mHealth Regulations. Navigating the M

PA Consulting Group

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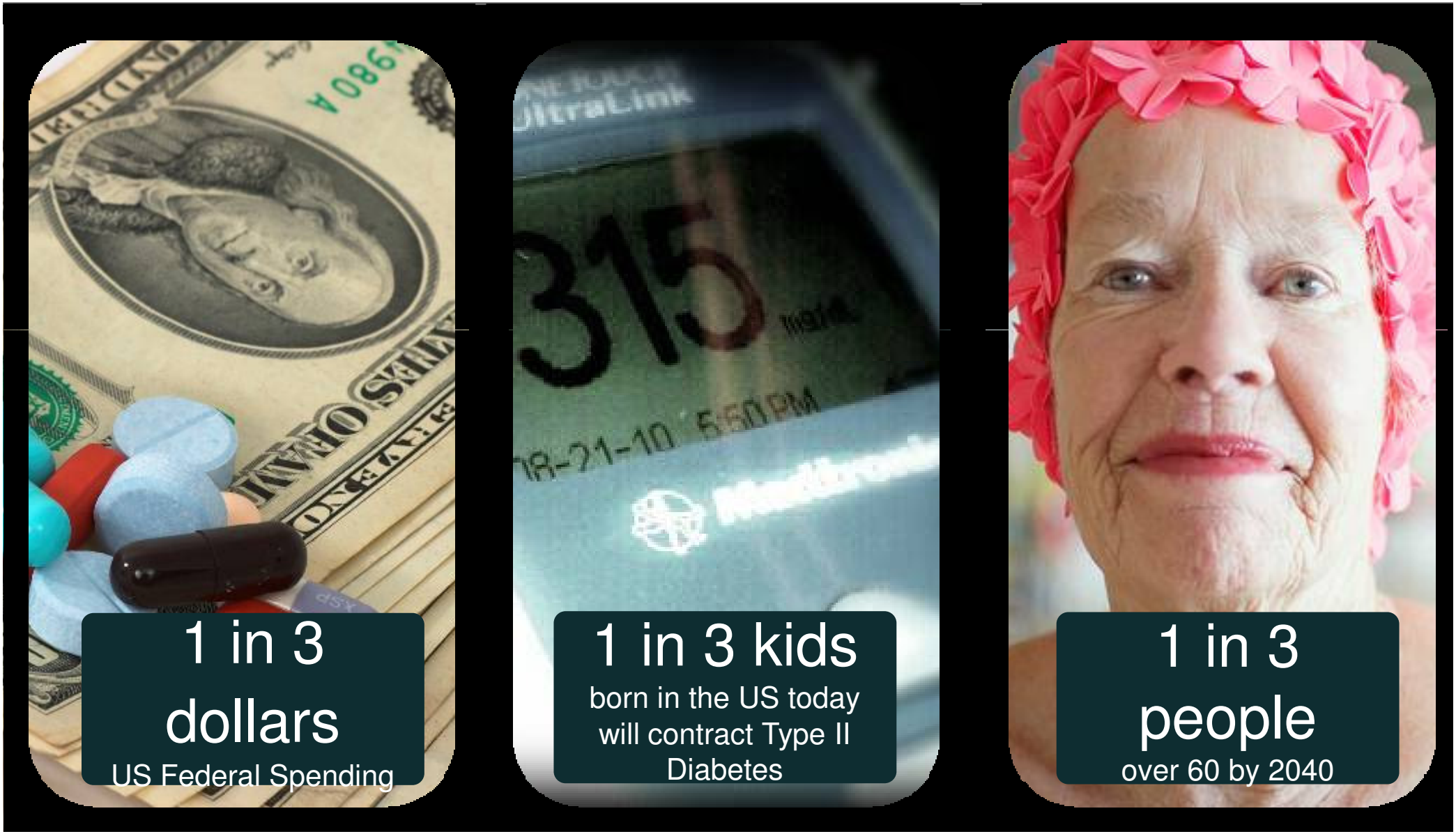
This is not a problem of need …



