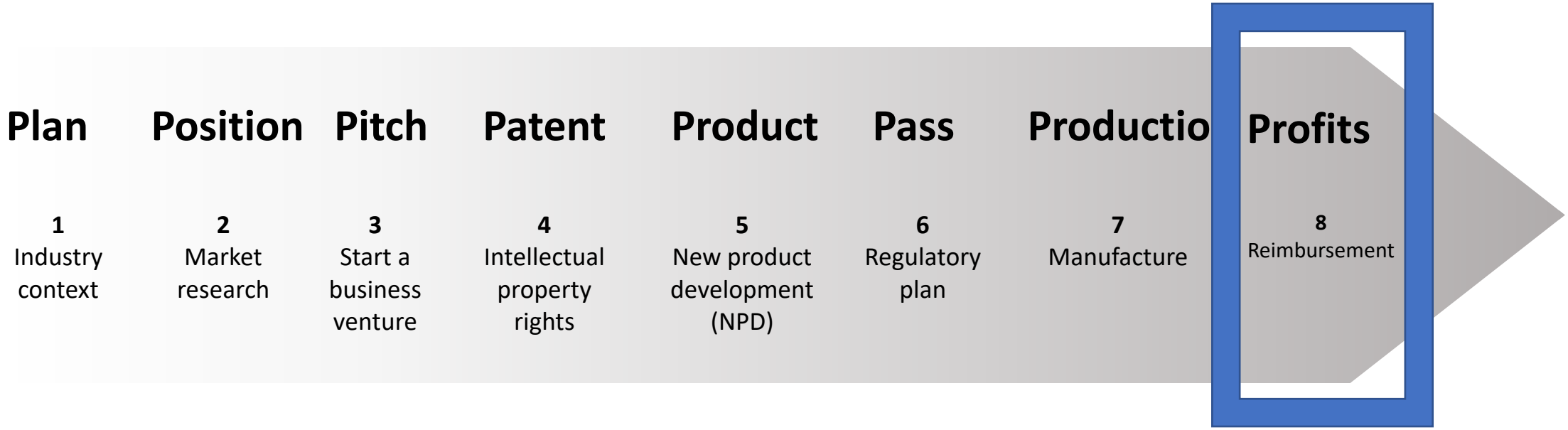
Commercializing Successful Biomedical Technologies 2nd Ed.

Shreefal Mehta



Reimbursement, marketing, sales, and product liability

Shreefal Mehta

Chapter 8

National Health Expenditures as a Share of USA Gross Domestic Product (GDP)

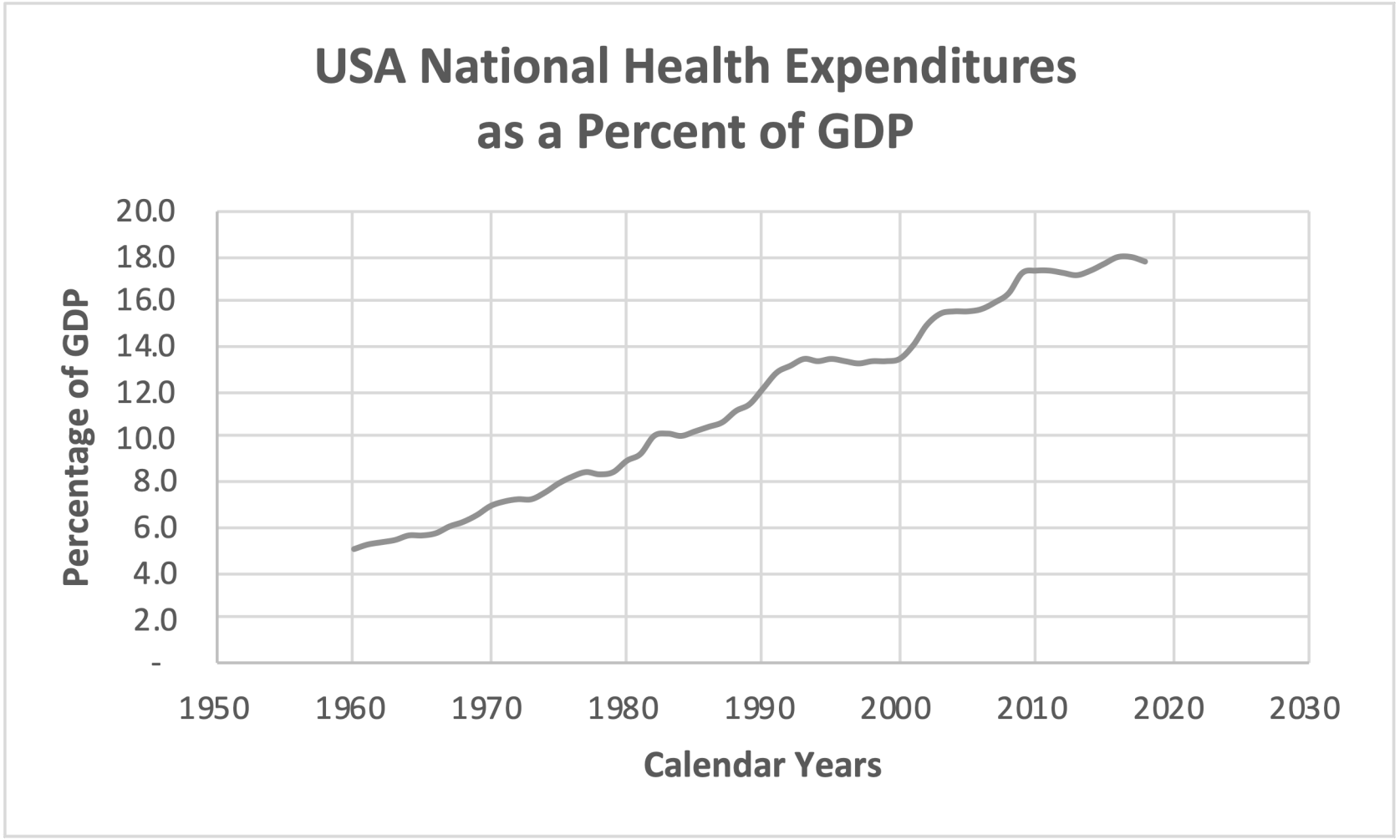


FIGURE 8.1

Source: CMS, Office of the Actuary, National Health Statistics Group

Who pays for the national healthcare expenditures ?

