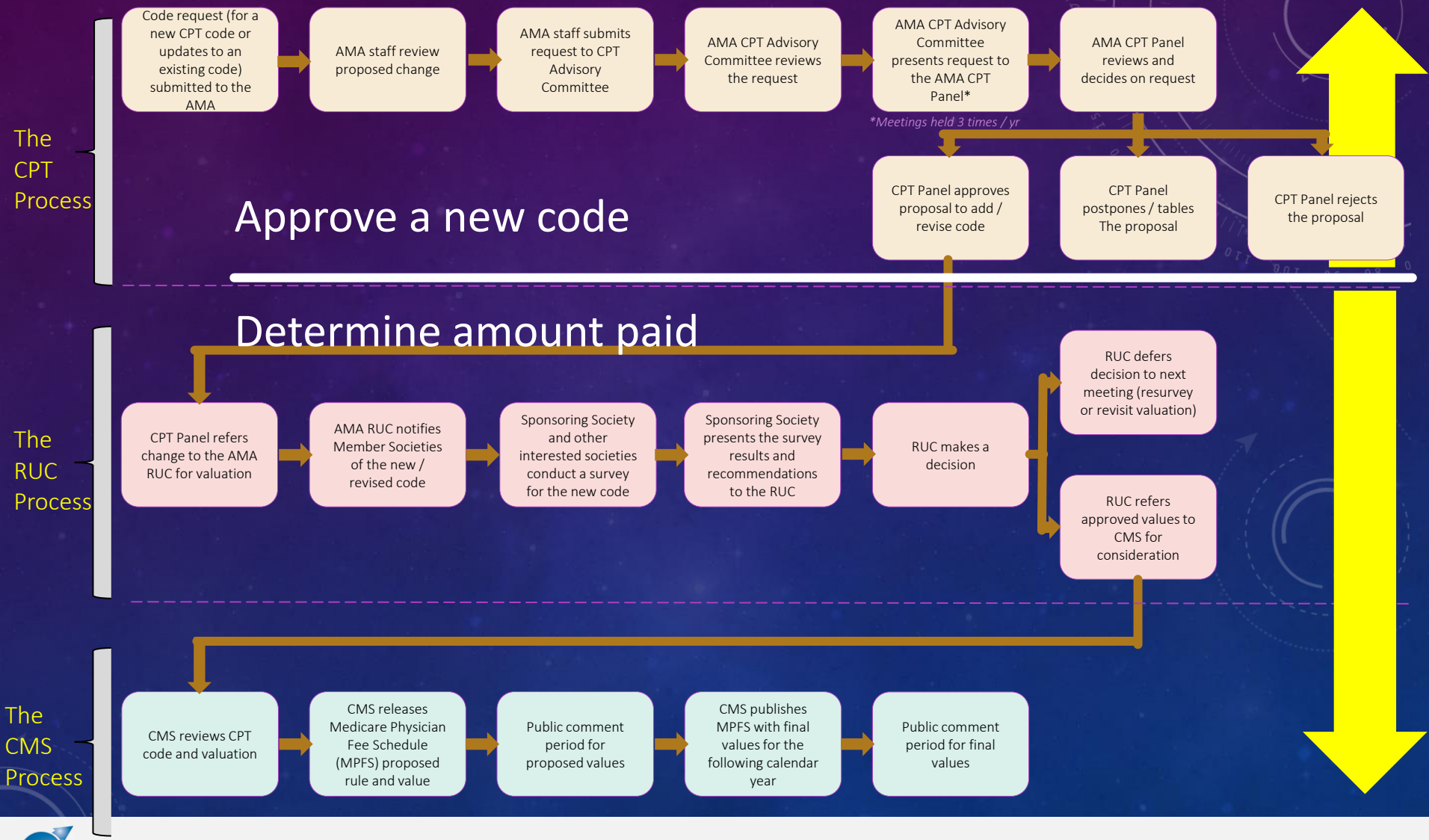
Reimbursement by payers is more likely

Category III

- Assigned to **emerging technologies**, for services that do **not meet requirements for a Category I code**.
- Remain in effect for 5 years, unless replaced earlier by a Category I code.

