



EARLIER REIMBURSEMENT AS A DRIVER OF VALUATION

*WHY DEVELOPING REIMBURSEMENT STRATEGY IS CRITICAL
FOR MEDTECH COMPANIES?*

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

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

Our Focus

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

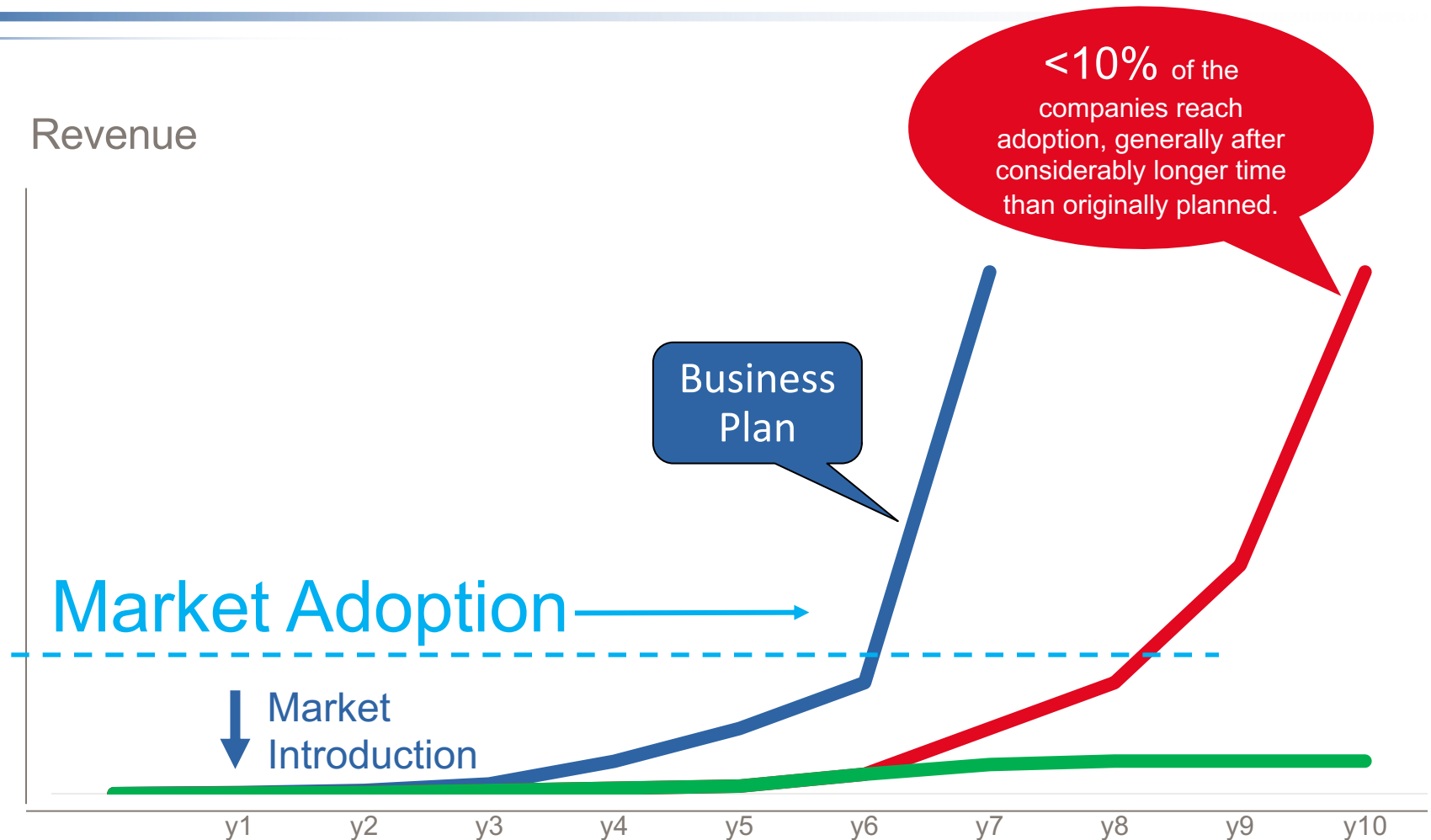


Today's Agenda

- ❖ Why 'Reimbursement' is important?
- ❖ Codes and Coverage 101
- ❖ The changing landscape of reimbursement in the U.S.
- ❖ So, what do we need to do?
- ❖ Case studies
- ❖ Questions?

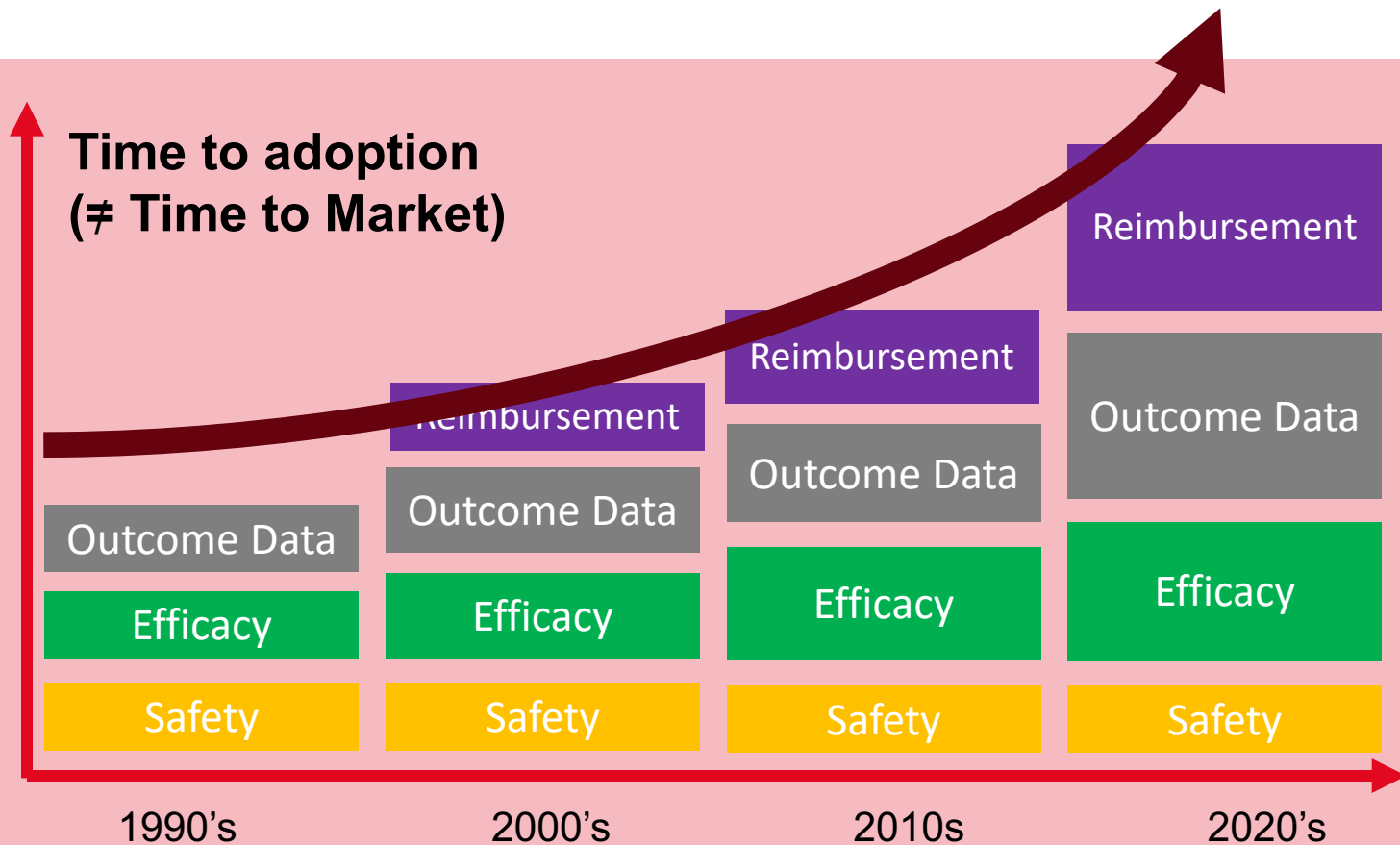
Why 'Reimbursement' is Important?

