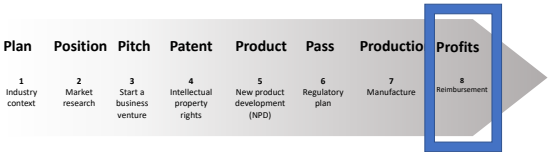
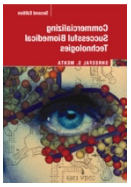


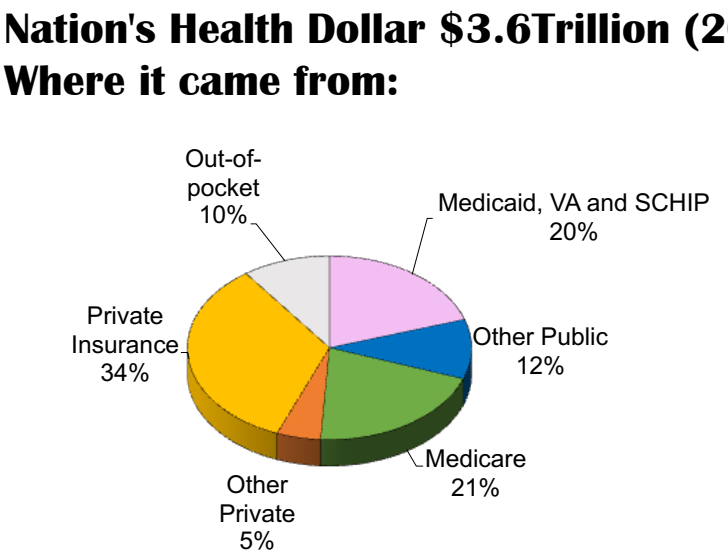



# Chapter 8: Practical Tips and Notes on Reimbursement and Sales

**Q. Who are the main payers for healthcare in USA and globally ?**

- In Europe and in most developed countries (other than the USA), the government is the dominant payer and also owns most of the healthcare facilities in the country.

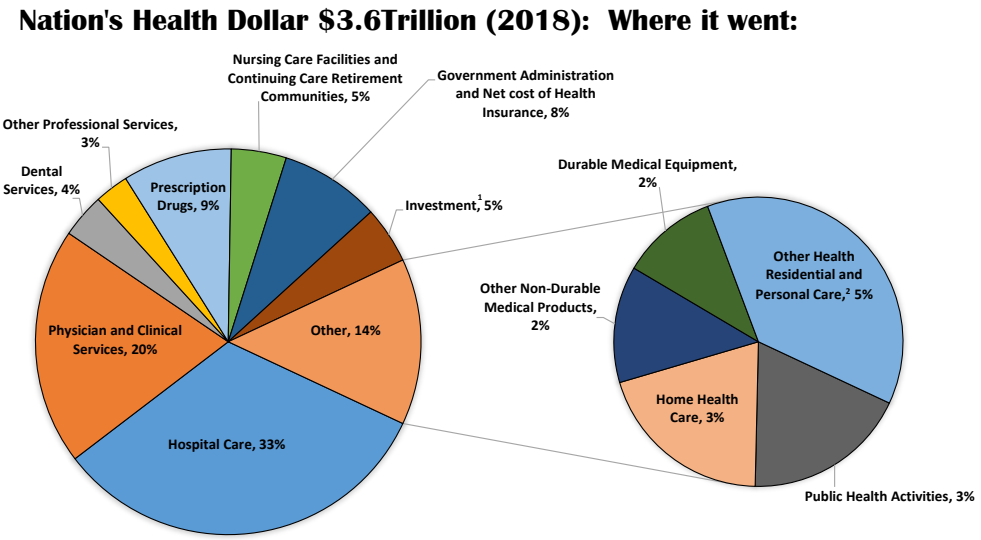
- In the USA, the payers are somewhat split by demographics – the government is the dominant payer for people over 65 years of age and for people of all ages whose income is below 138% of the federal poverty level. (Medicare and Medicaid programs respectively). See graph below for USA health care expenditure sources.