Less likely to be reimbursed

DEVELOPMENT OF A NEW CPT **CATEGORY I** CODE



FDA approval does not guarantee reimbursement

FDA approval of a device allows its marketing in the U.S.
Payers decide whether to cover the device or the procedure.

Clinical data supporting most FDA approval decisions - a single study, documenting safety and efficacy.

Payers' coverage decisions are based on evidence - multiple peer-review publications summarizing studies assessing clinical outcomes.

Code ≠ Coverage

COVERAGE - ASSESSED BY EACH PAYER

Medicare

Scope is governed by statue "reasonable and necessary for the diagnosis or treatment of illness or injury."

- Improved outcomes (e.g., return to regular activities)
- Benefits outweigh risks
- Clinical evidence shows outcomes in the relevant population

Private Plans (e.g., BCBS)

Each plan sets own criteria

- The technology improves health outcomes
- The technology is beneficial as established alternatives
- The improvement is attainable outside of investigational settings

Coverage ≠ Sufficient Payment

PRICING

Medicare

- Formal pricing process
- Standardized fee schedule (modulated by geography, teaching affiliation, etc.)
- Fee schedule not negotiable
- Public information

Commercial Payers

- No formal pricing process (typ. using Medicare as benchmark)
- Fee schedule negotiated with each provider
- Confidential information

Fee schedules are subject to changes by payers.
Supporting fees are an ongoing effort.

Reimbursement and Pricing Environment May Finally Change….