. . . or technology

5Bn
mobile users worldwide

80%
worlds population live within range of a mobile network

66%
of mobile users live in emerging markets

>25% pa
Smartphone adoption growing worldwide

$15
2010

500M
Active user

founded: 2006

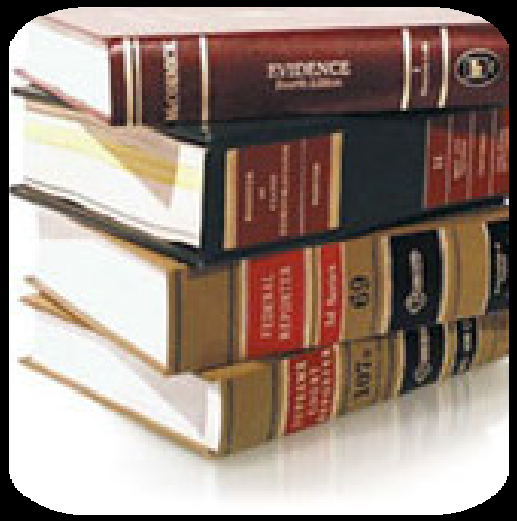
100M
tweets daily

founded: 2006

So what's the problem ?

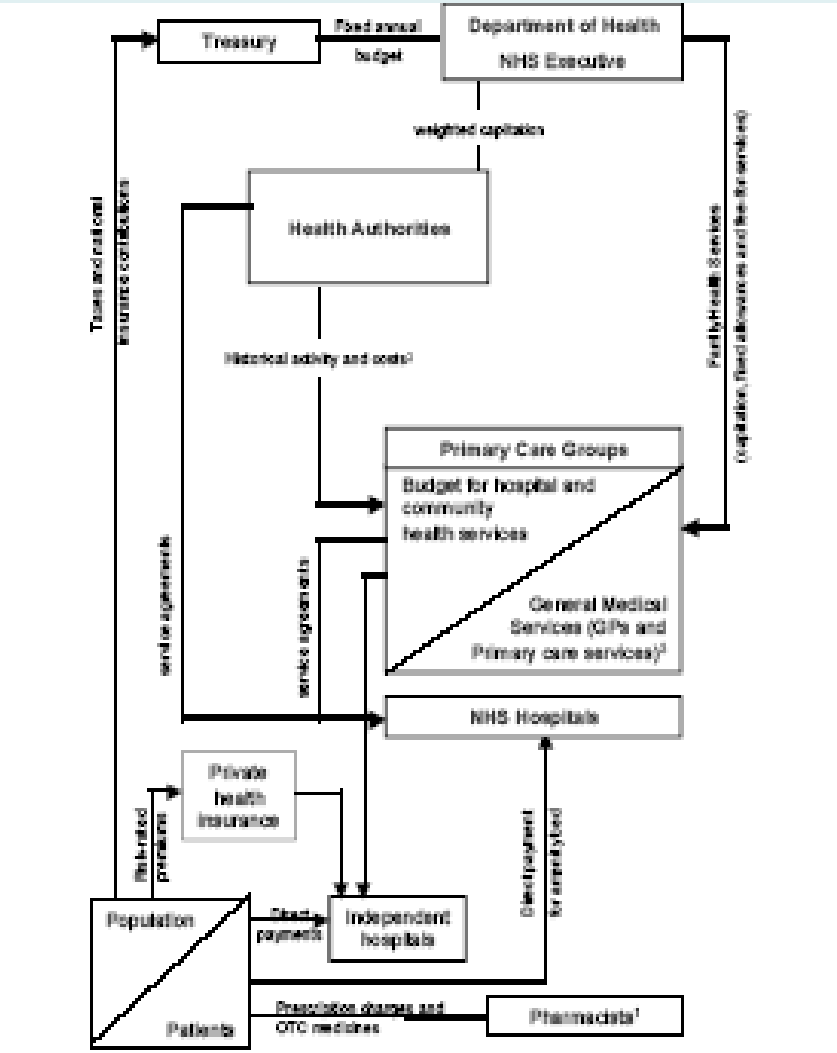
Business Model

Regulations

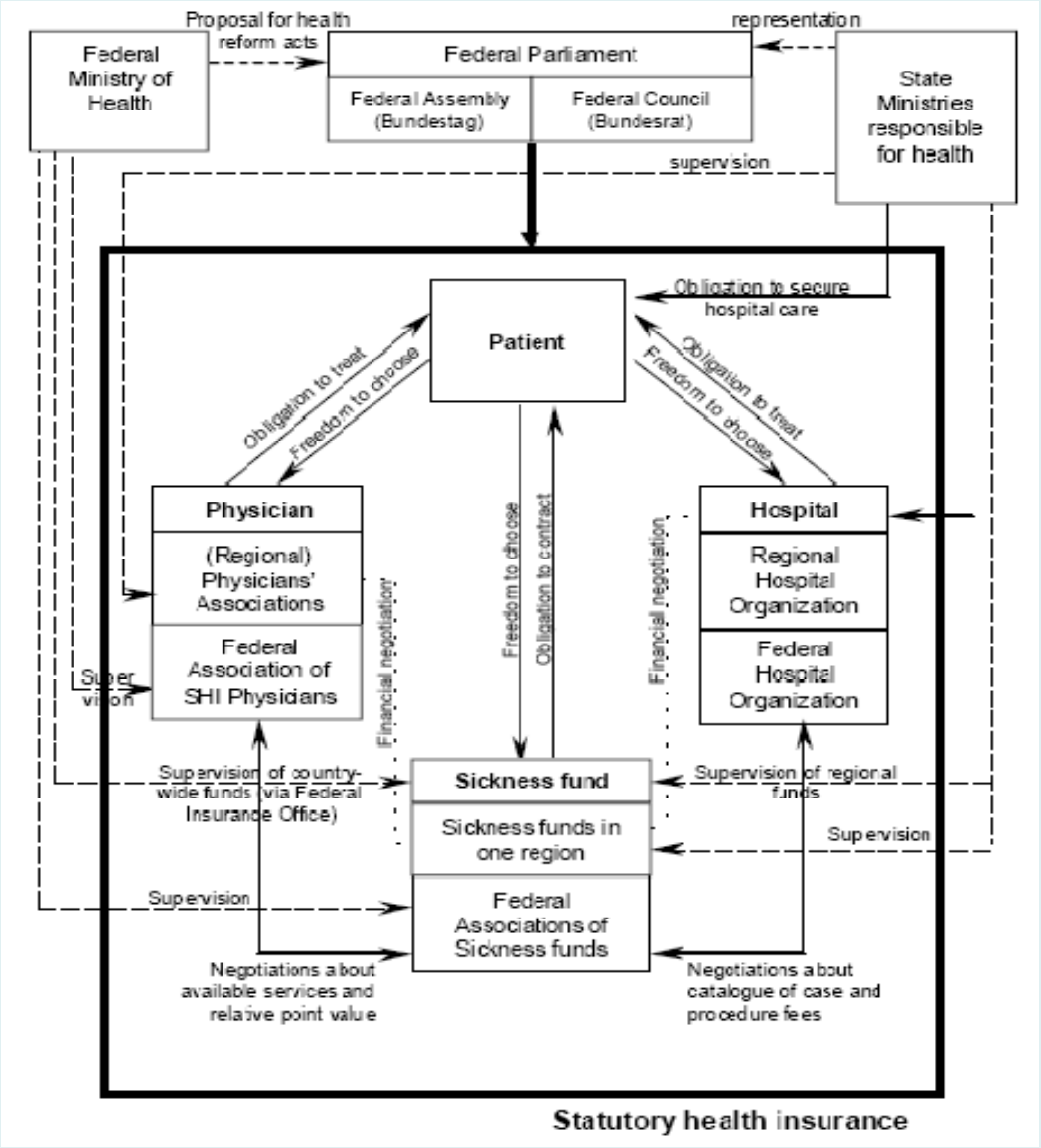


Business Model

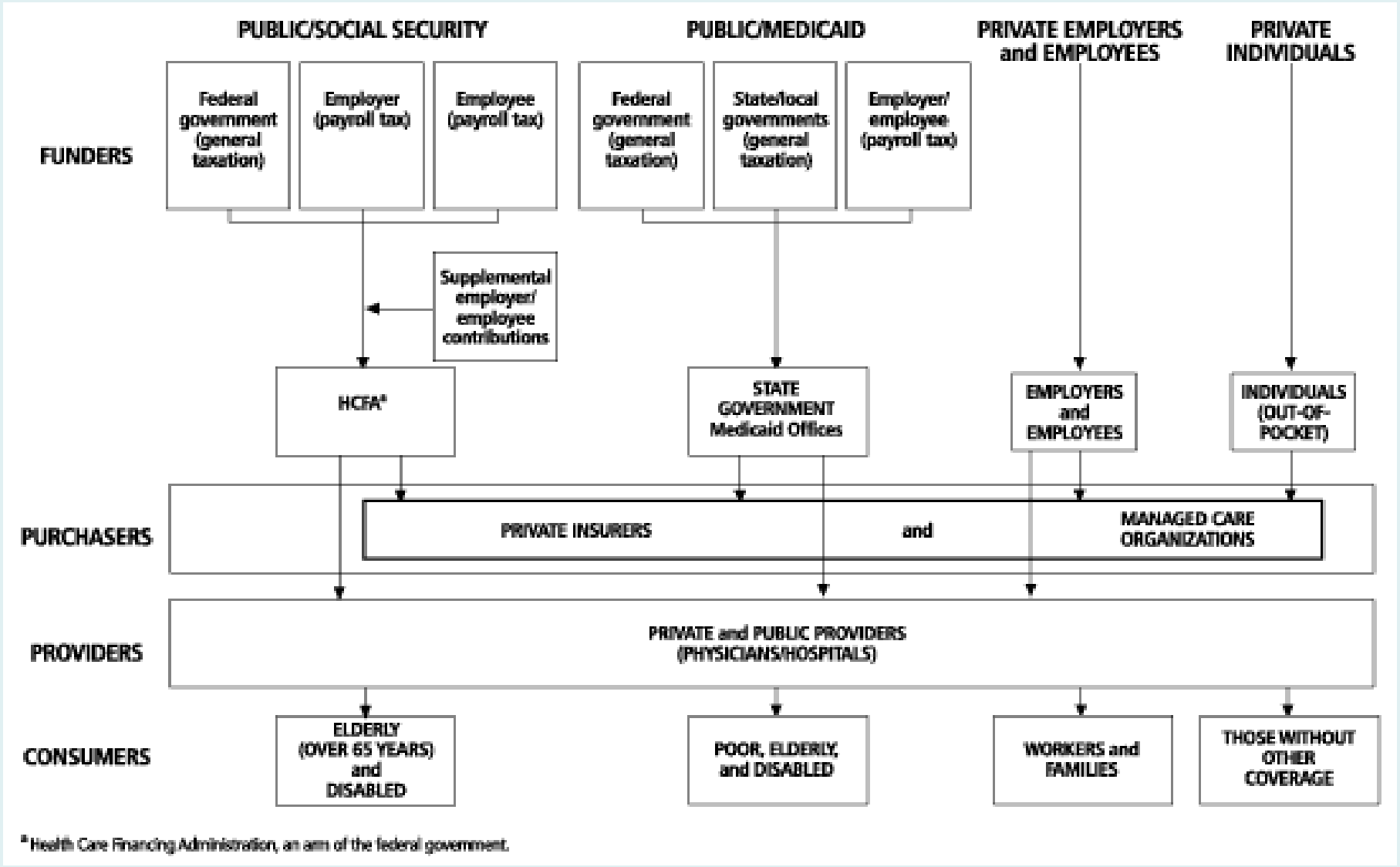