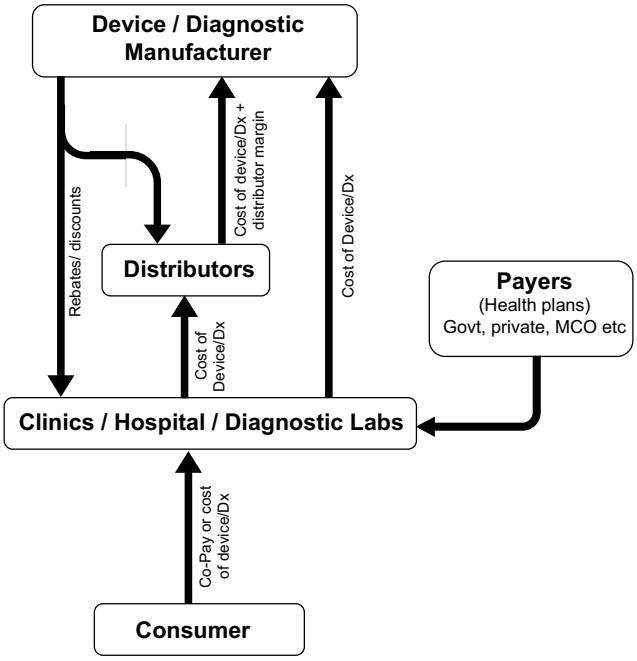

*Data from Centers for Medicare & Medicaid Services, Office of the Actuary, National Health Statistics Group.*

- In developing countries with large rural populations like China, India and Africa, The government programs strive to expand payment and coverage of at least basic healthcare needs but typically most people who can afford it get private insurance or pay out of pocket. Private insurance is slowly expanding through work related insurance coverage in China and India but people still typically pay out of pocket and then get reimbursed.

**Q: What are the sources of the costs in the health care system in USA?**




**Q. What is the flow of payments and reimbursements for medical devices in the USA?**




- Device reimbursement is usually bundled with the overall procedure reimbursement and payment level is dependent on site of delivery,

- For infused drugs, devices and diagnostics, the provider purchases the product and submits a claim to the payer charging for the services and the product.

- Medical devices and infused drugs are sold through specialized distributors or through a direct sales force to hospitals or clinics or to their purchasing consortia.

- Clinical diagnostic tests are usually sold to large, centralized laboratories or to one of thousands of local clinical or hospital-based diagnostic labs.

*Some of the above text is excerpted from the book :*
*Commercializing Successful Biomedical Technologies, ( 2nd Edition, Cambridge University Press)*

- Reimbursement is claimed directly from the insurers/payers per use as part of a procedure claim for the specific test or panel of tests based on the patient condition diagnosis.

- Medicare determines payment rates for clinical laboratory tests reimbursed for under the Clinical Laboratory Fee Schedule (CLFS).

**Q: What determines if a new product will be reimbursed ?**

For adequate reimbursement by payers, three components must be in place for approved drugs and devices :

1. **Coverage** – will the payer cover the product and approve its use
2. **Coding** – is there an appropriate code that the provider can use to bill the payer ?
3. **Payment** – Is the payment rate of reimbursement adequate for the provider / manufacturer?

To establish **coverage** the manufacturer has to not only get the product approved by the FDA but must also collect specific data on clinical outcomes and costs – i.e. for a payer to include the new product in their program or plan benefits they evaluate the clinical outcomes and cost effectiveness of the new product.

To fit a new product into an existing **code**, the procedure or the function of the product must be similar to prior products. However, getting a code assigned to the product is no guarantee of adequate reimbursement.

To achieve adequate **payment** level in the reimbursement schedule, it is necessary to have the right code and understand the current reimbursement levels for similar products. An economic argument must be presented to the payers with supporting data to provide for an appropriate payment rate.

**Q: When should a reimbursement plan be put together ?**

- The reimbursement plan should be part of the business plan. Identify patient demographics based on the indication chosen, which will give a breakdown on payers.

- In addition, at each major milestone review, the strategic review team must incorporate updates on the reimbursement plan.

- The active engagement with the end market must incorporate payer interactions as soon as some clinical data is available.