Maybe

U.S. Healthcare

$3.8 trillion

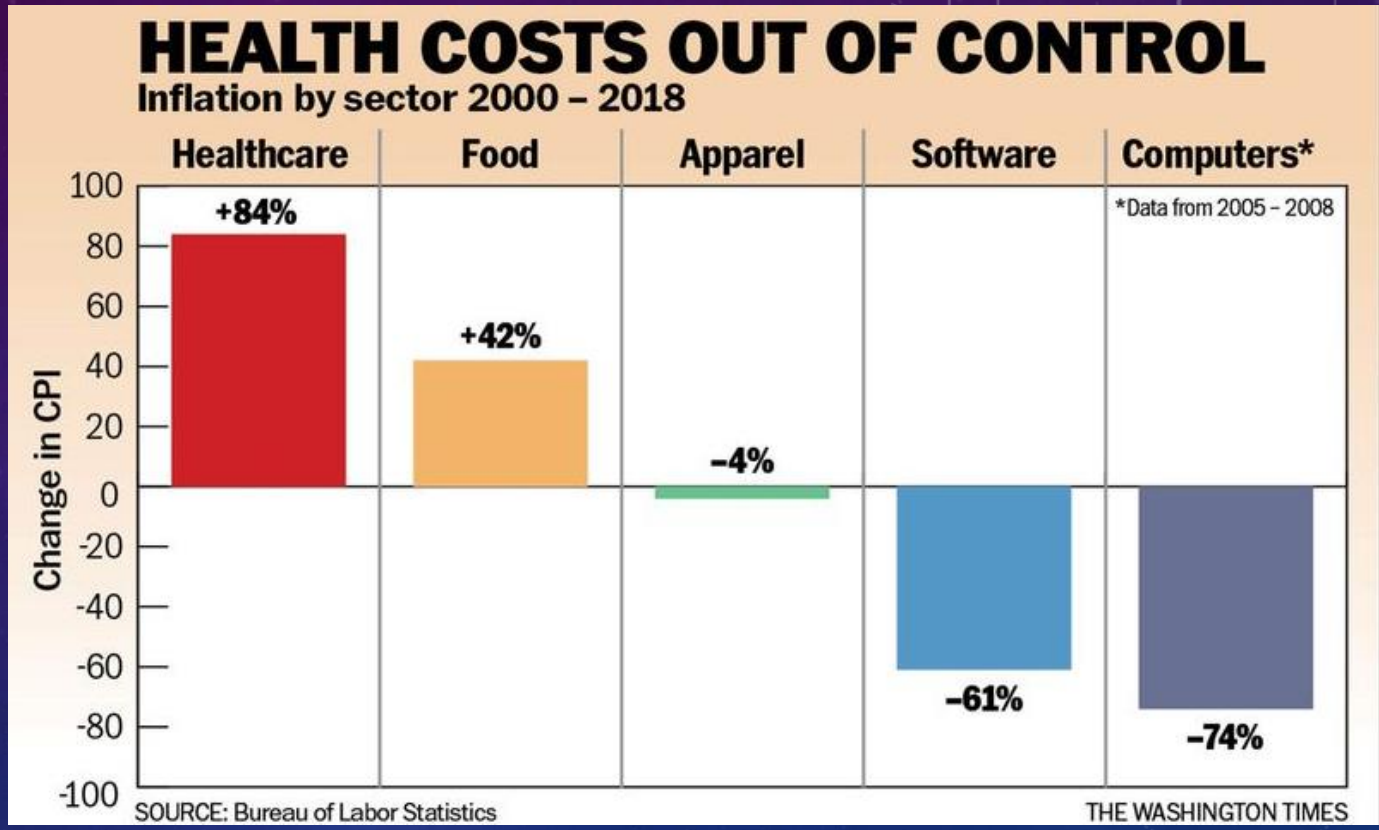
$11,500 per person

17.7% of GDP

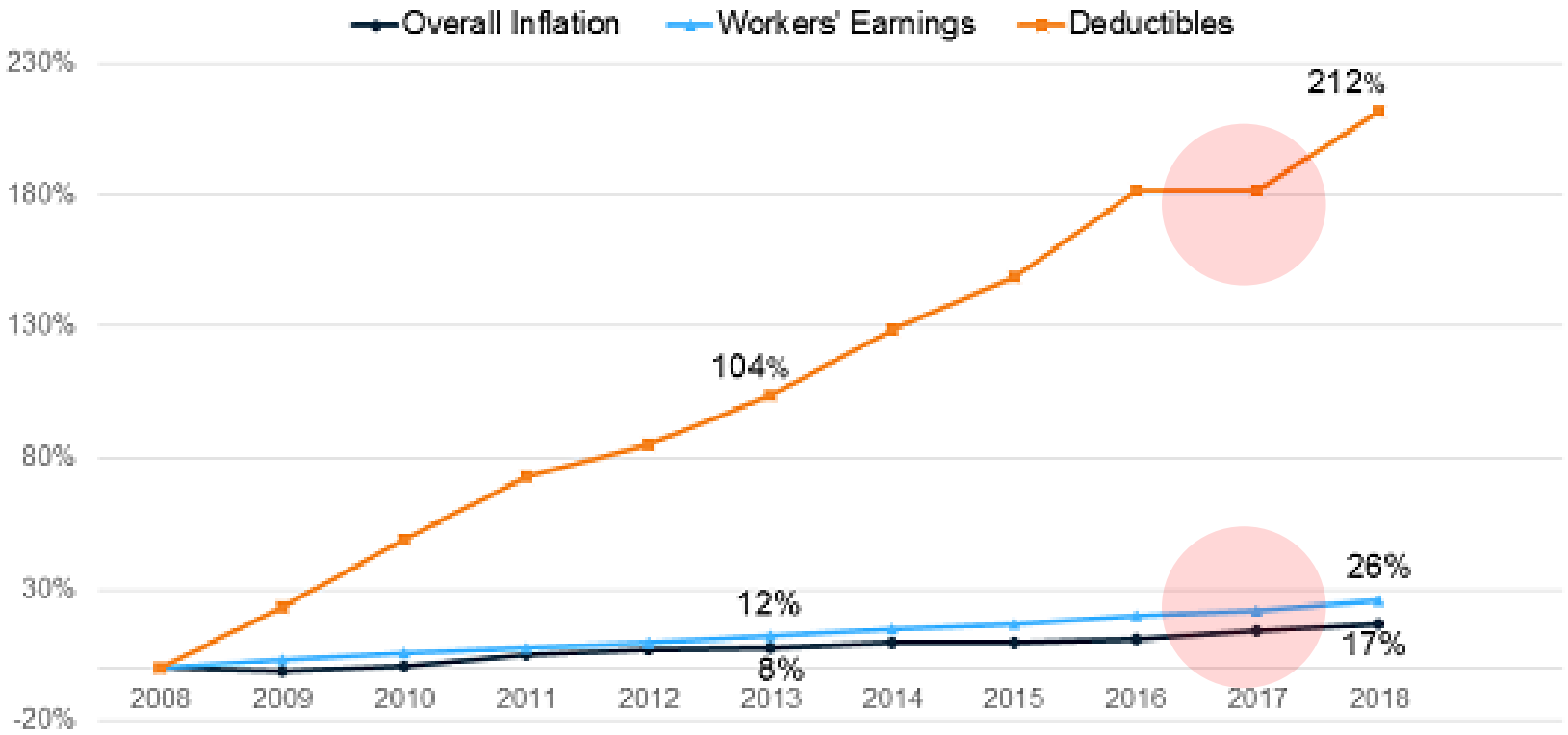
Germany	11.7%
Israel	7.5%

Federal government	28%
State and local governments	17%
Private business	20%
Individuals	28%
Other private sources	7%

Most expenditures - Fee for Service



Since 2008, General Annual Deductibles for Covered Workers Have Increased Eight Times as Fast as Wages



NOTE: Average general annual deductibles are among all covered workers. Workers in plans without a general annual deductible for in-network services are assigned a value of zero.

SOURCE: KFF and KFF/HRET Employer Health Benefits Surveys. Consumer Price Index, U.S. City Average of Annual Inflation (April to April); Seasonally Adjusted Data from the Current Employment Statistics Survey (April to April).

KFF
HENRY J KAISER FAMILY FOUNDATION

CHANGE IS UNDERWAY

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

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."

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

WHAT CONSTITUTES VALUE?

"Value is measured by patient health outcomes per dollar spent."

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
- Less need for long-term care
- Fewer recurrences
- Reduced need for ER visits
- Slower disease progression

Many Reforms and Initiatives are Being Evaluated

- **Accountable Care Organizations (ACO)** - shift from fragmented and inconsistent care to coordinated care and measured performance
- **Value-Based Purchasing (VBP) Program** - reward value and patient outcomes, instead of just 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
- **Risk sharing**

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, operations, marketing, economics***

Digital Technologies -

Additional Considerations and Decisions

PRICING MODEL - INFLUENCED BY NUMEROUS FACTORS