Most Companies Miss Their plans



The Adoption Paradox

While the **need** for new technologies is increasing,
It is increasingly more difficult to gain **clinical and market adoption**.



Reimbursement -

A Key Requirement for **Adoption** of NEW Technologies

What does it mean to 'have reimbursement'?

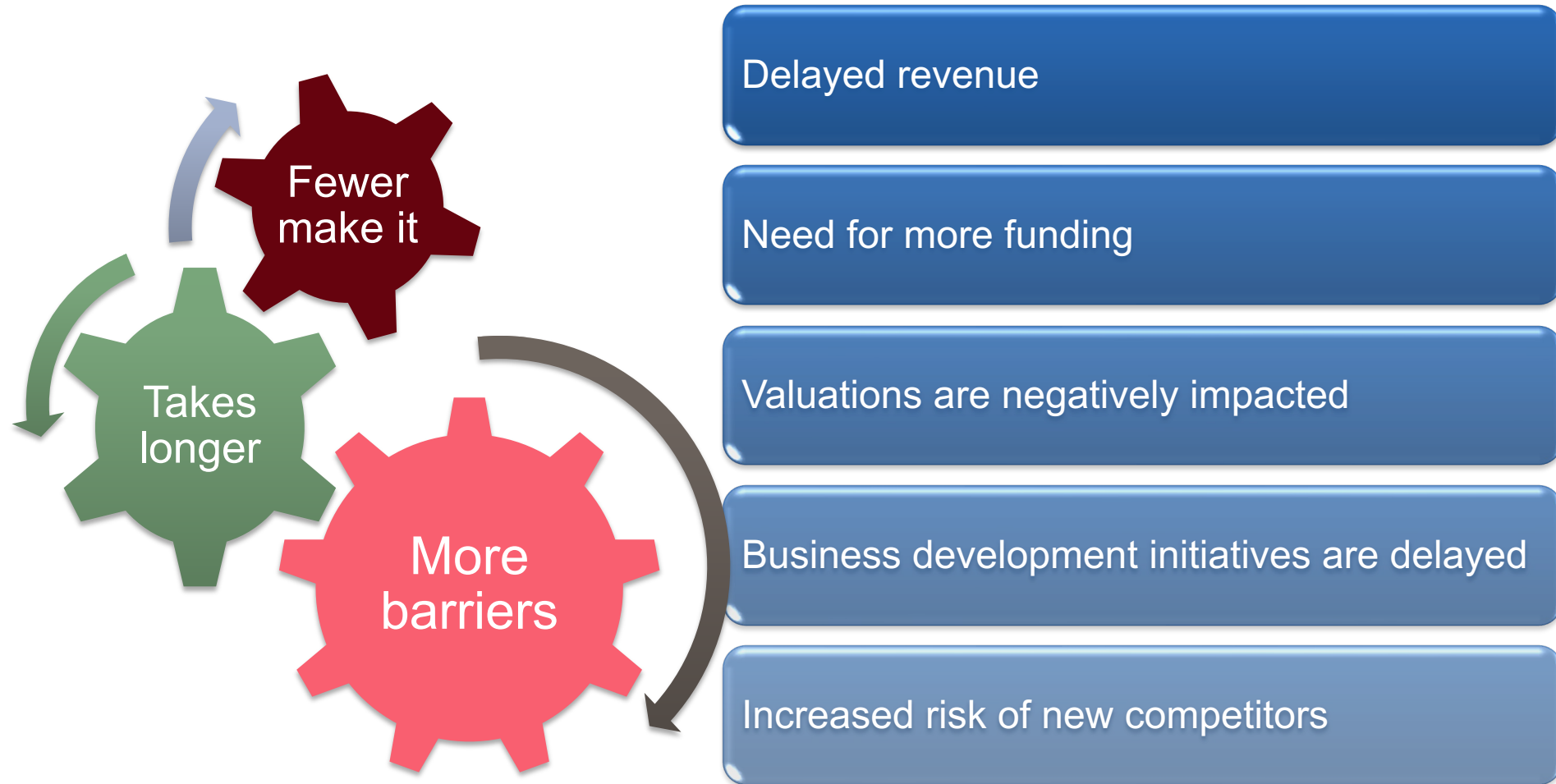
- ✓ The technology or procedure is **covered...**
- ✓ The coverage is **sufficiently broad...**
- ✓ The **payment is appropriate** - covering the costs of physicians, hospitals, distributors and manufacturer

Favorable reimbursement does not guarantee utilization of the technology...

