INTRODUCTION TO THE U.S. HEALTHCARE SYSTEM

THE LARGEST AND MOST COMPLEX MARKET

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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)*

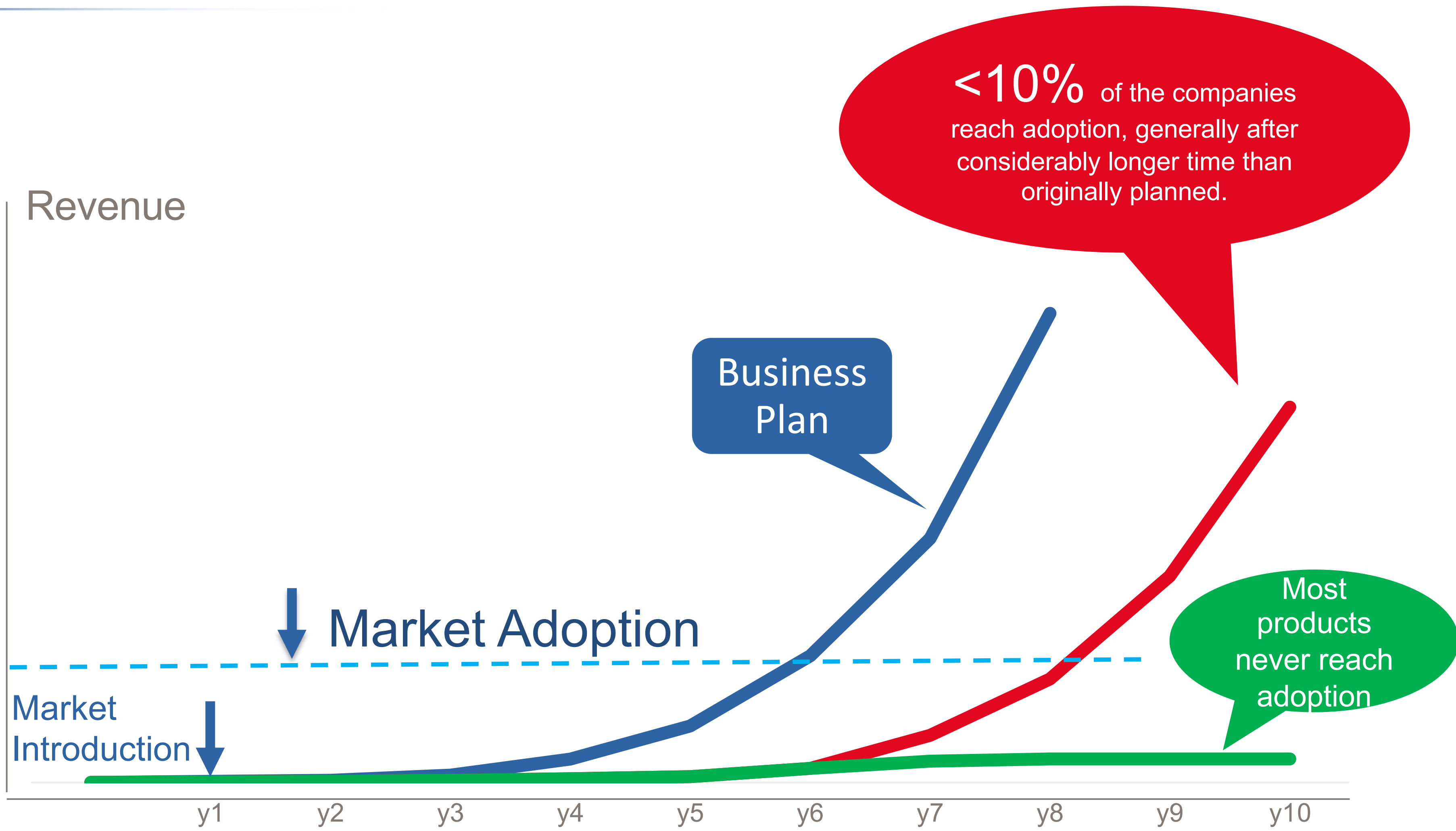
Aesthetic Medicine	*Allergy*	*Ambulatory Monitoring*	*Anesthesiology*	*Biologics*	*Biomarkers*	*Brain / Neurosurgery*	*Cancer Therapies*
Cardiology	*Cellular Therapies*	*Critical Care*	*Cryosurgery*	*Dermatology*	*Diabetes*	*Digital Health*	*Drug Delivery*
Drug / Device Combinations	*Durable Medical 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

- Business realities
- The U.S. healthcare system 101
- Who pays?
- Change is underway
- The take home message
- Q&A

Business Realities

Most Companies Miss Their plans



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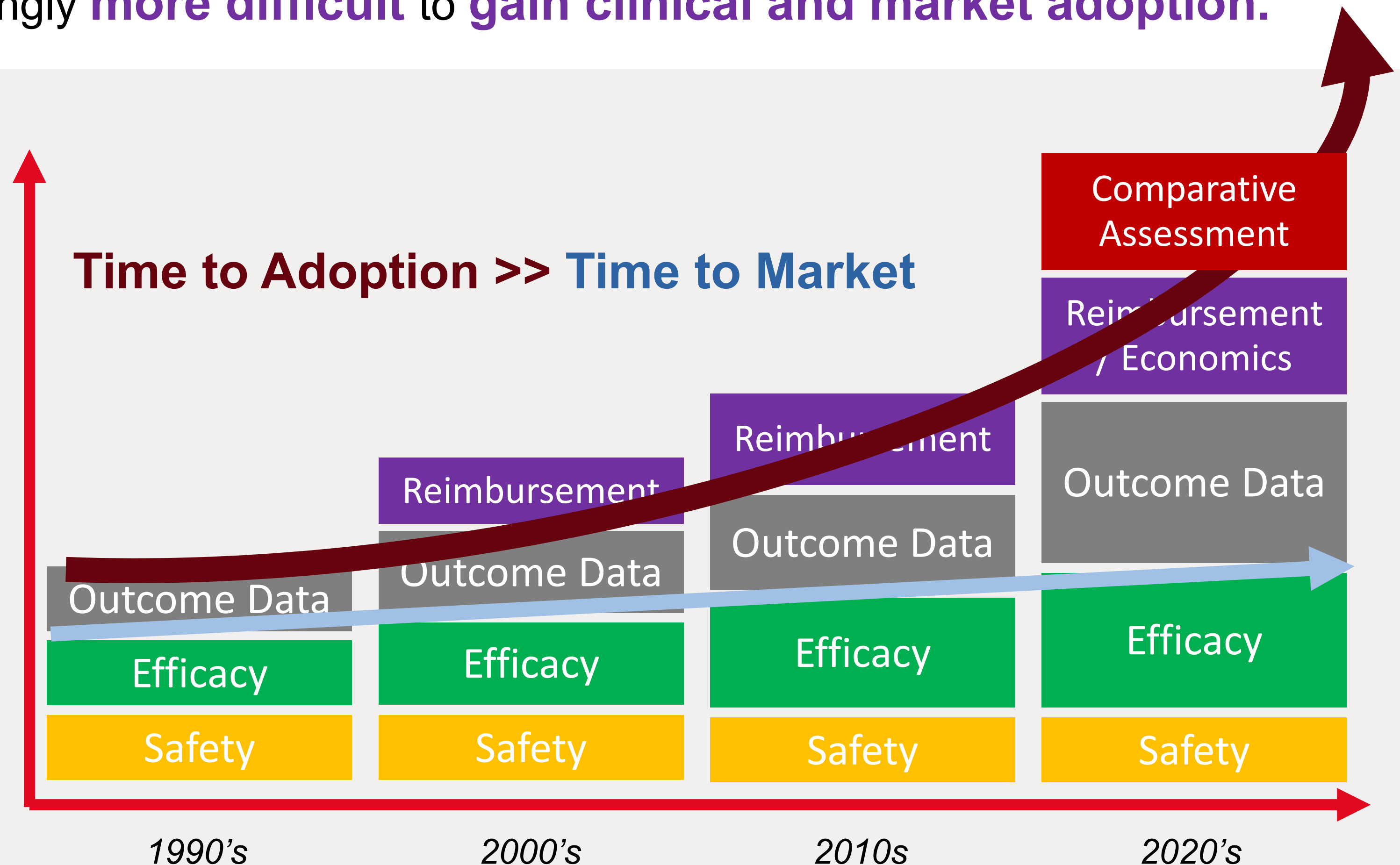
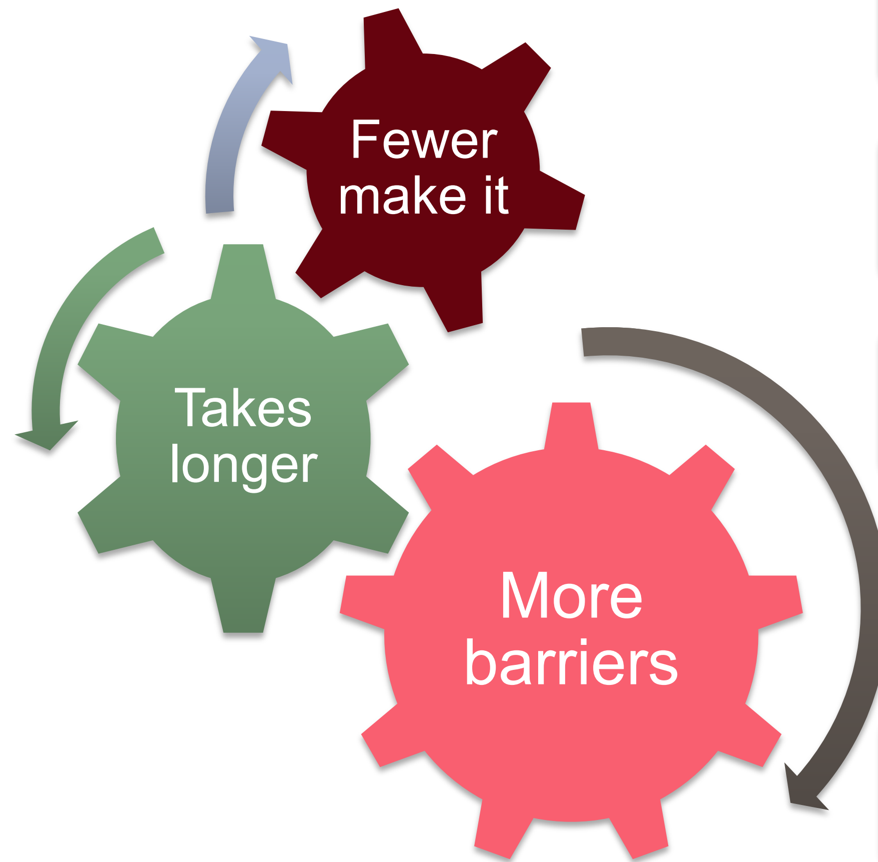
More Experience ▶ Better Results