Healthcare Business Model



Healthcare Business Mode

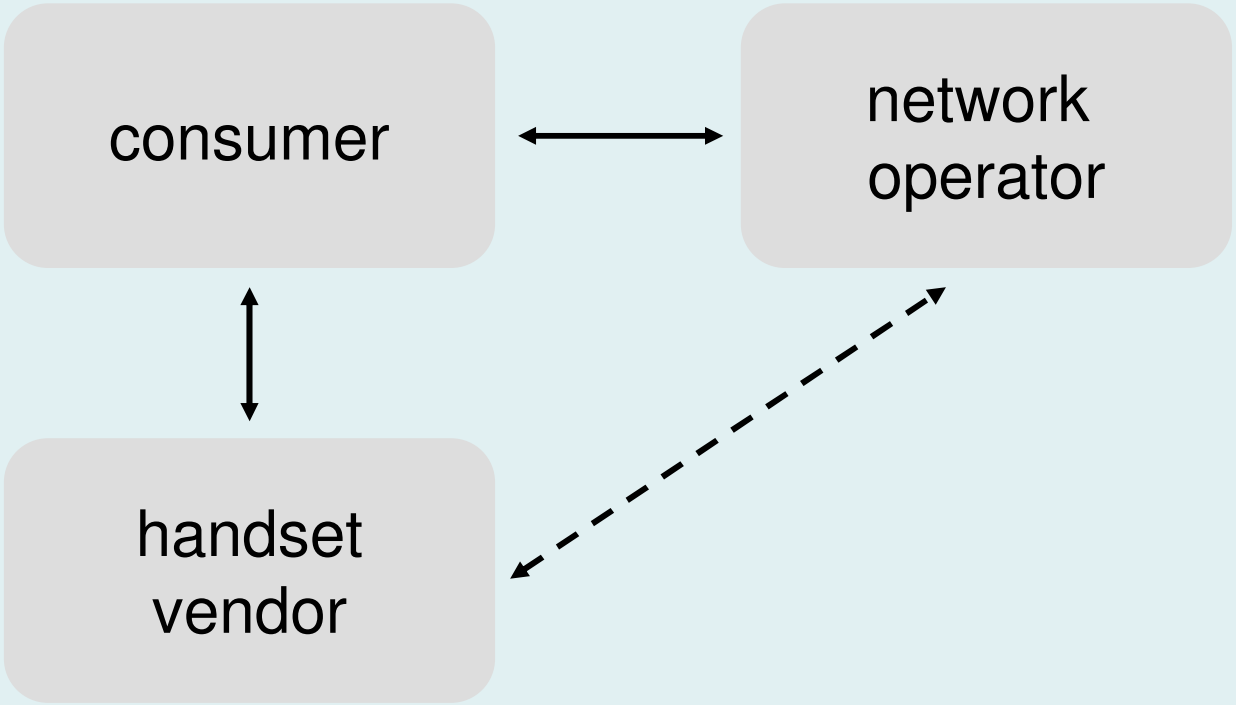


Healthcare Business Model

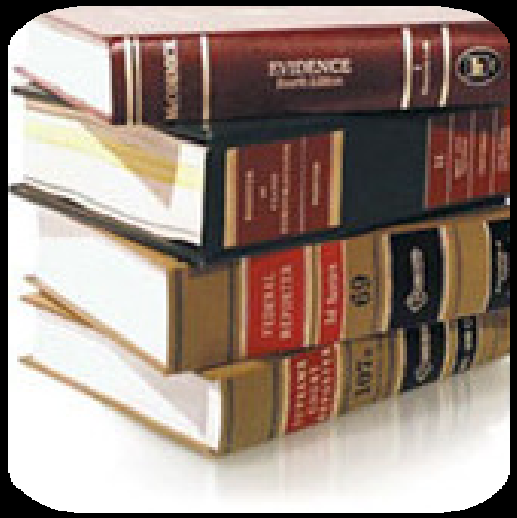


[a] Health Care Financing Administration, an arm of the federal government.