But,

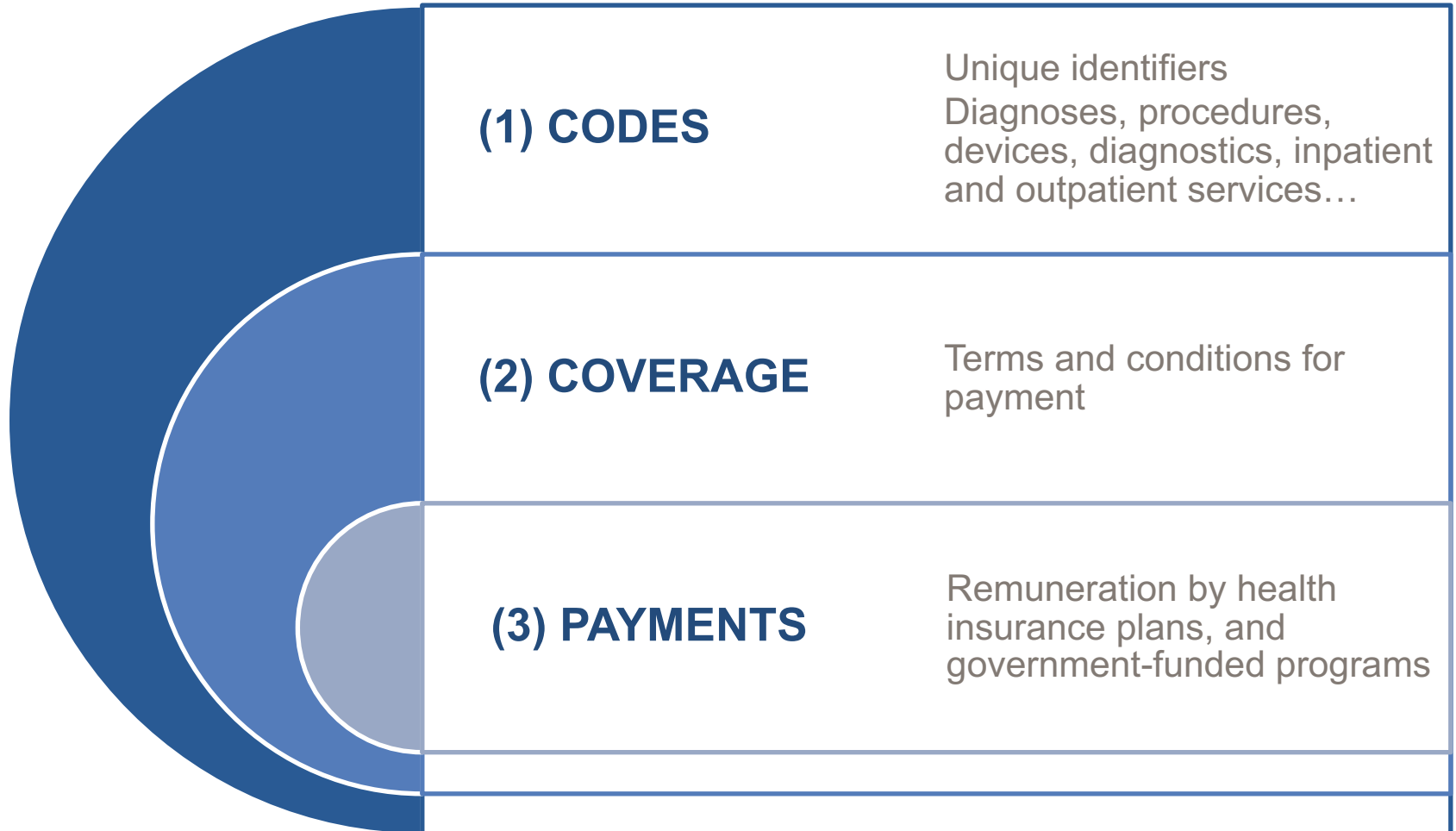
Lack of reimbursement adversely impacts utilization.

Longer **Time-To-Adoption** Has Considerable Implications



Codes and Coverage 101

Reimbursement - Three Distinct Elements

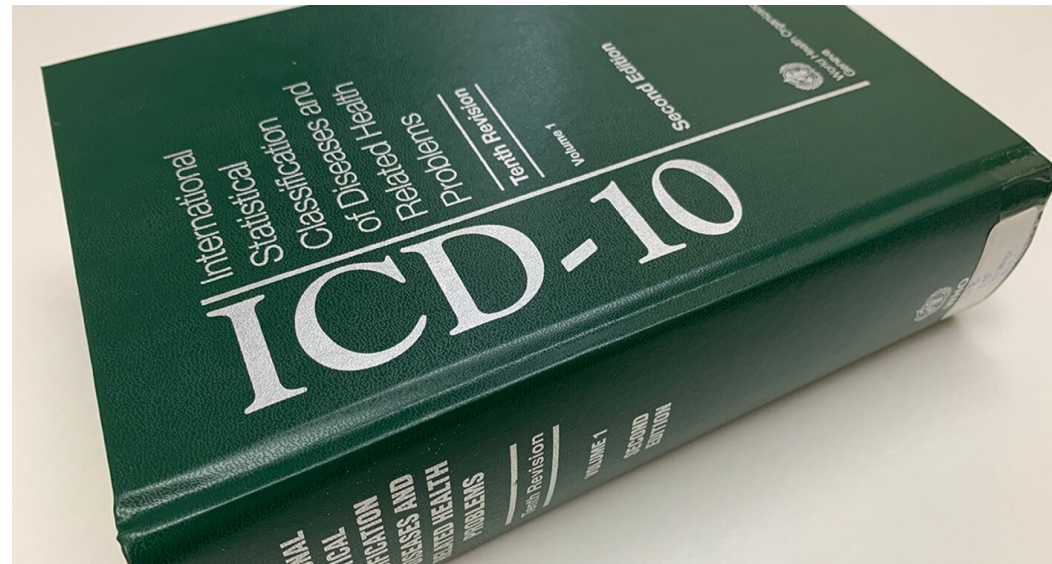


The International Classification of Diseases, 10th Edition (ICD-10)