The Adoption Paradox

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



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



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

To sell medical products / services in the U.S., understanding the healthcare system is a **MUST**

Understanding the environment is required to determine -

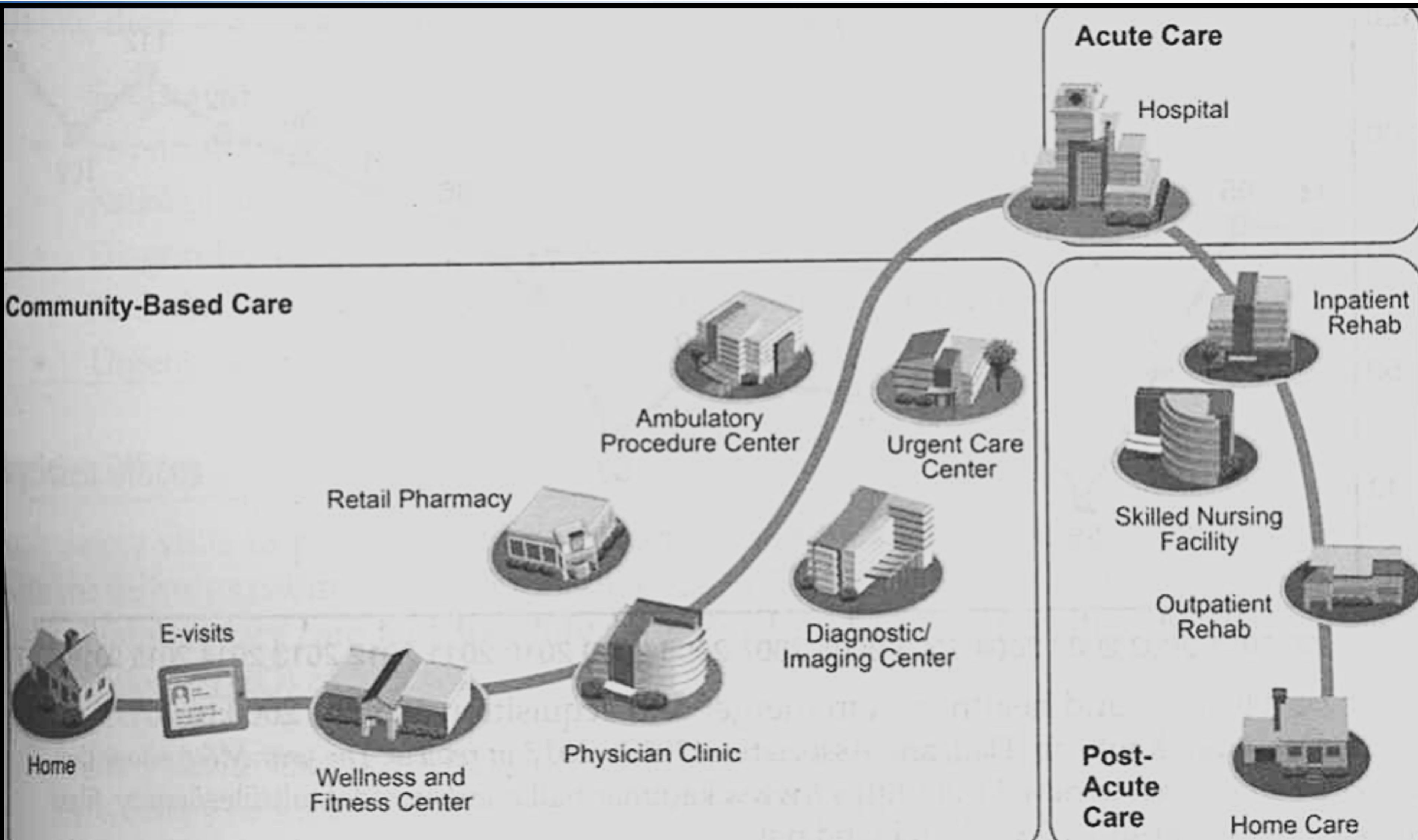
- ✓ The specific clinical application offered
- ✓ Providers using the product / service
- ✓ Healthcare system(s) targeted
- ✓ Who will pay for the product / service

Specific considerations:

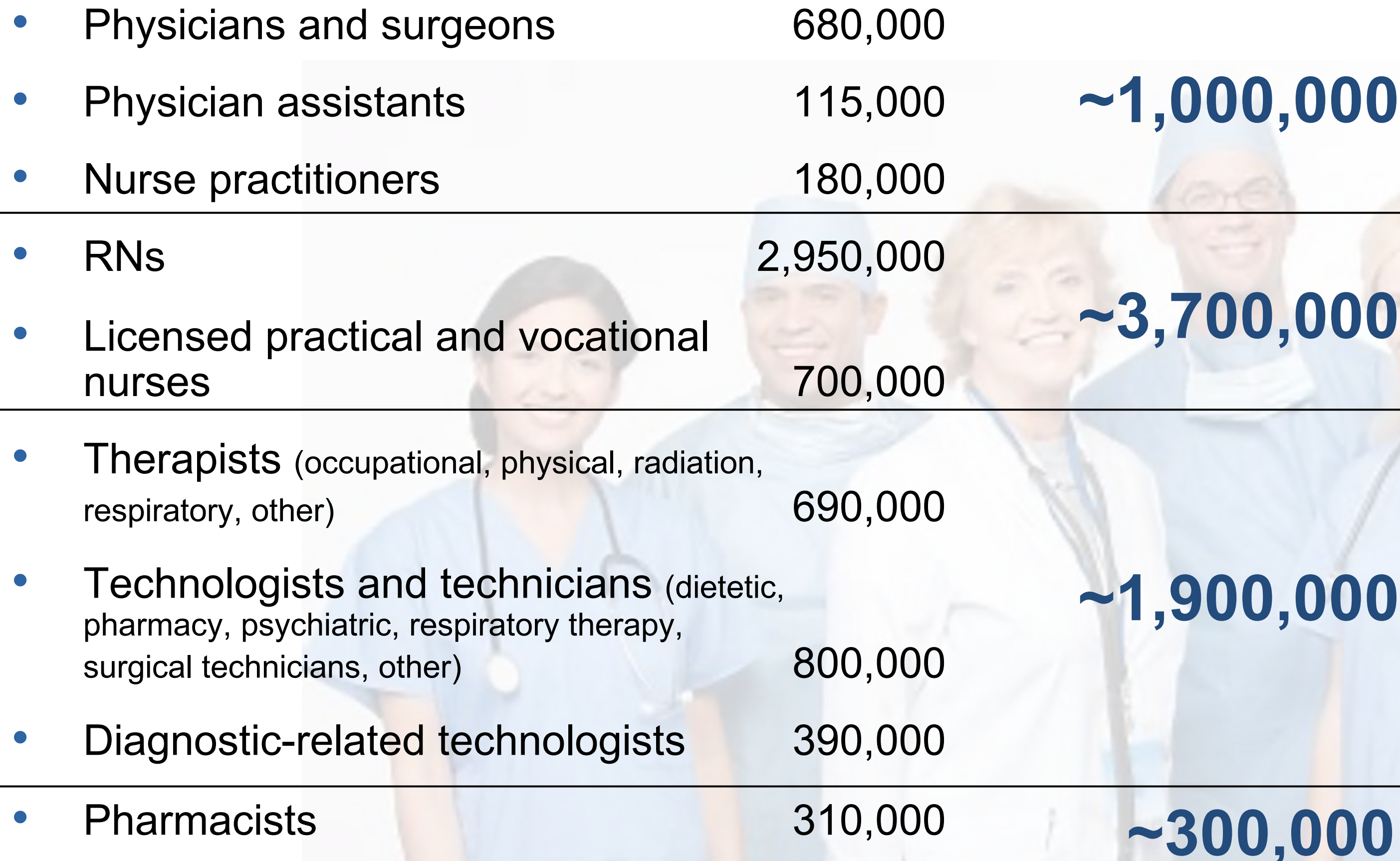
- Need addressed / clinical utility
- Workflow
- Economics
- Legal / regulatory
- Decision makers
- Barriers
- …