Mobile Business Model



Regulations



Rockville meets Silicon Valley

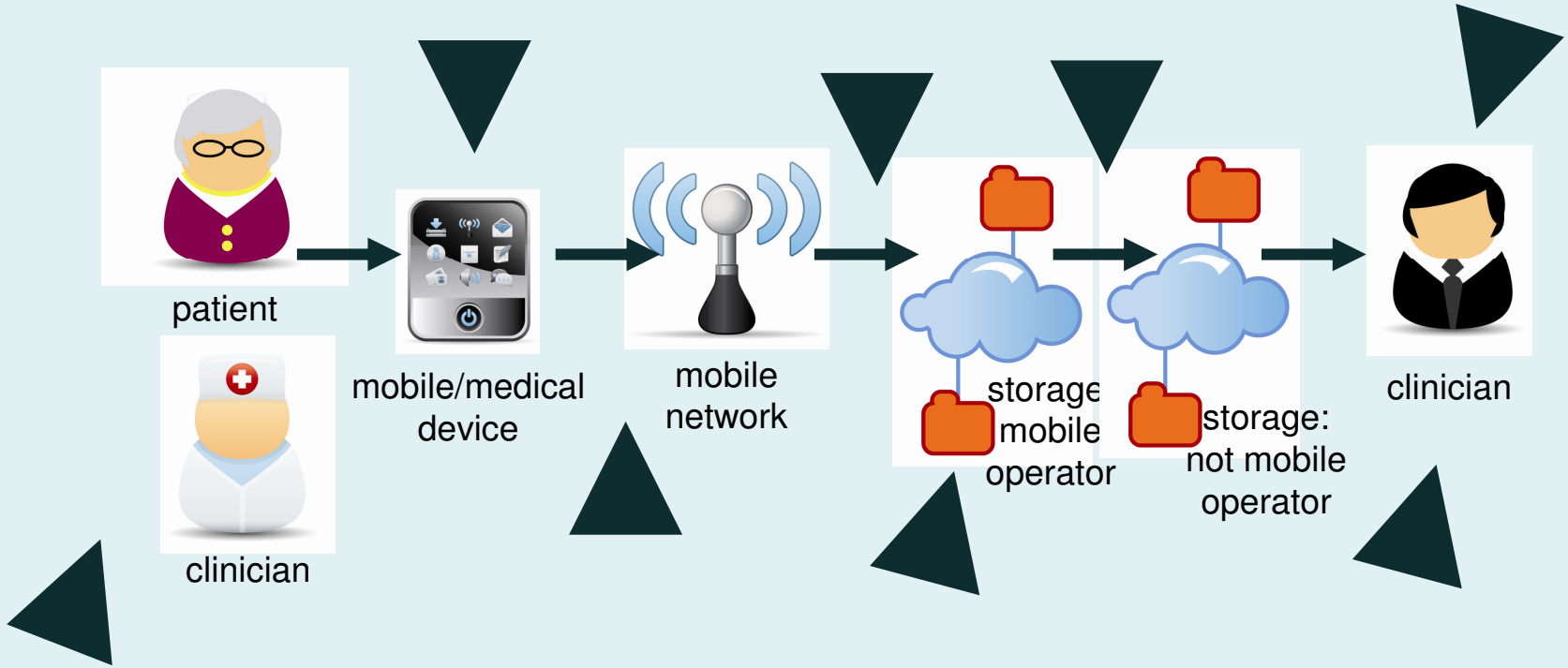
Google™

Rockville meets Silicon Valley