- Healthcare systems using the technology
- Where the technology will be used (hospitals, outpatients, home, etc.), by whom?
- Who will purchase the technology? Capital / operating budget, purchasing considerations
- Economic landscape; available reimbursement? Need to develop new reimbursement? How will money flow from payer to provider to manufacturer
- Competing products and clinical alternatives
- Clinical evidence
- Workflow

Setting a business model and pricing without understanding the influence of other factors will lead to sub-optimal strategy *(in most cases…)*

Categorizations of digital services

- Synchronous / Asynchronous services
- Non-automated / Automated services
- Work-time requiring services / No-work-time requiring services

Different pricing models for different offerings

- **Synchronous / non-automated / work-time requirements.** Patient and a clinician interacting remotely at the same time (e.g., e-visit)
- **Asynchronous / non-automated / work-time requirements.** Interaction is not simultaneous, work-time is required, although delayed (e.g., patient sends an inquiry and/or data and waits for a response from the clinician).
- **Asynchronous / automated / work-time requirements.** Automation is built into the interaction. Patient acts independently performing assigned activities, guided by the autonomous digital app. Professionals interacts with the patient when necessary, using the platform. The work-time reflects the monitoring done by the therapist, but generally, not affected by the frequency of use by the patient (e.g., virtual therapy).
- **Asynchronous / automated / no work-time requirements.** Services do not require work-time by a clinician. The treatment is offered via the digital service using a virtual platform, designed to guide the patient independently, at any time (self treatment).