U.S. Healthcare 101

Healthcare Settings



Professional Caregivers



Category	Count	Group total
• Physicians and surgeons	680,000	
• Physician assistants	115,000	**~1,000,000**
• Nurse practitioners	180,000	
• RNs	2,950,000	**~3,700,000**
• Licensed practical and vocational nurses	700,000	
• Therapists (occupational, physical, radiation, respiratory, other)	690,000	
• Technologists and technicians (dietetic, pharmacy, psychiatric, respiratory therapy, surgical technicians, other)	800,000	**~1,900,000**
• Diagnostic-related technologists	390,000	
• Pharmacists	310,000	**~300,000**
		~7,000,000

2018 data

Outpatient Settings

- **Physician Office**
  - **900 million visits**
  - PCPs ~40% / Specialists ~60%

- **Emergency Departments**
  - **145 million visits**
  - Teaching institutions 15% / Non-teaching 85%

- **Hospital Outpatient**
  - **126 million visits**
  - General medicine 55%
  - Surgery 19%
  - Pediatrics 10%
  - Obstetric and gynecology 9%
  - Substance abuse / other 7%

- **Other Ambulatory Care Settings**
  - Ambulatory surgery centers
  - Community Health Centers
  - Public health clinics
  - Retail pharmacies
  - Walk-in clinics
  - Workplace health clinics
  - School health clinics
  - Telehealth
  - Home visits

2016 data

Inpatient Acute Care

6,200 hospitals

- 930,00 beds
- Daily census >500,000
- 36 million admissions
- ALOS 5.5 days
- <10% of the population is hospitalized each year, at cost >30% of the National Healthcare Expensitures

- **Teaching hospitals**
  - ~20% of hospitals
  - Providing ~50% of hospital-based services
- **Community hospitals ~5,300**
  - 64% urban / 36% rural
  - Not-for-profit hospitals 2,970 (56%) / 545,000 beds
  - For-profit hospitals1,320 (25%) / 142,000 beds
  - State & local government 970 (19%) / 111,000 beds
- **Federal government - 210**
- **Psychiatric, non-federal - 620**
- **Other - 120**

Long Term Care

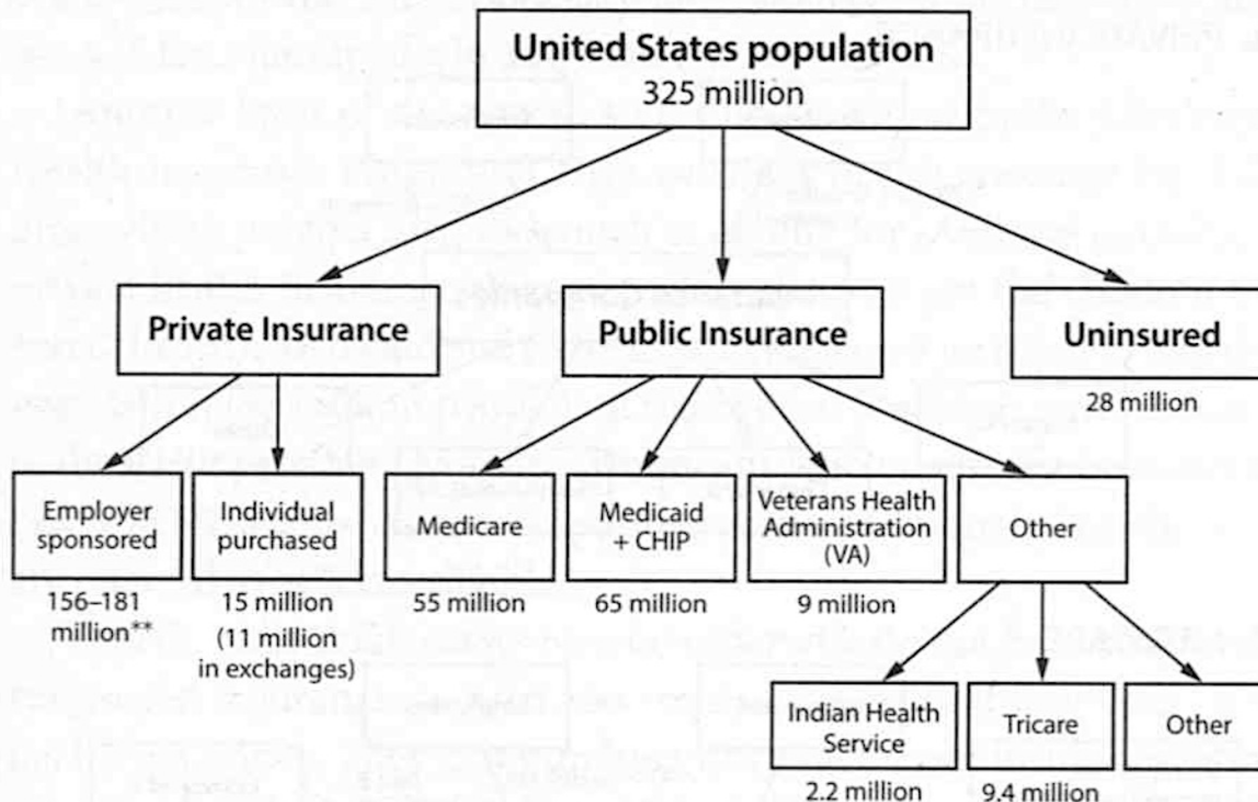
90,000 - 100,000 facilities

8-10 million people served

- Adult day services………………… 4,600 facilities / 286,000 participants
- Home health agencies…………… 12,000 facilities / ~4.5M patients discharged
- Hospice…………………………….. 4,300 facilities / 1.4M patients cared for
- Nursing homes…………………… 15,600 facilities / 1.3M residents
- Residential care communities…… 29,000 facilities / 810,000 residents (assisted living)

Who Pays?

Healthcare Coverage in the U.S.



Medicare.

Federal program, ages >65 (52 million) and permanently disabled (9 million).

18% of population.

~40% Medicare Advantage.

Medicaid.

Lower income (administered by states)

CHIP (Children's Health Insurance Program): children not covered by parents' insurance