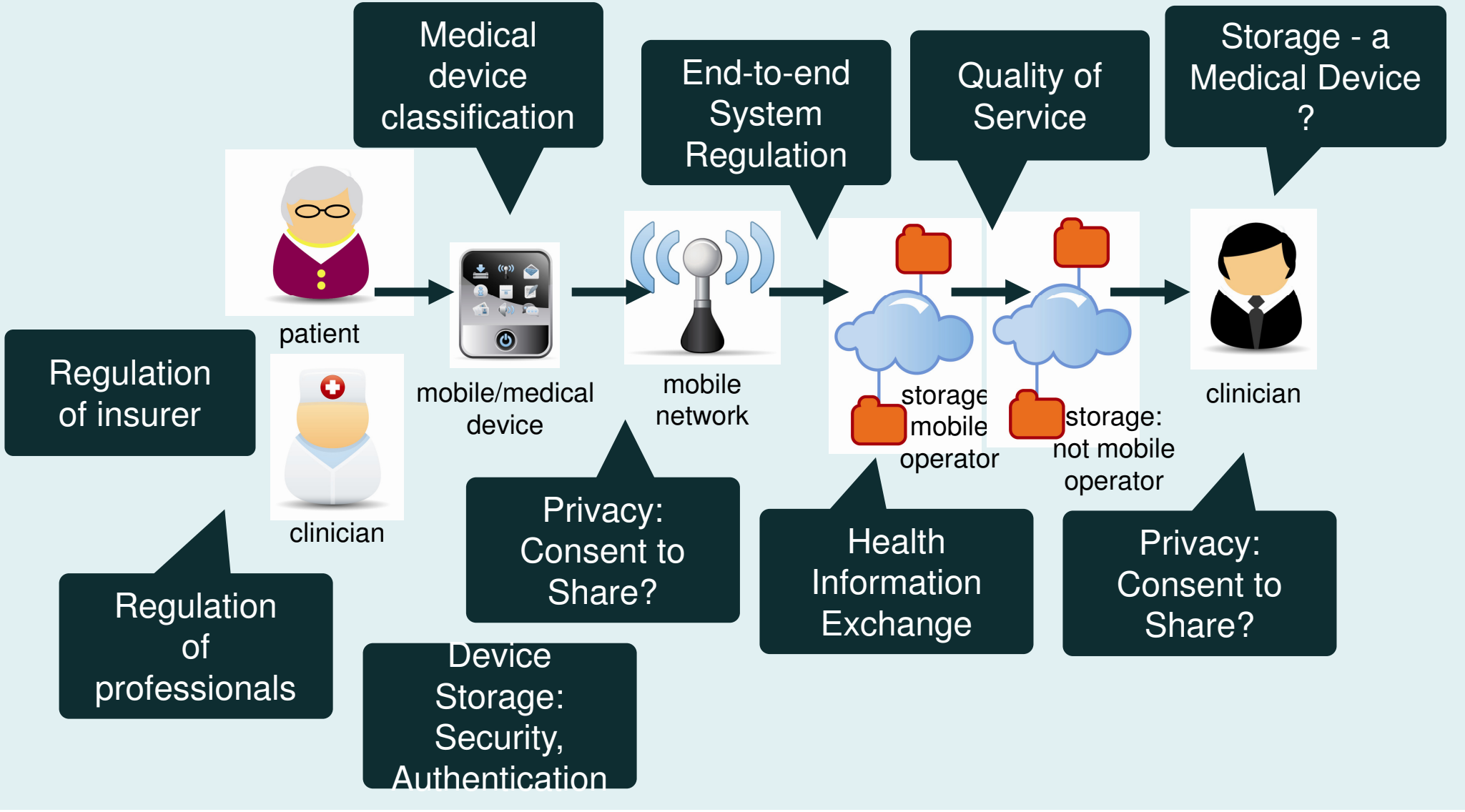
- Patient Centric
- Safety First
- Demonstrate efficacy
- “at least, do no harm”