Case Studies

itamar® medical

- Itamar Medical introduced a user-friendly, home-based OSA device (WatchPAT).
- The AASM objected to codes and coverage for home studies (loss of income to physicians).
- Without codes and coverage from CMS and most commercial payers, sales of WatchPAT were nominal.

BMTA:

- Convinced CMS to issue coverage prior to having CPT codes.
- CMS temporary codes were also gradually adopted by commercial payers.
- Eventually, AASM agreed to new CPT codes.
- Fee schedule - supports premium pricing.

- Pricing of WatchPAT higher than competitors
- Justified by faster turnover and less handling

With **new codes and expanding coverage**, sales of WatchPAT increased to ~$50M run-rate

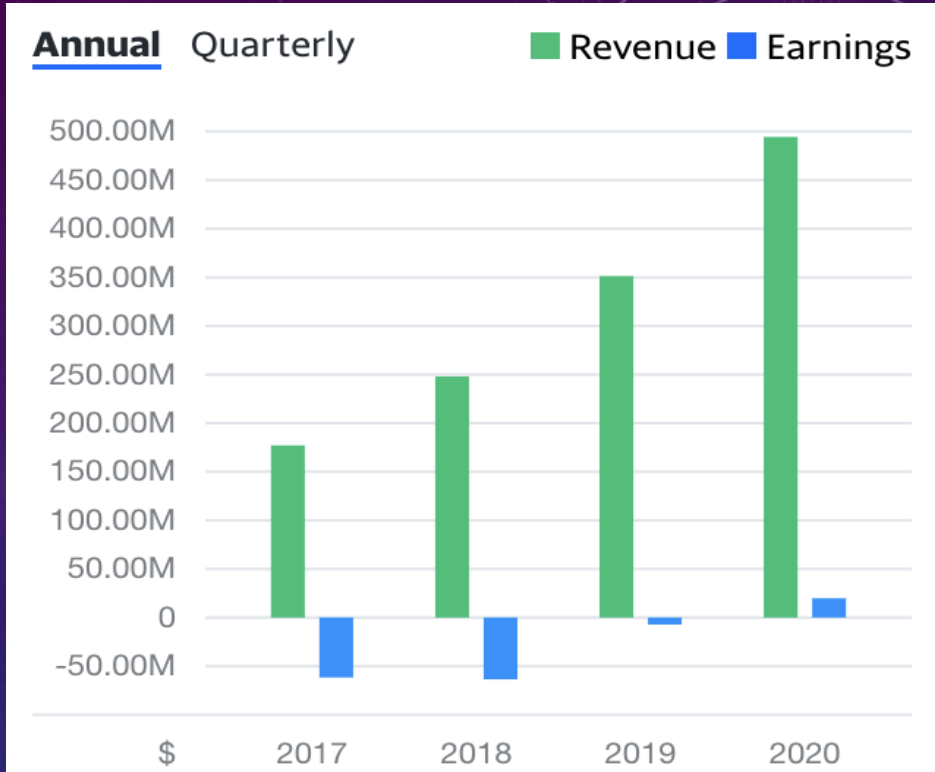
Acquired by Zoll Medical for ~$500M (2021)

- A new treatment modality for solid tumors
- Low intensity electrical field, applied through external electrodes; 24/7 treatment
- First FDA approval - GBM
- Large number of studies - additional tumors

BMTA:

- Developed pricing rationale for the treatment - compared to drug therapy, not device-based
- Assessed reimbursement structures for the home-based therapy
- Advised the company to become the provider for the therapy rather than sell devices to oncology clinics

- Company received a HCPCS code for its equipment
- Reimbursement >$10K /month
- Rev >$500M / year
- Valuation ~$10B



THE PROCESS - IN BOTH CASES

- Understand the market - guidelines, practices, workflow, barriers, politics…
- Identify the value of your products / services, as perceived by the users
- Focus on specific market segment
- Design the product to maximize specific value attributes
- Develop a rational pricing position
- Identify / develop the appropriate delivery system / providers
- Develop and execute supportive reimbursement strategy -- codes and coverage

- Start planning early… waiting until you are in the market is too late
- Pricing is never an independent function. It is part of your strategy.