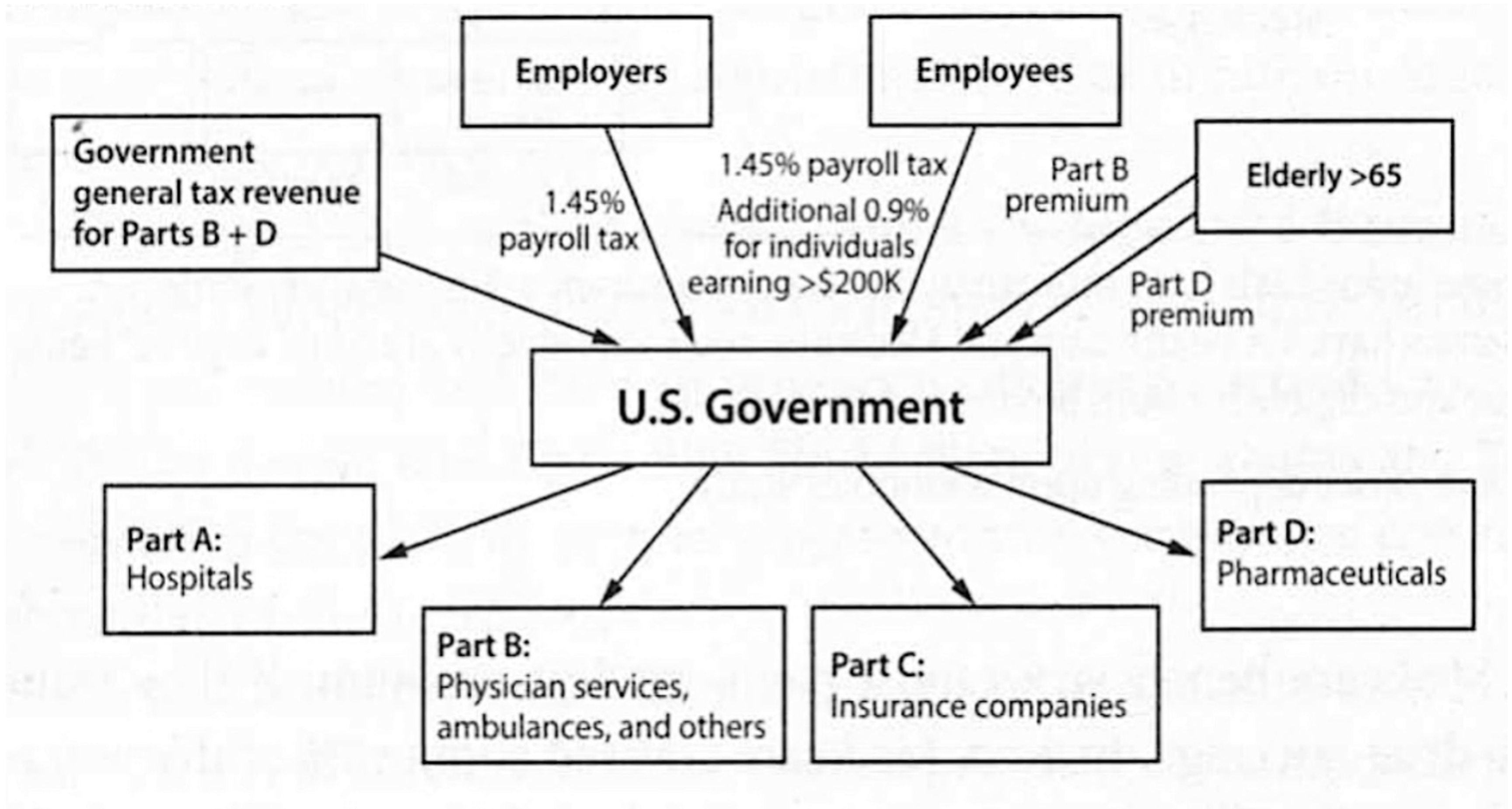
>25% of population.

Commercial / private Insurance.

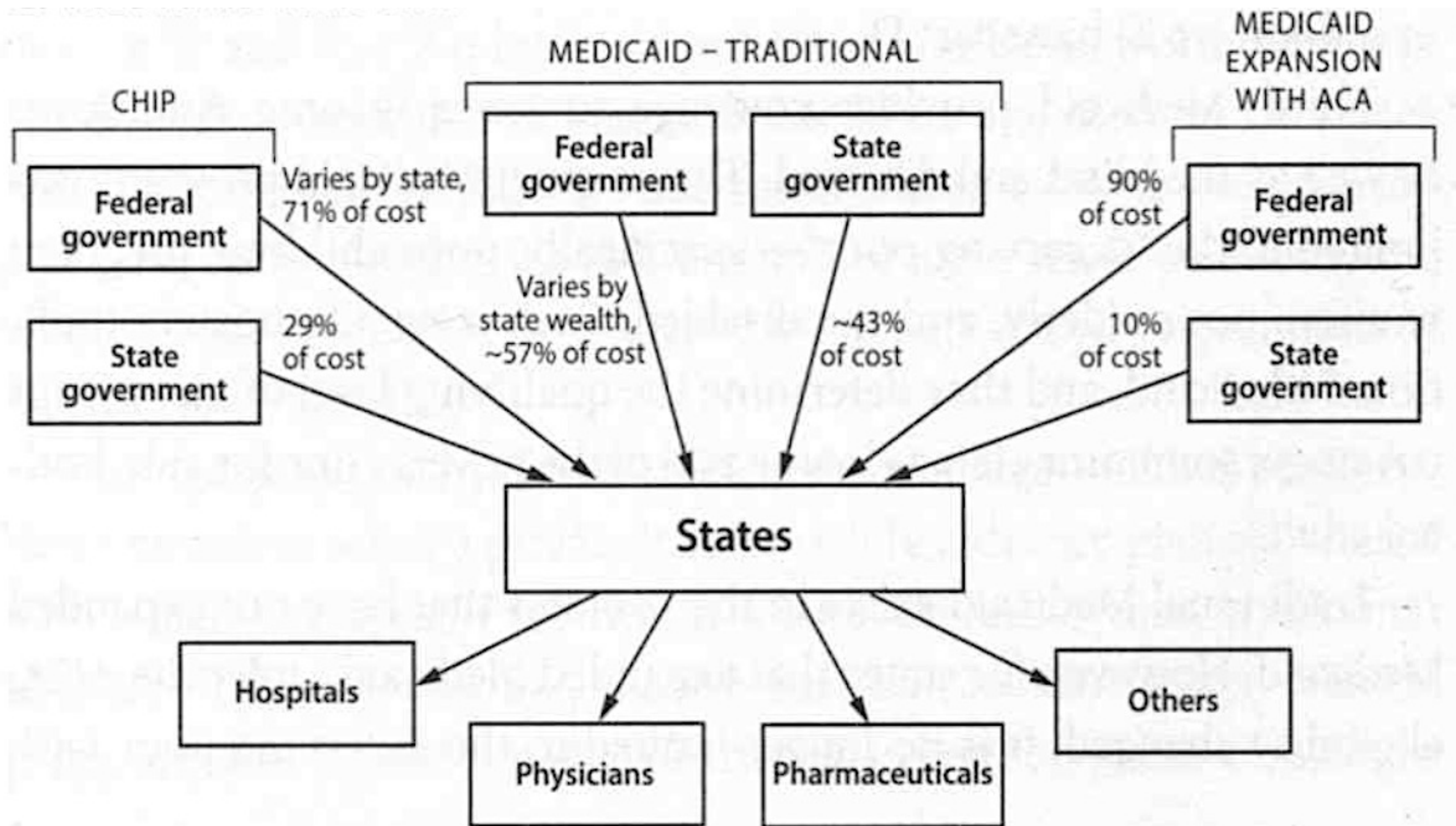
Employers funded and self-pay

Individual purchase

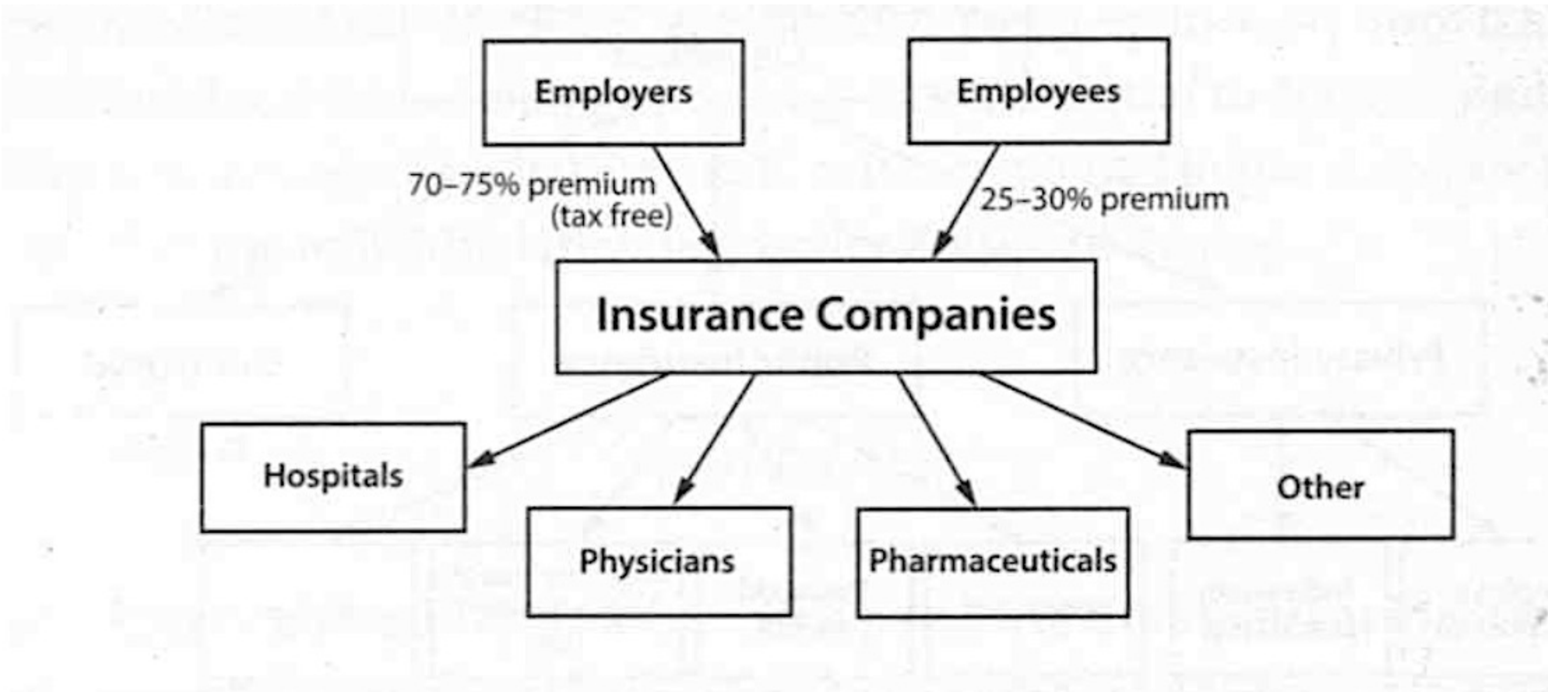
Medicare



Medicaid and CHIP



Private Insurance



Who Pays?