- Market Centric
- Maximize consumer value
- Foster competition
- “Just enough”

Regulatory Touchpoints



Regulatory Touchpoints



Medical Device

Geographic Variabilities

USA

Many take the lead from USA.

Patients are accustomed to paying ‘out of pocket’ for healthcare

Gulf

With good funding, and fast-evolving infrastructure this region is an ‘emerging market’ from the point of view of maturity of infrastructure and regulations

Developing Economies

one of the fastest growing regions in adoption of mobile technologies. The appetite for innovation is high, and the regulatory restrictions are relatively low.

Regulatory Innovation.
From DHealth to MHealth

Regulatory Innovation – parallels with D-Health

"At least do no harm"

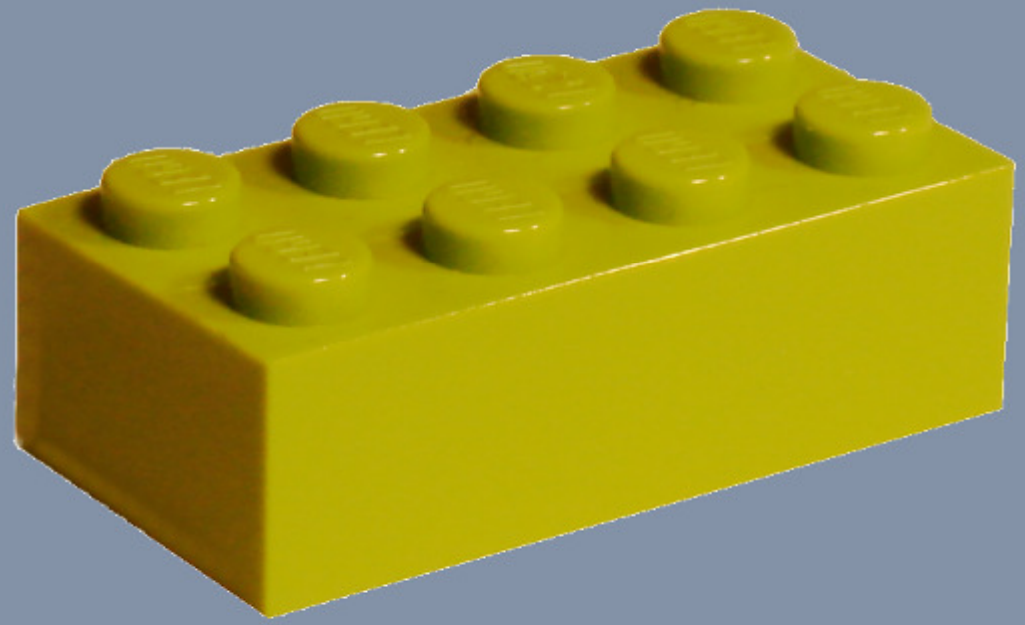
Encourage Modularity

Regulatory Innovation – “At least do no harm”

Parallel Throughput Trials

Adaptive Regulatory Systems

Regulatory Innovation – Encourage Modularity



Conditional Approval

Open Systems

Information improves trials

Information improves outcomes

Regulatory Innovation

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