~70,000 **diagnosis** codes

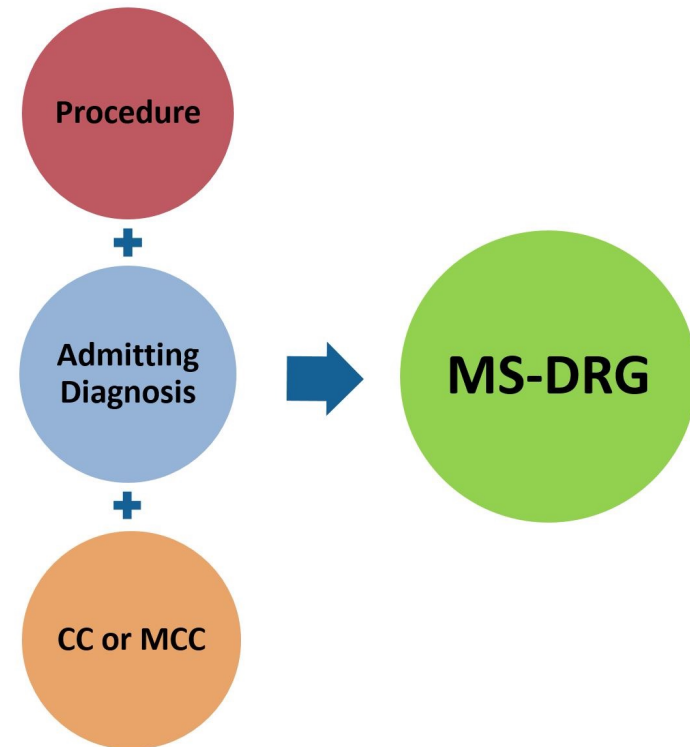
~70,000 **procedure** codes

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



Diagnosis Related Groups (DRG)

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

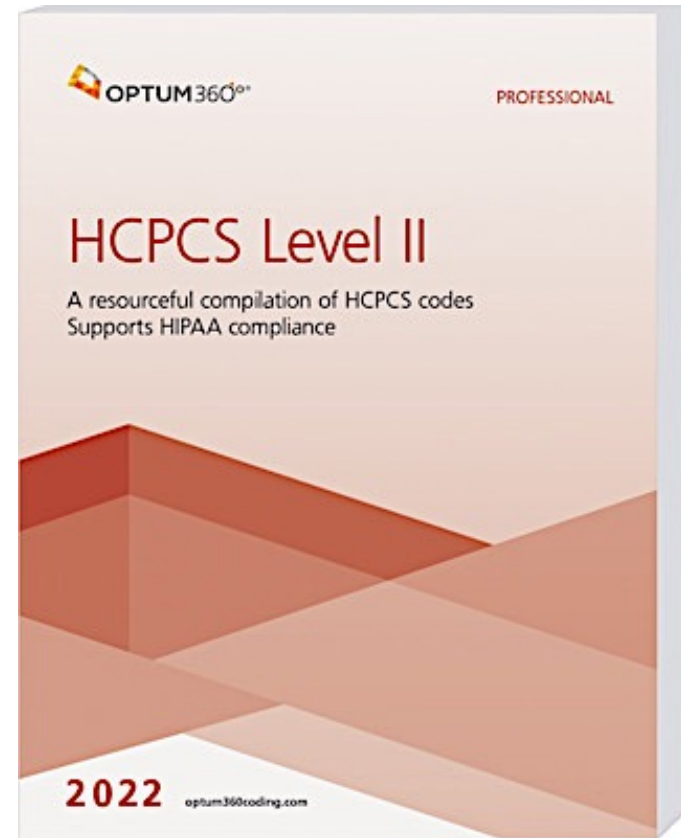


DRG payments cover all charges associated with an inpatient stay from admission to discharge, including nursing services, room and board, diagnostic and all ancillary services, **EXCEPT PAYEMNTS TO PHYSICIANS.**

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

Used to report **medical, surgical, and diagnostic procedures and services.**

- Over **10,000 codes**
- CPT codes are maintained by AMA

Recent initiatives include codes for

- Digital services
- Remote monitoring and therapeutic services
- AI-based technologies
- Software-only devices



Category I

Significant requirements, including -

- Multiple publications
- Installed / growing user base in the U.S.
- Support of relevant professional societies

Reimbursement by payers is more likely

Category III

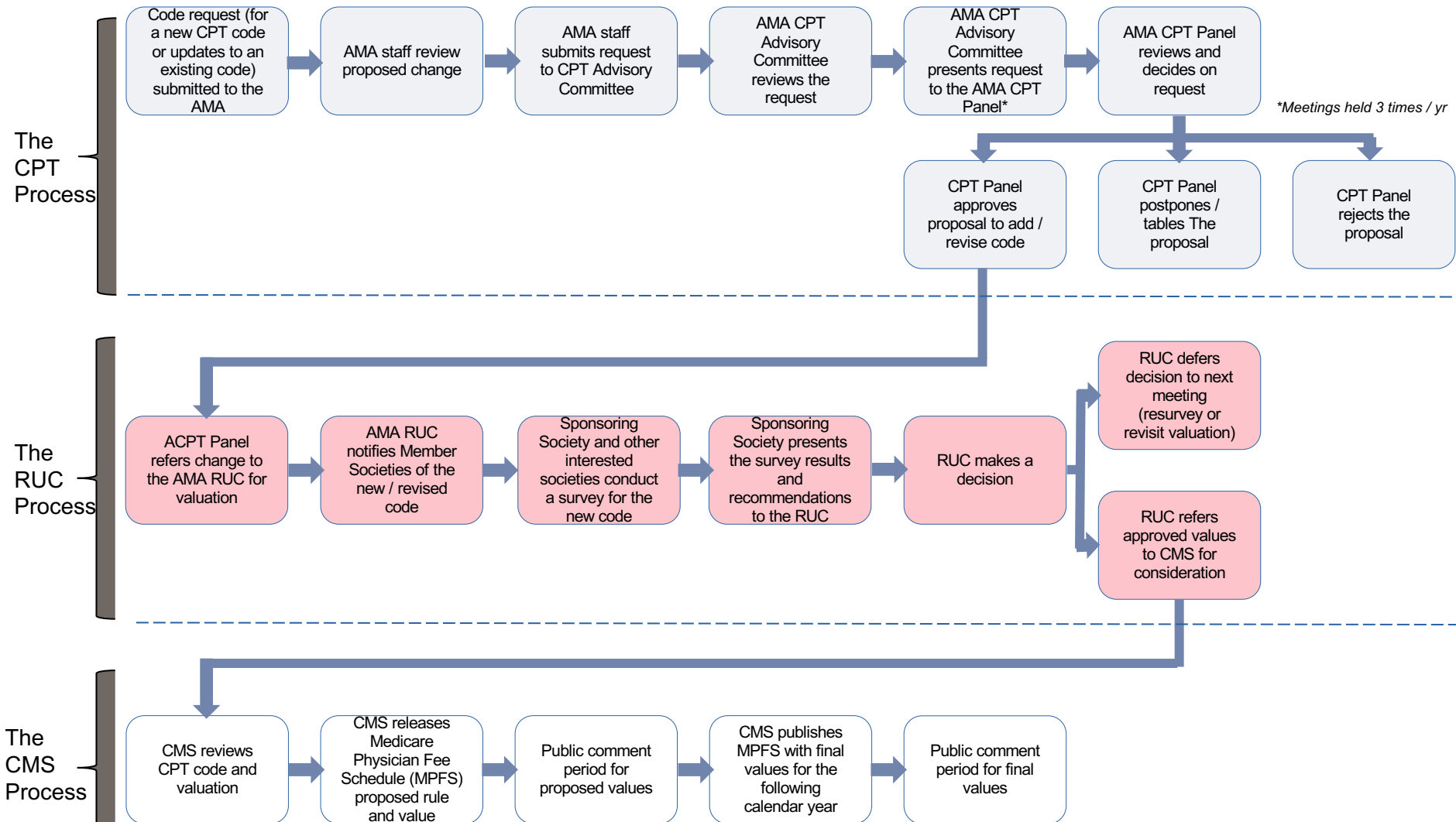
Assigned to **emerging technologies**, for services that do not meet requirements for a Category I code.