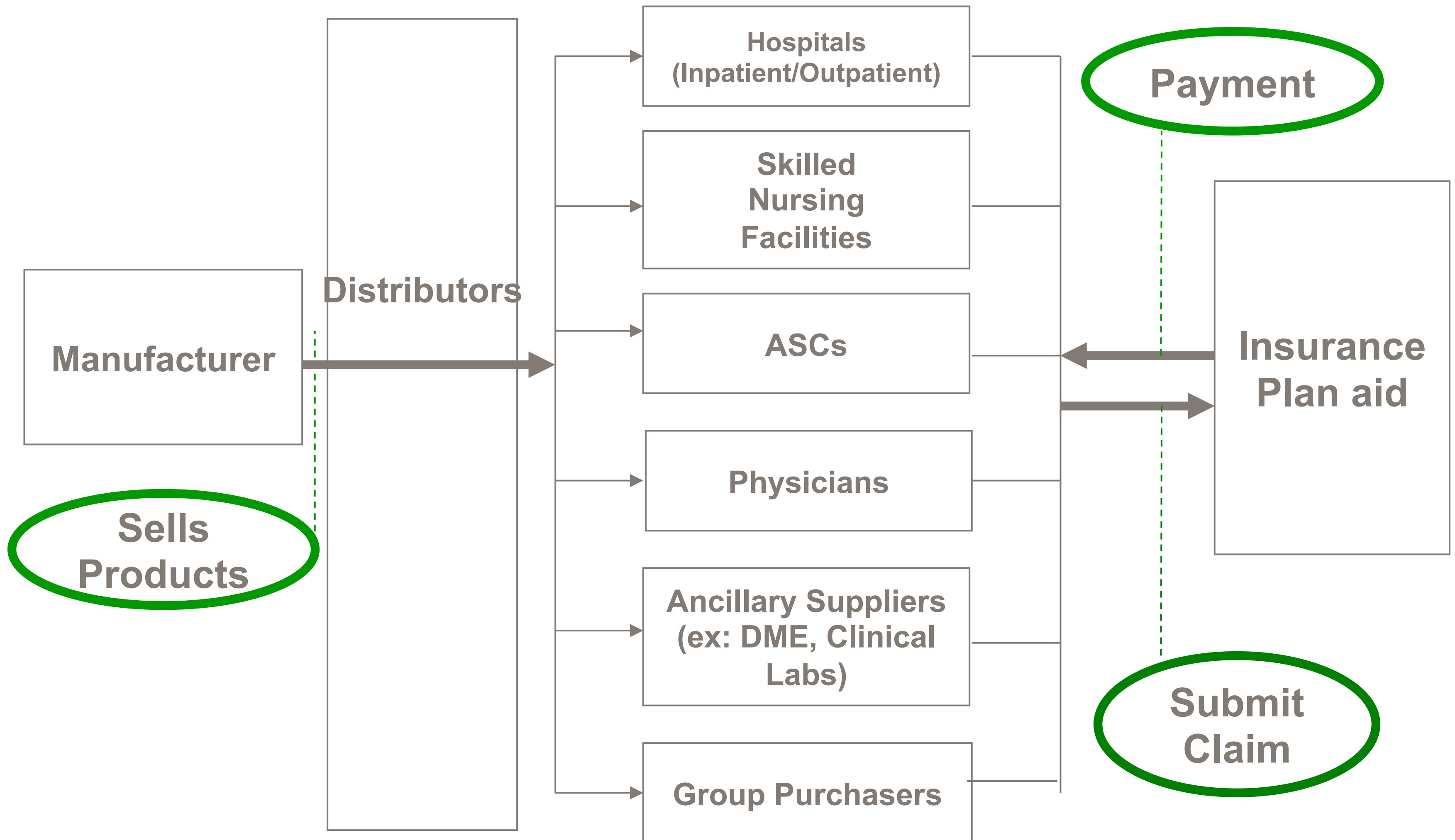
Private health insurance	**34%**
Medicare	**20%**
Medicaid (incl. federal and state)	**17%**
Other health insurance programs[a]	**4%**
Other 3rd party payers and programs[b]	**10%**
Out-of-pocket	**10%**
Investment	**5%**

a. CHIP, DoD, VA

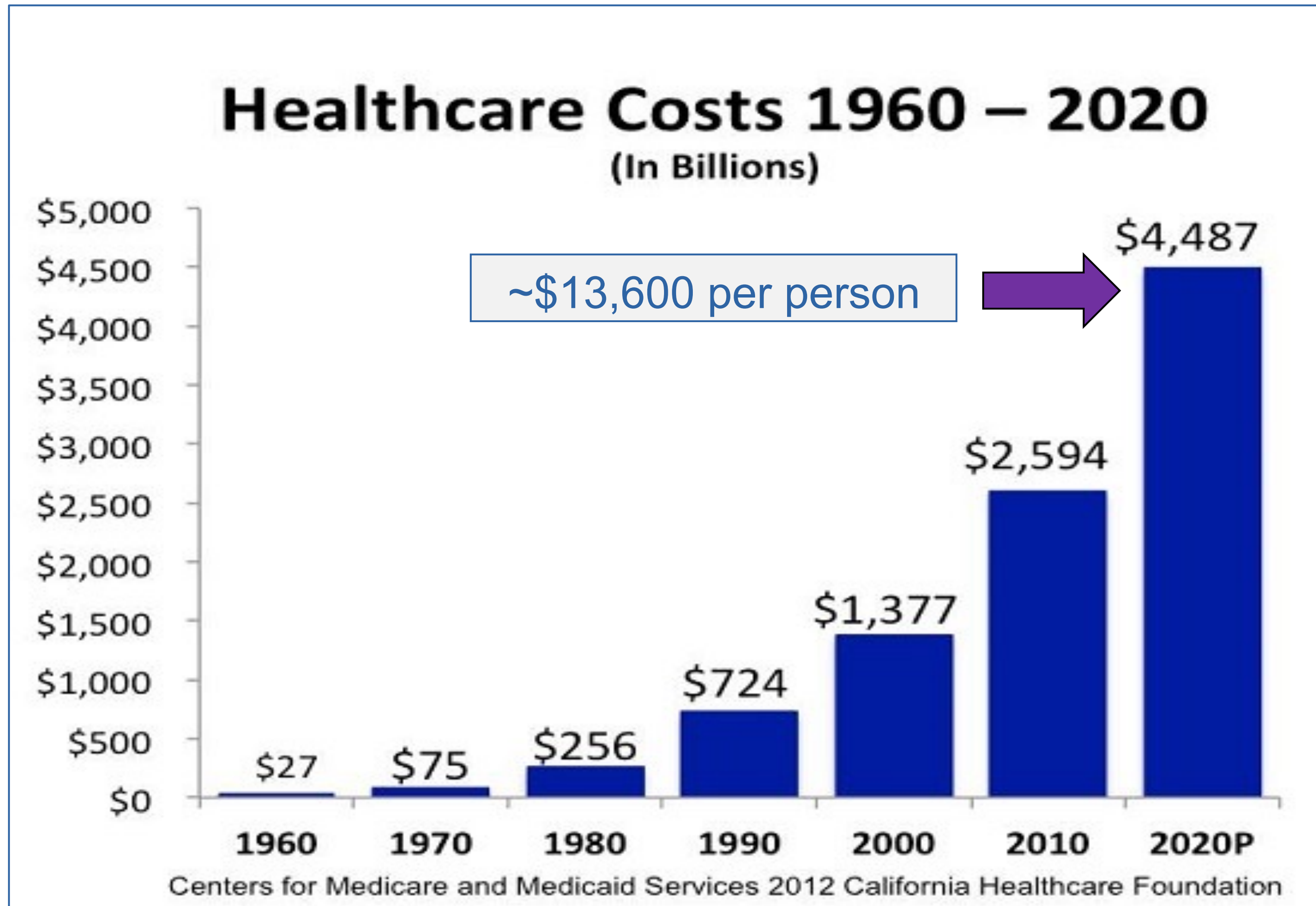
b. Indian Health Service, worker's comp, school health, Substance Abuse and Mental Health Services Admin, etc.