So, What Do We Need To Do?

	Addressing pricing and reimbursement early in the process changed from:	Failure to address pricing and 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

Assess HOW 'Pricing' and 'Reimbursement' Affect YOUR Plans

Selection of first application / indication / market segment	**Product configuration / users' requirements**	**Regulatory strategy / IFU**
Required clinical data to support reimbursement, pricing position and marketing	**Go-to-market strategy**	**Financial plans**
Business and operating models	**Identifying appropriate advisors**	**Required people, skills & budgets**

The Initial Review Must Address All Relevant Elements

What will be reimbursed?

- Professional services
- Facility costs
- Device / product

Medical practice

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

Who are the users?

- PCP / specialties
- Nurses
- Licensed therapists
- Patients

Who will pay?

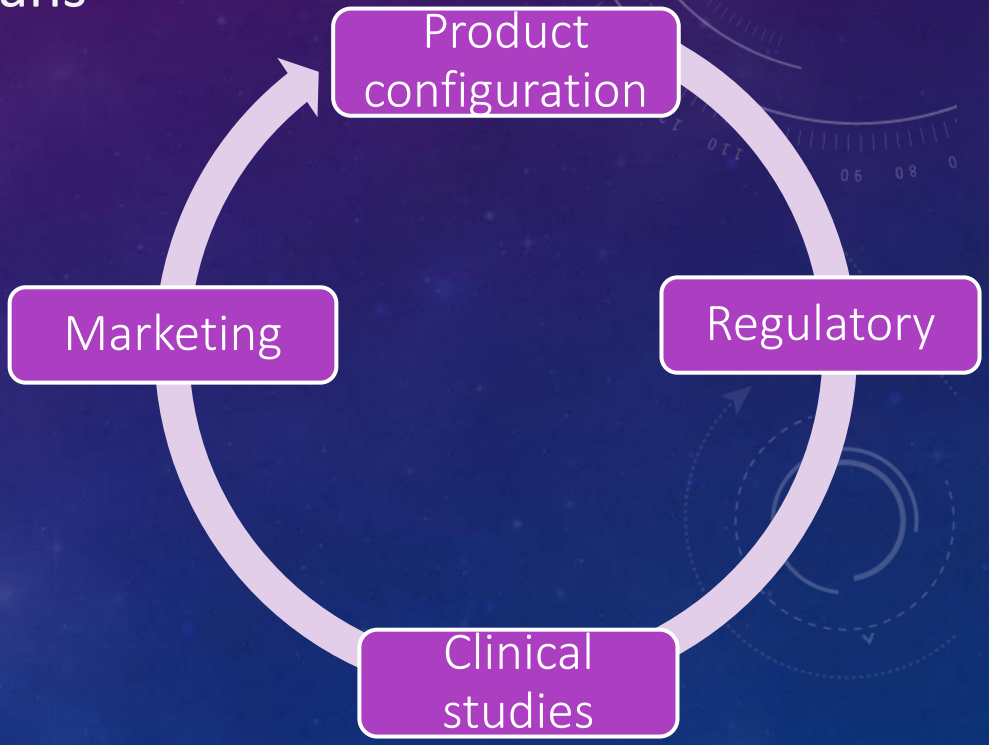
- Medicare
- Medicaid
- Commercial payers
- IDNs
- Government
- Employers
- Patients

Where will the service / technology be used?