- Remain in effect for 5 years, unless replaced earlier by a Category I code.

Possible, but less likely to be reimbursed.

Most new technologies start with Cat III

Development of a New CPT Category I Code

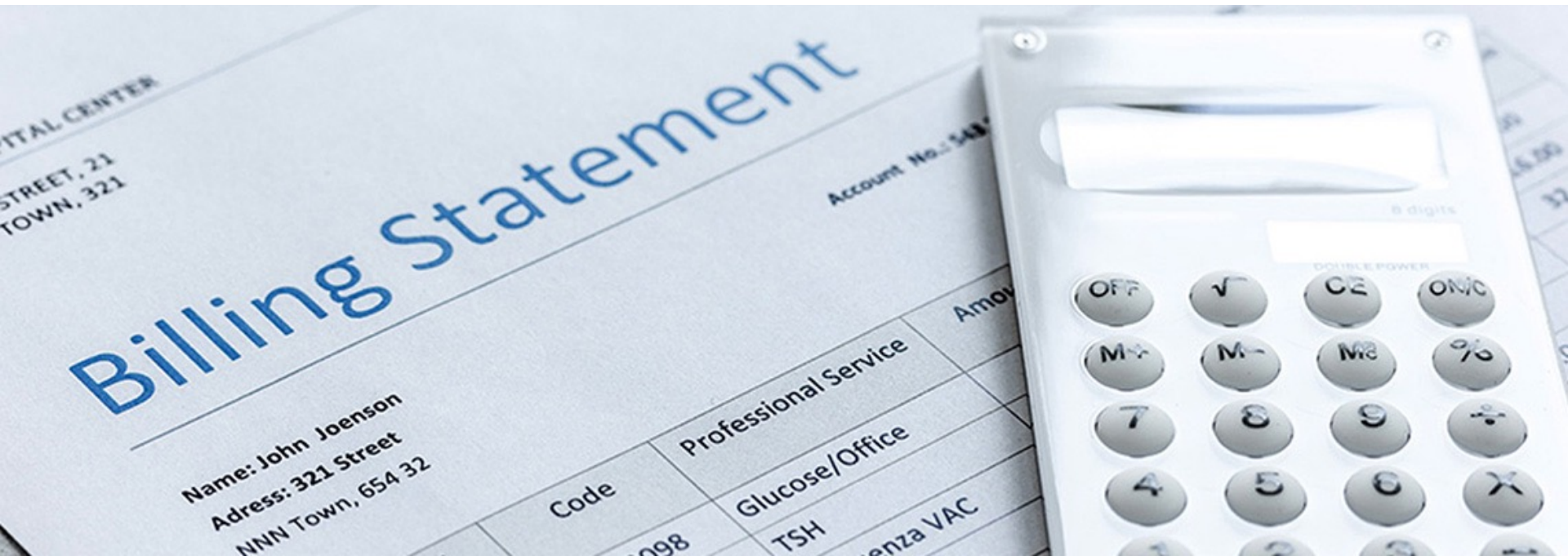


The Coding Industry

~100,000 coders

1.4 billion claims / year

14% of claims (200M) denied



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.

Most FDA approvals for new technologies require a single study documenting safety and efficacy.

Payers' decisions are based on multiple peer-review publications assessing clinical outcomes.

Coverage - **ASSESSED BY EACH PAYER**

Medicare

Coverage is governed by statute -
“reasonable and necessary for the diagnosis or treatment of illness or injury.”

- Economics - not a consideration (*at least not formally*)

Private Plans (e.g., BCBS)

Each plan sets own criteria for coverage

- The technology improves health outcomes
- The technology is beneficial as established alternatives
- Considering clinical and economics of procedure

Is Reimbursement Environment Finally Changing?

Maybe...

Healthcare Coverage in the U.S.

Medicare.

Federal program, ages >65 and permanently disabled

17% of population.

~35% Medicare Advantage.

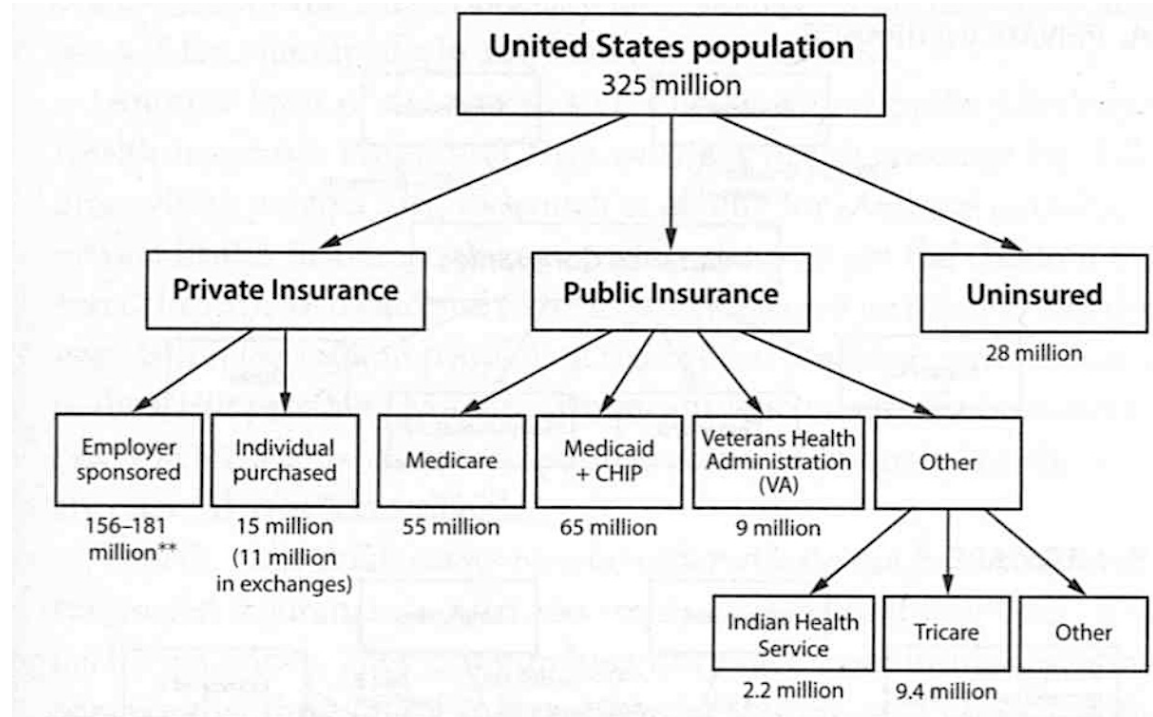
Medicaid.