Payments are Made To Providers, Not to Manufacturers of Medical Devices

(at times, manufacturers are also the providers)



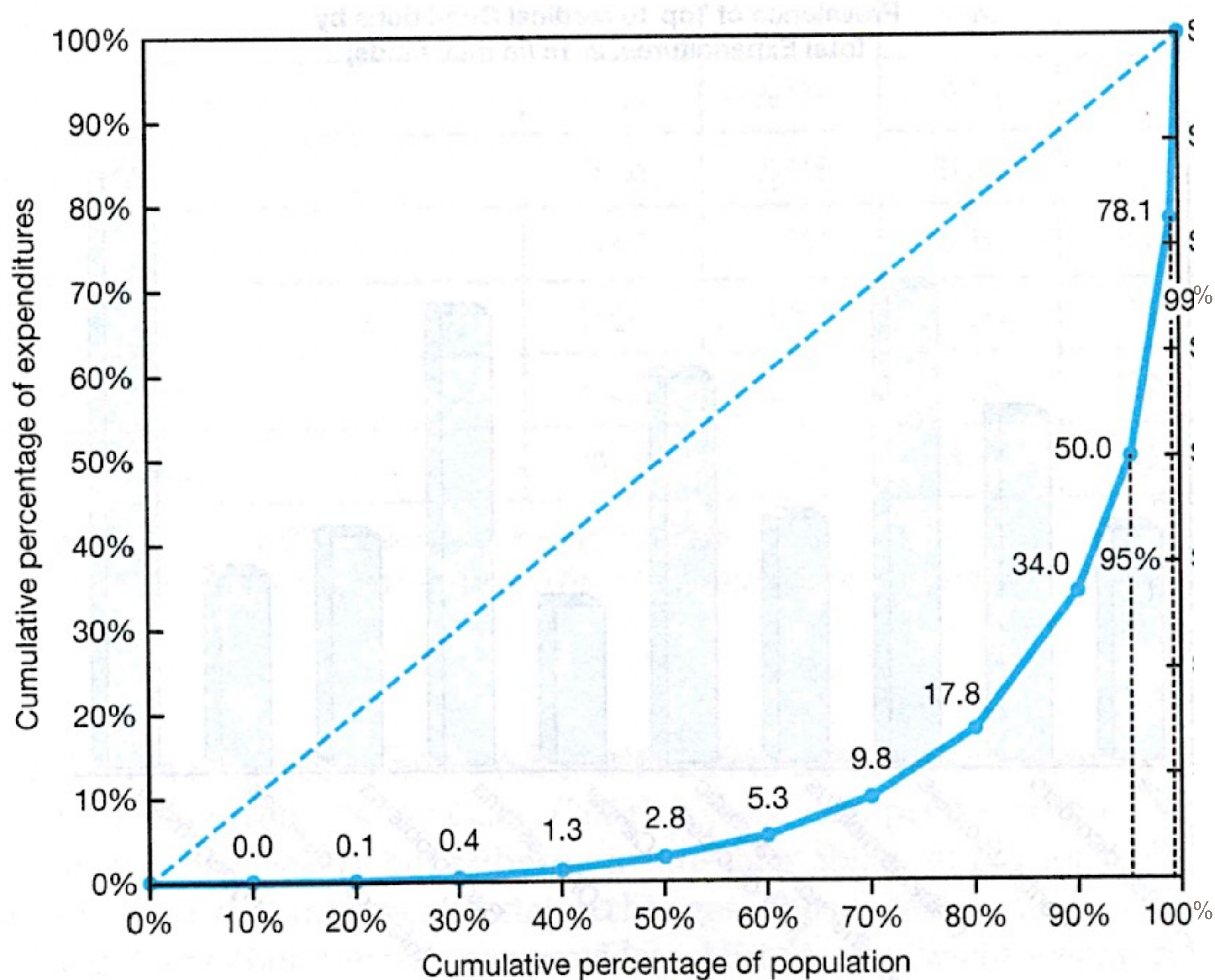
National Healthcare Expenditures (NHE)



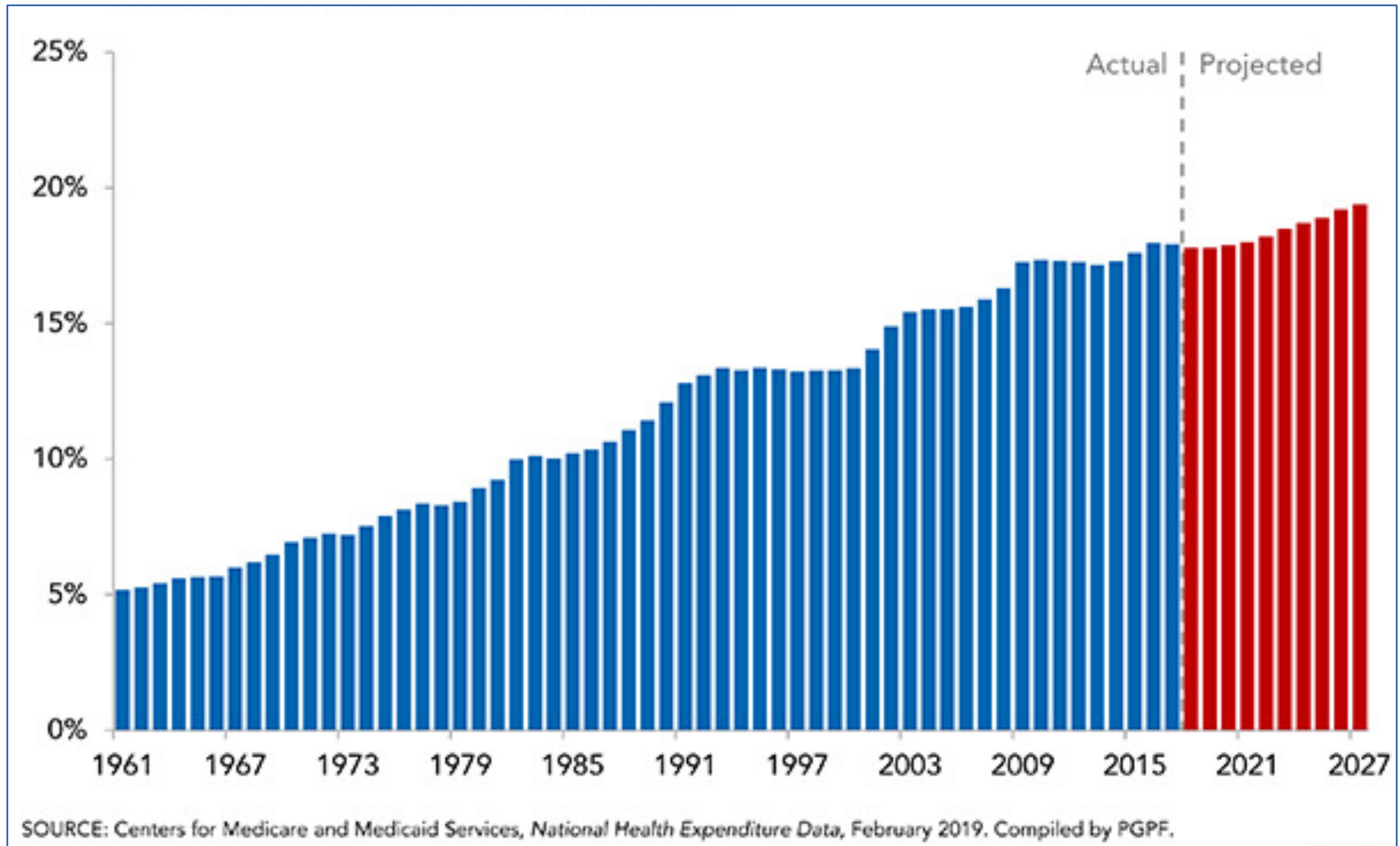
Where is the Money Spent?