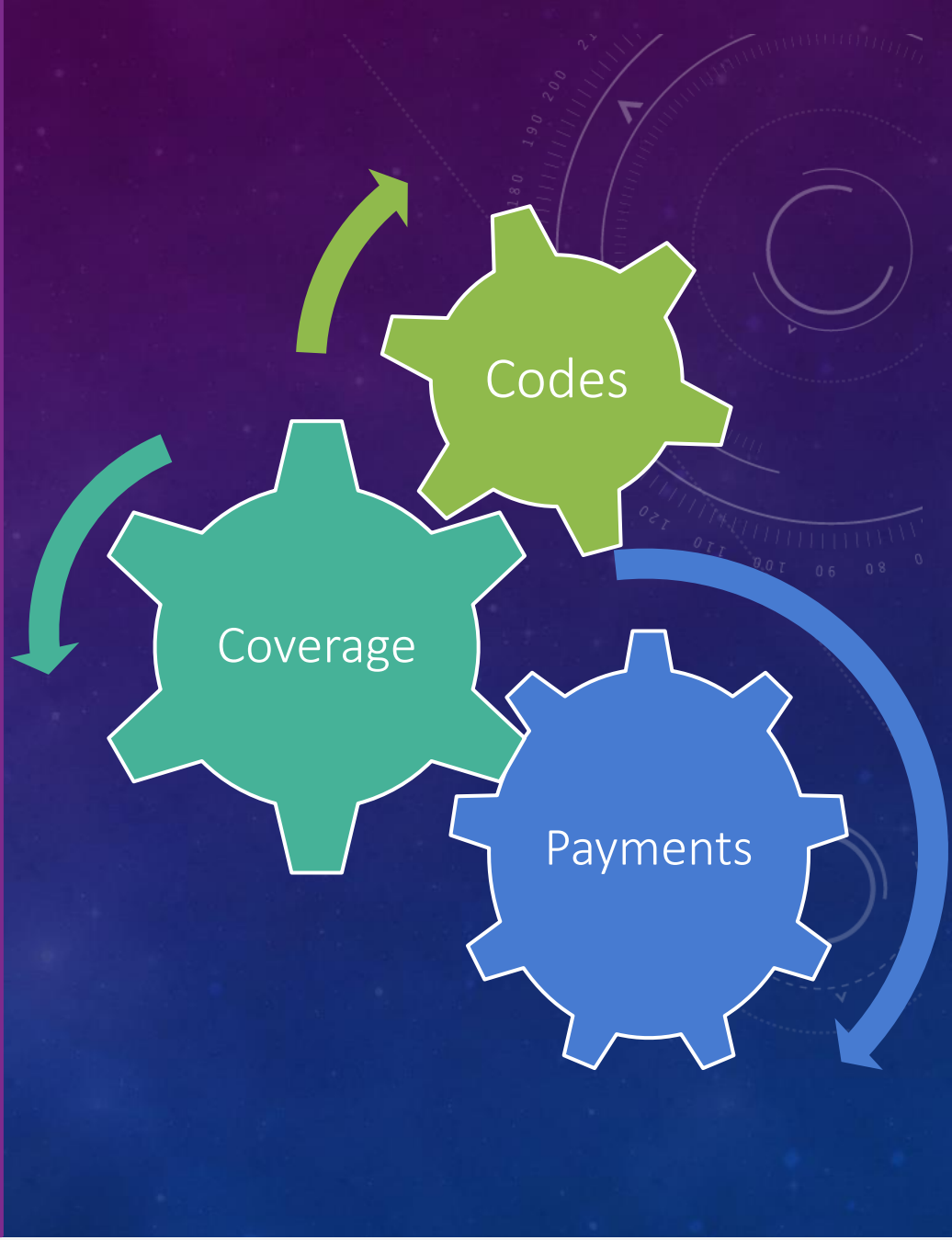
- Inpatient facility
  - Hospitals
  - Long term care
- Outpatient
  - Hospital-based
  - Ambulatory surgical centers
  - Physician offices
- Home

So, When Should We Start Reviewing Pricing and Reimbursement?

- Reimbursement and pricing plans will affect all key activities
- Remember:
  - FDA approval does not guarantee reimbursement
  - Codes ≠ Coverage



The sooner you understand your market and roadmap to adoption - including pricing and reimbursement - the better you are

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