Lower income (administered by states)

>25% of population.

Commercial / private Insurance.

- Employers funded and self-pay
- Individual purchase



U.S. Healthcare

~\$4 trillion

~\$12,000 per person

2020: >19% of GDP

(1980: 8.9%)

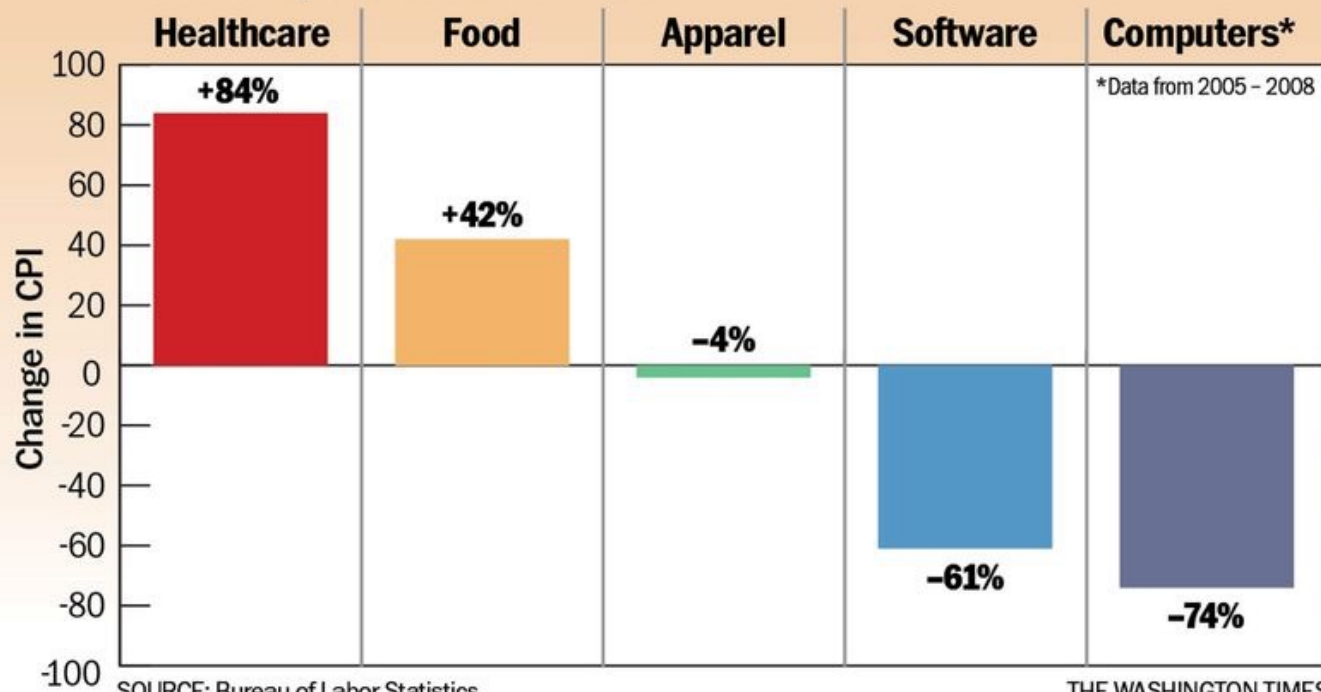
Germany 11.7%

Av. OECD <10%

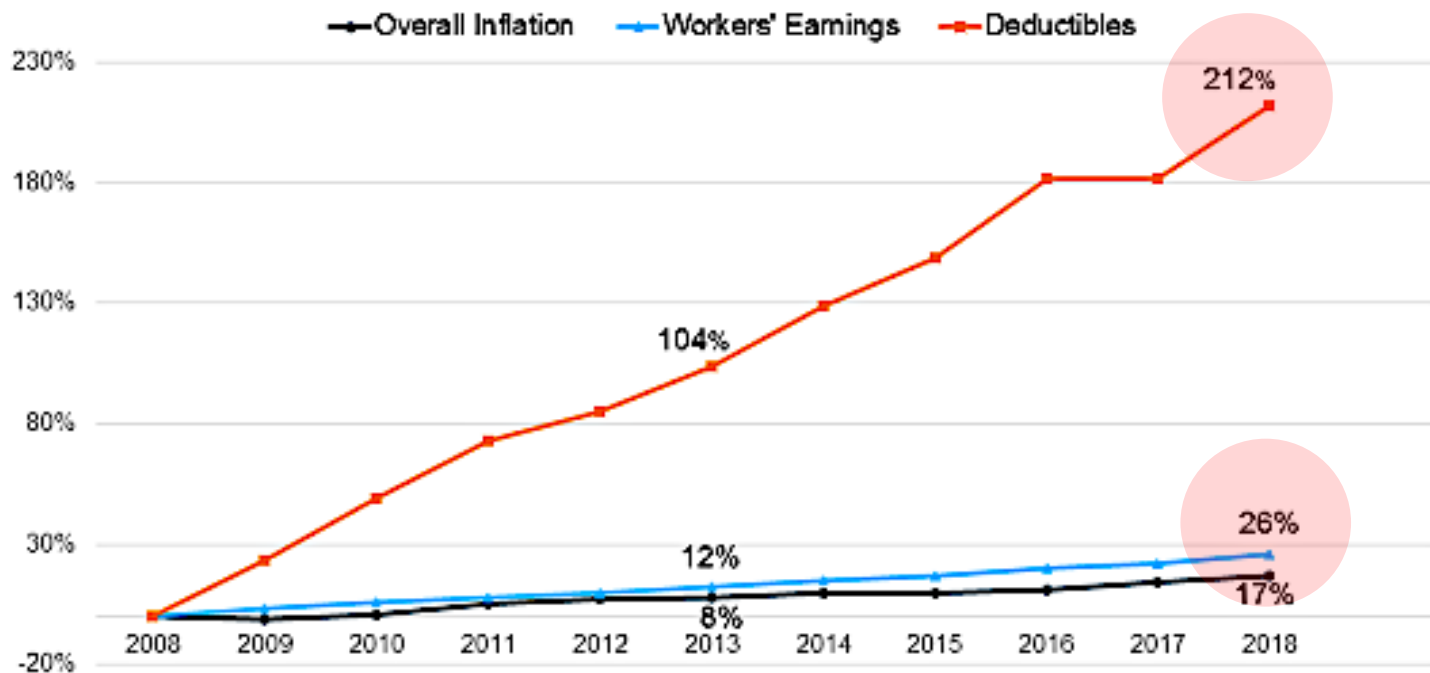
Federal government	28%
State and local governments	17%
Private business	20%
Individuals	28%
Other private sources	7%