Category	Share	Group
Hospital care	33%	~60%
Professional services	26%	
Home & residential healthcare, personal care	8%	~25%
Nursing care facilities and CCRC	5%	
Prescription drugs	10%	
DME and other medical products	3%	
Health insurance (net)	7%	~10%
Government administration and government public health	4%	
Investment (research, facilities)	5%	~5%

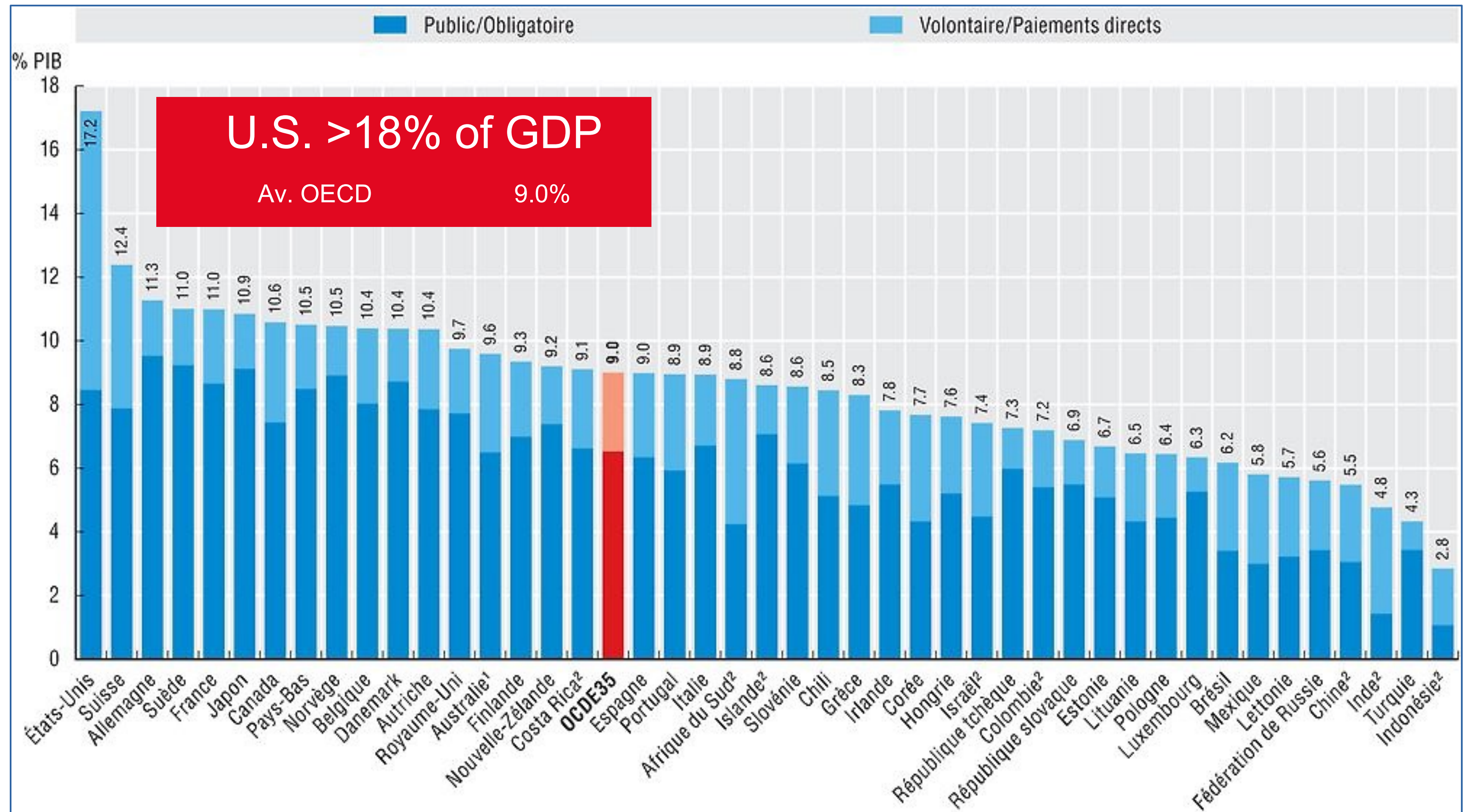
Concentration of Healthcare Expenditures



National Health Expenditures (% of GDP)