HEALTH COSTS OUT OF CONTROL

Inflation by sector 2000 – 2018

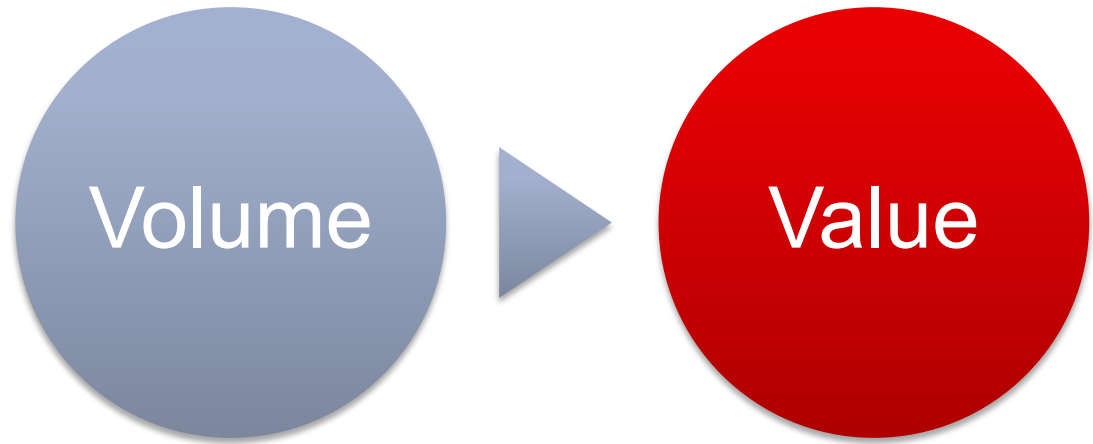


Since 2008, General Annual Deductibles for Covered Workers Have Increased Eight Times as Fast as Wages



Source: 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 by providing the highest quality care at the lowest cost.”

What Constitutes Value?

“Value is measured by patient 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
- Less 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 →

System decisions

Clinical, operations, marketing, economics

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**

So, What Do We **Need To Do** ?

'Reimbursement' Affects Financial Success

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

GTM strategy is impacted by lack or availability of reimbursement and scope of coverage

Sales are difficult to ramp-up until reimbursement is established

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

*Addressing reimbursement
early in the project life*

*Failure to address
reimbursement early in
the project life*

Past

Not important



Not a big deal

Yesterday

Nice to do



Bad practice

Today

Important / critical



Business malpractice

Reimbursement Assessment Must Address All Relevant Elements

Changes to medical practice?

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

What will be reimbursed?

- Professional services
- Facility costs
- Device / product

Where will the service / technology be used?

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

Who are the users?

- PCP / specialties
- Nurses
- Licensed therapists
- Patients

Who will pay?

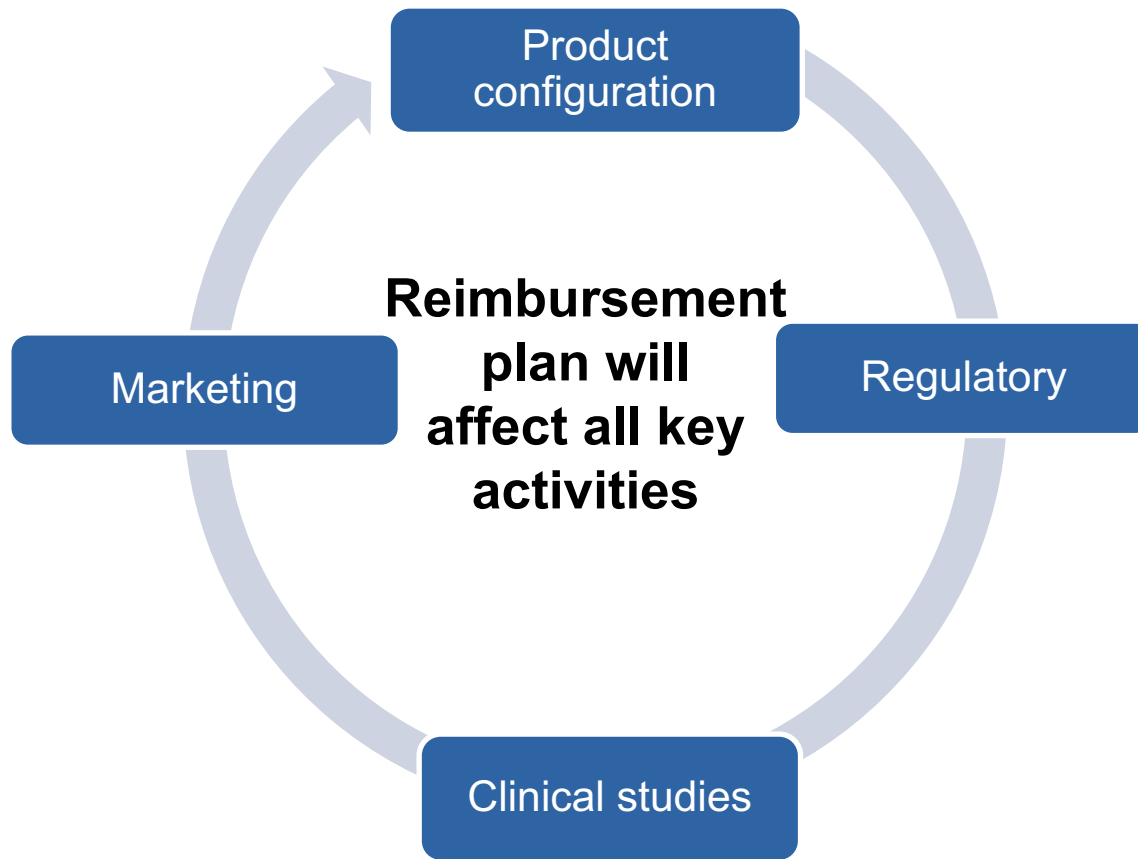
- Medicare
- Medicaid
- Commercial payers
- IDNs
- Government
- Employers
- Patients

**Can use current
codes and
coverage
policies?**

OR

**Understand
optional
strategies and
develop roadmap
to reimbursement**

SO, When Should We **Start** Reviewing Reimbursement?