U.S. vs. OECD



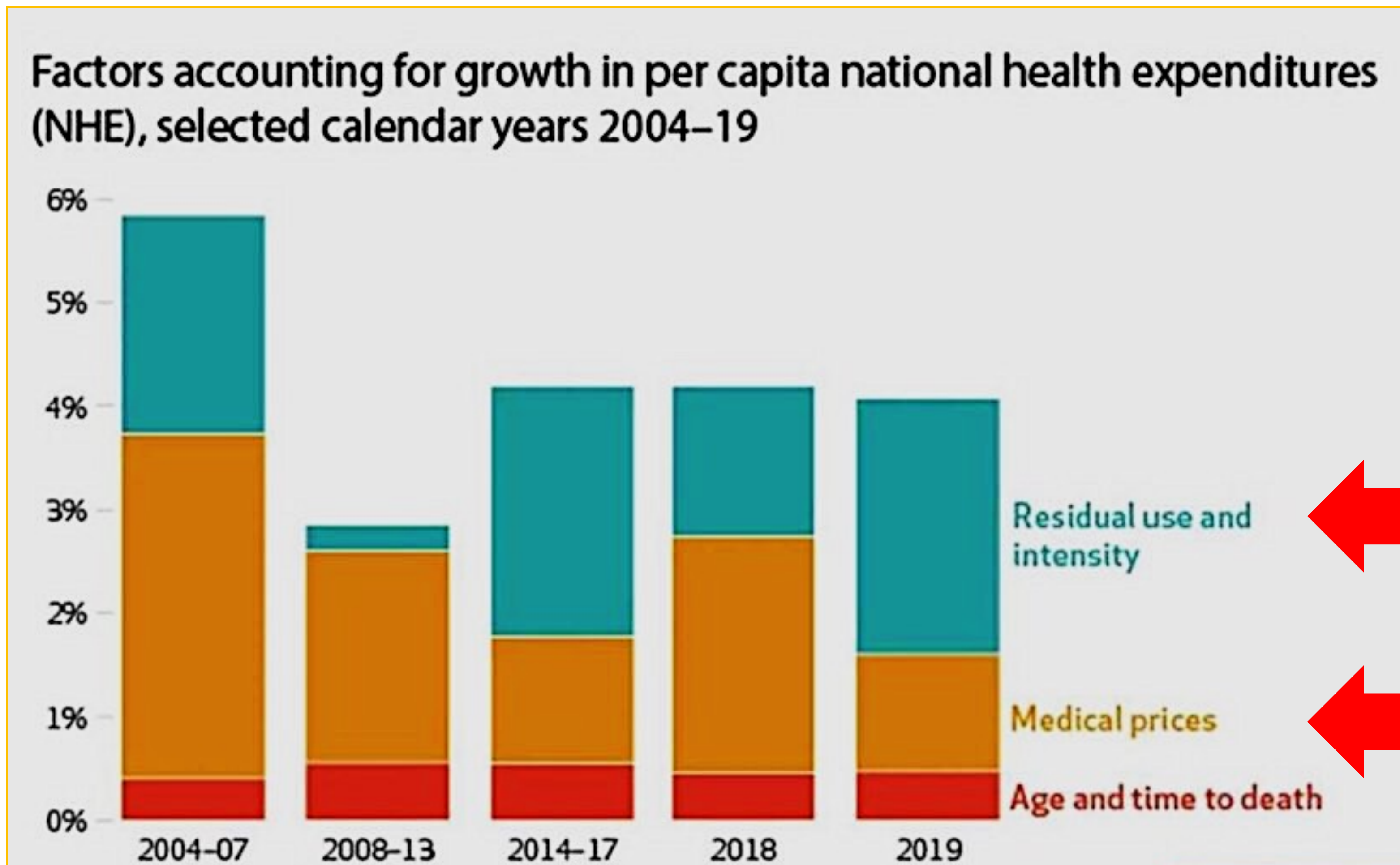
U.S. System is Unique

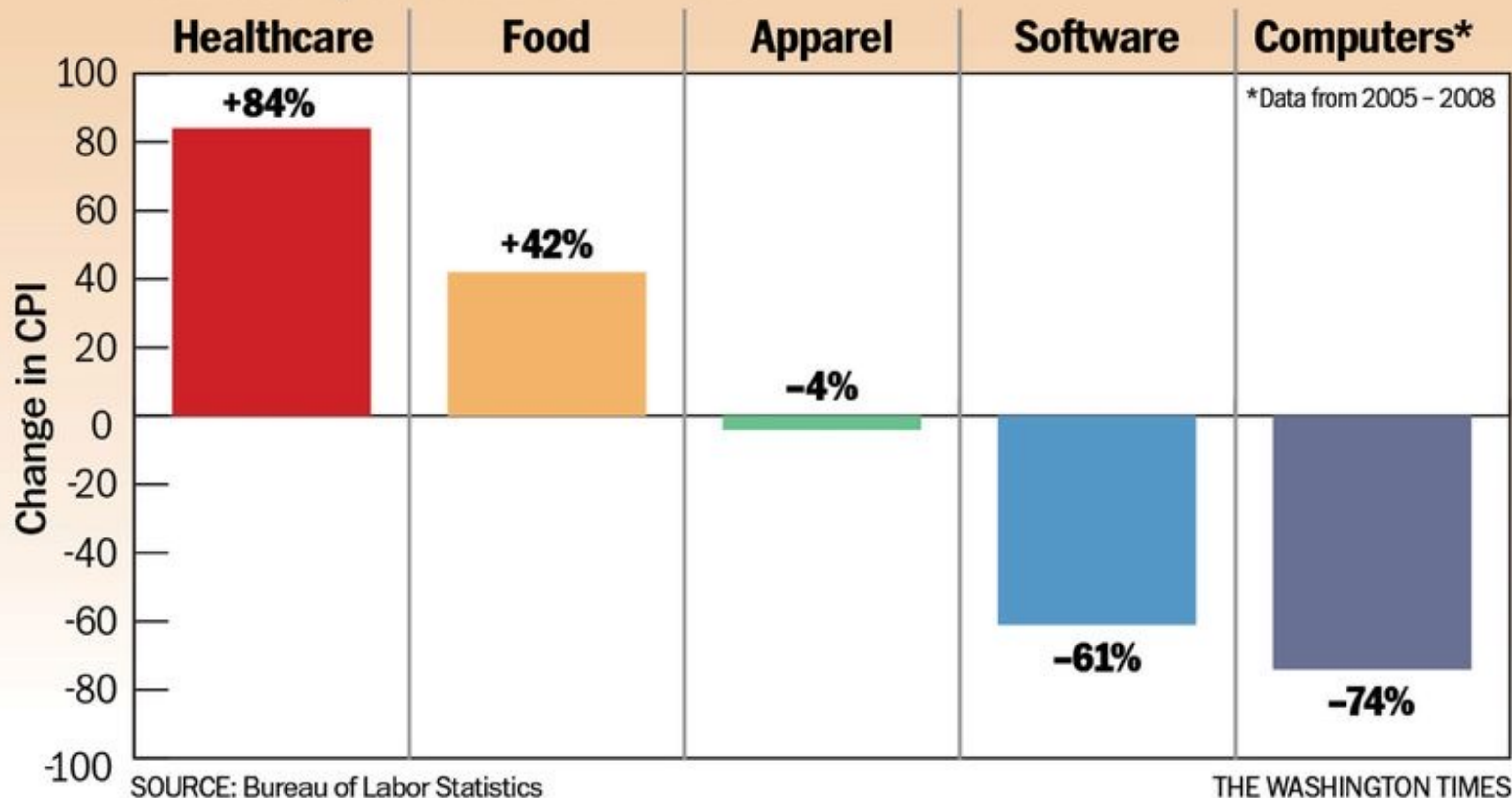
- Highly complex system
- No single entity paying for or operating the healthcare system.
- No single-payer system; numerous sources of funding for healthcare services, including multiple private and public entities.
- Decentralized healthcare, with a mix of private and government organizations providing, paying and setting policy for health care.
- Private organizations of providers and payers, including nonprofit and for-profit.
- Nonprofit insurance companies converting to for-profit.

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

“Which Country Has the World’s Best Health Care?”, Ezekiel Emanuel

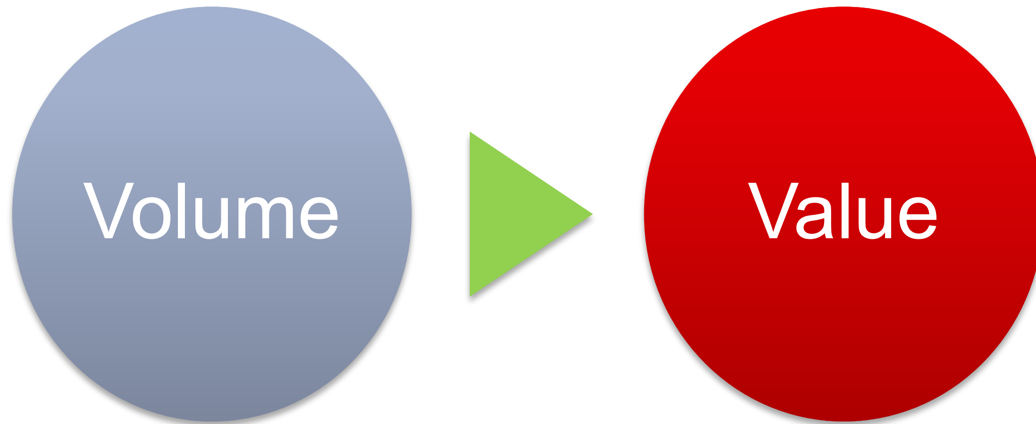
Health Expenditures Growth Drivers




HEALTH COSTS OUT OF CONTROL
Inflation by sector 2000 – 2018
Healthcare
Food
Apparel
Software
Computers*
100
80
60
40
20
0
-20
-40
-60
-80
-100
Change in CPI
+84%
+42%
–4%
–61%
–74%
*Data from 2005 – 2008
SOURCE: Bureau of Labor Statistics
THE WASHINGTON TIMES

Since 2008, General Annual Deductibles for Covered Workers Have Increased Eight Times as Fast as Wages
Overall Inflation
Workers' Earnings
Deductibles
230%
180%
130%
80%
30%
-20%
212%
104%
26%
12%
17%
8%
2008
2009
2010
2011
2012
2013
2014
2015
2016
2017
2018

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."

Current payment structures

- 'Do more', no incentive for efficiency
  - **Fee-for-service**
  - **Fixed price**
  - Cost-plus
  - Hourly (time + material); per diem
- 'Do less', no incentive for quality
  - **Capitation**

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

Many Reforms and Initiatives are Being Evaluated

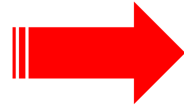
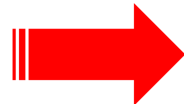
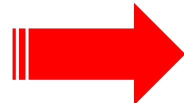
- **Accountable Care Organizations (ACO).** Shift from fragmented and inconsistent care to coordinated care and measured performance
- **Value-Based Purchasing (VBP) Program.** Reward value and patient outcomes, instead of just volume of services
- **Reduced Payments for Hospital Acquired Conditions.** 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 Take Home Message

The Emerging Landscape

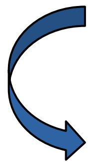
Past		Future
Volume based incentives	→	Value based / outcomes
Fee-for-service	→	Bundled care
Payers assume financial risk	→	Payers & providers share risk
Devices selected by physician	→	System decisions *Clinical, operations, marketing, economics*

Failure to **understand early in the project life cycle** your roadmap beyond regulatory approval…

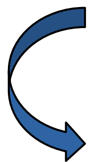
Past		Not a big deal
Yesterday		Bad practice
Today		Business malpractice

When Should We Start Identifying Our Target Market?

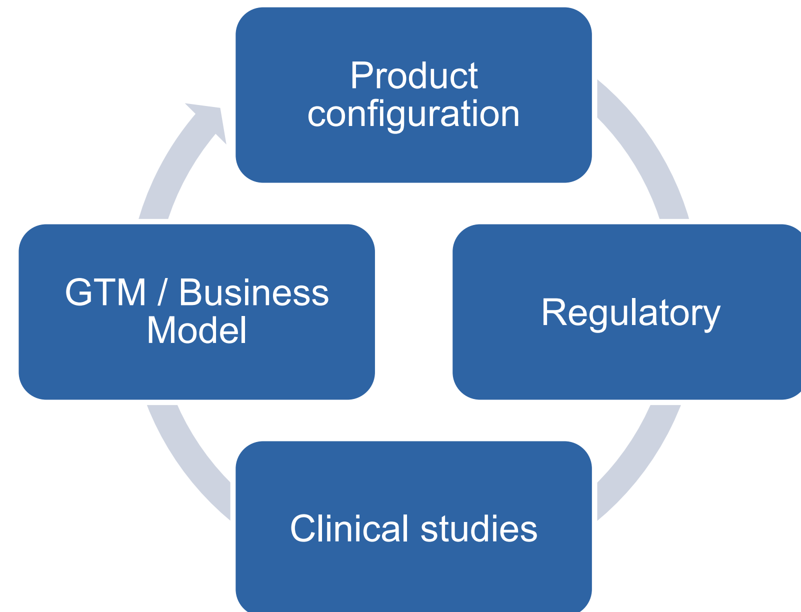
- **The success of a company is predicated upon demonstration of market adoption of the technology, or at the minimum, convincing investors, partners and acquirers that it is on track to gain adoption.**



- **Adoption requires COMPREHENSIVE understanding of the target market**



- **Defining the optimal market enables the development of coherent strategy.**



Sooner the better…

شكرًا
рахмат
danke
謝謝
ngiyabonga
teşekkür ederim
баярлалаа
mersi
barka
welalin
tack
спасибо
faafetai lava
vinaka
blagodaram
dank je
misaotra
malondo
paldies
grazzi
thank you
gracias
tapadh leat
хвала
kiitos
dankie
dhanyavad
asante
manana
obrigada
hvala
mauruuru
bedankt
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мерси
kam sah hamnida
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merci