Sooner you understand your roadmap to reimbursement, the better you are

Case Studies.

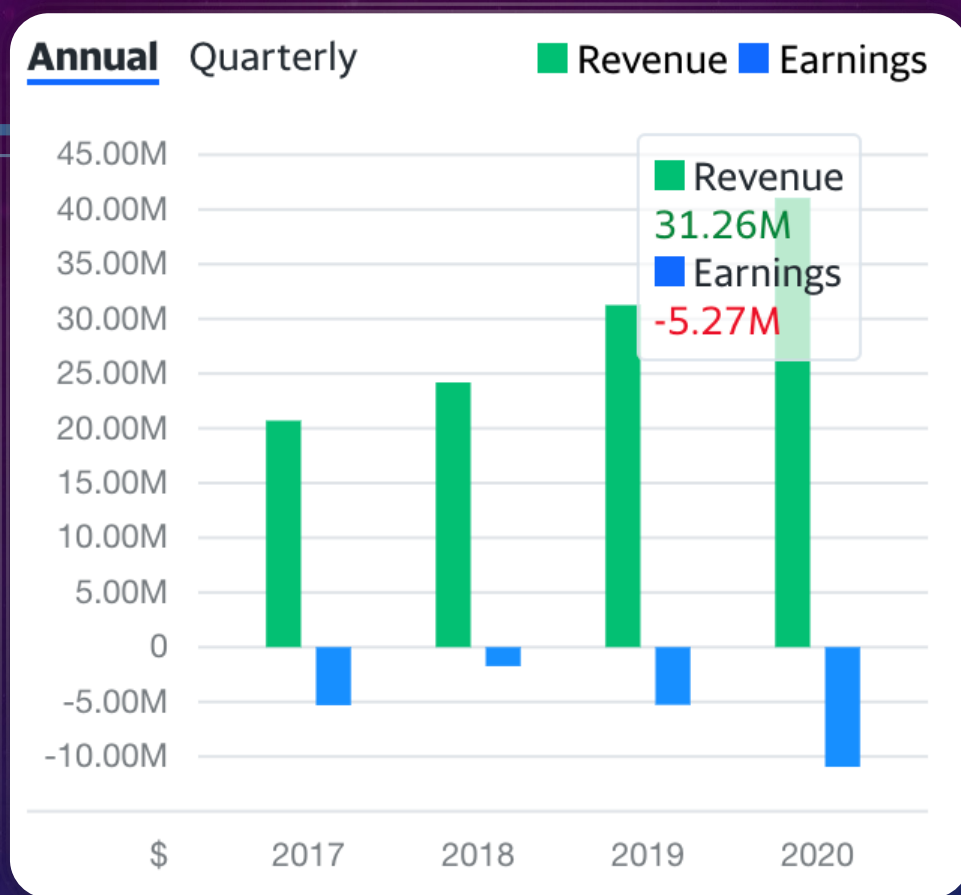
Reimbursement → Valuations



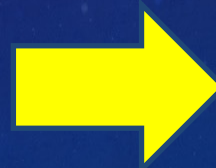
- Itamar Medical introduced a user-friendly, home-based OSA device (**WatchPAT**).
- The AASM objected to codes and coverage for home studies (loss of income to physicians).
- Without codes and coverage from CMS and most commercial payers, sales of WatchPAT were nominal.

BMTA:

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



With **new codes and expanding coverage**, sales increased to ~\$50M



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

Novocure

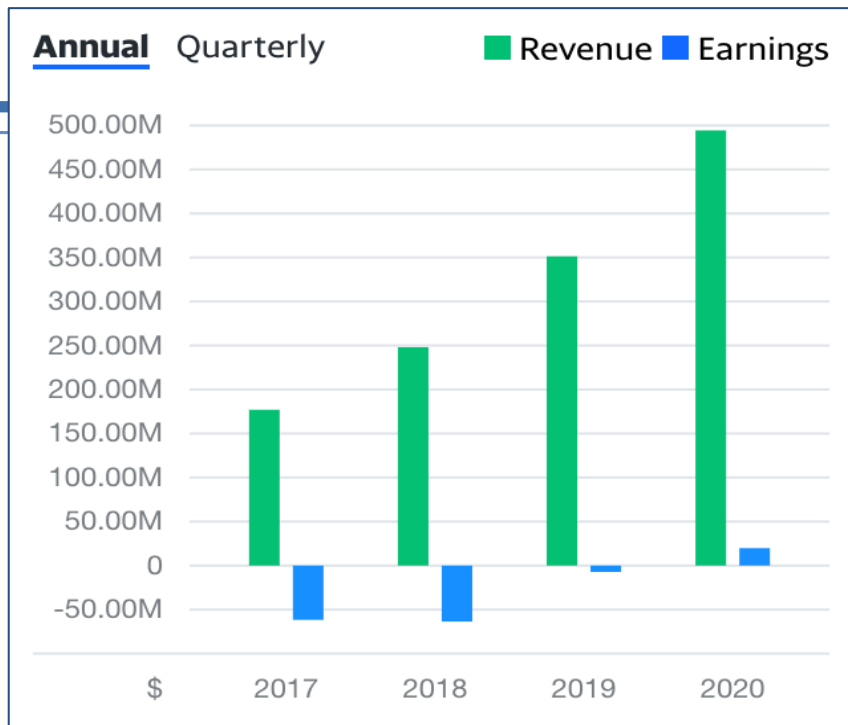
2019 Baird Global Healthcare Conference

patientforward



- 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
- 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 > \$10,000 /month
- Rev (2021) > \$500M
- Valuation ~\$8B