Public payers and private payers

- ***Public payers*** include the U.S. government's Department of Health and Human Services (DHHS).
- The main agency, Centers for Medicare & Medicaid Services (CMS), whose programs *(Medicare and Medicaid, described below)*
- Veterans Administration and other programs are added in, the state and federal governments pay almost half of the healthcare bills.
- ***Medicare*** is a federal insurance program that covers most individuals over the age of 65, the disabled (who satisfy certain statutory requirements) and end stage renal disease sufferers.
- ***Medicaid*** is a state-administered assistance program that covers people below 65 years of age with income below 138% of the federal poverty level,
- ***The Medicaid*** program is administered by state health services and each state sets its own guidelines regarding eligibility and services.

- Private insurers, who are paid premiums by employers and individuals, include companies

Eg: Blue Cross Blue Shield of Massachusetts, Anthem, Aetna, Cigna, and Wellpoint, and health maintenance organizations like Kaiser Permanente.

- As the U.S. population demographic shifts towards a more aged population, Medicare reimbursement policies greatly influence the private payers

Insurance coverage in US Population (2019)

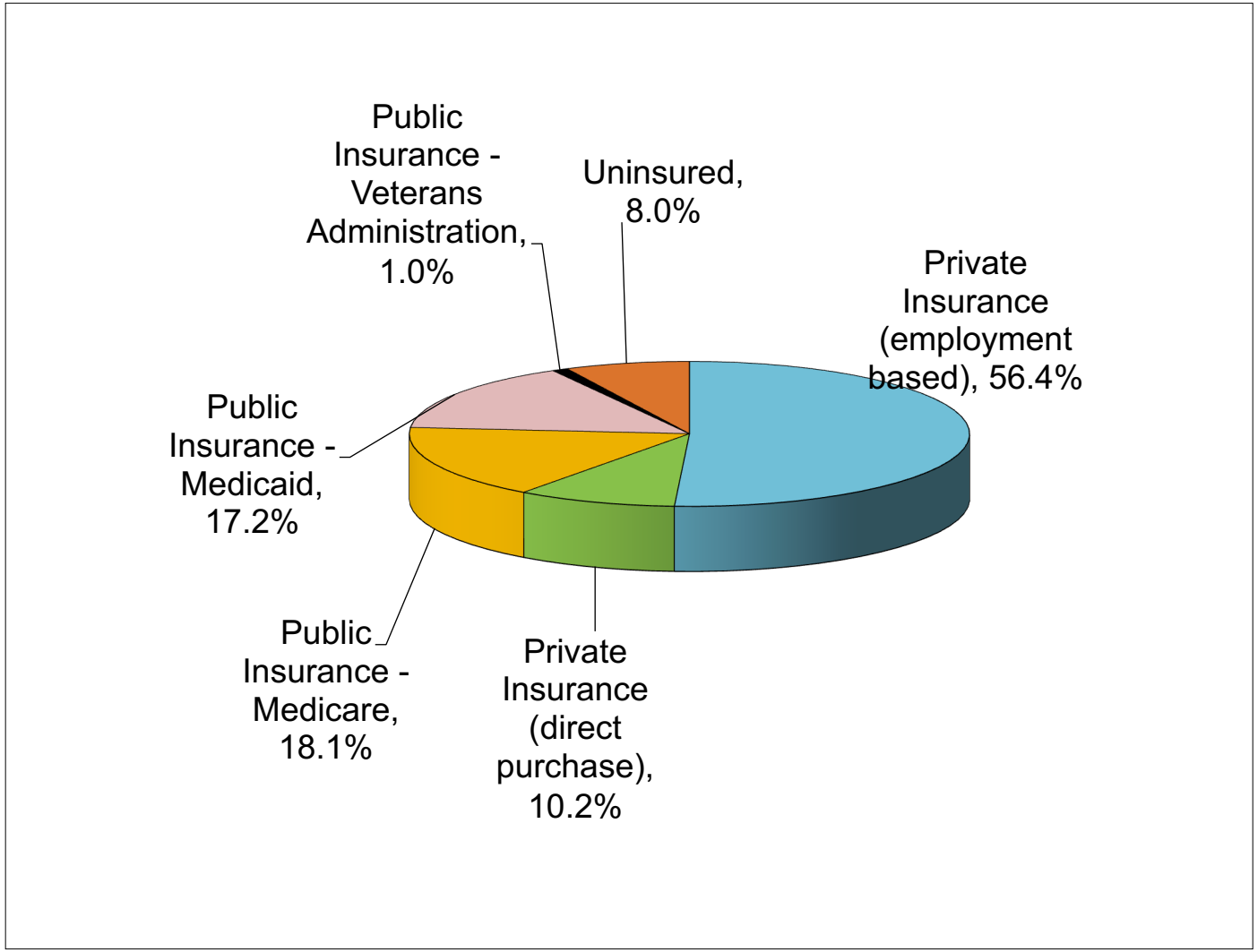


FIGURE 8.2

Source: CMS, Office of the Actuary, National Health Statistics Group

Nation's Health Dollar $3.6Trillion (2018): Where it came from

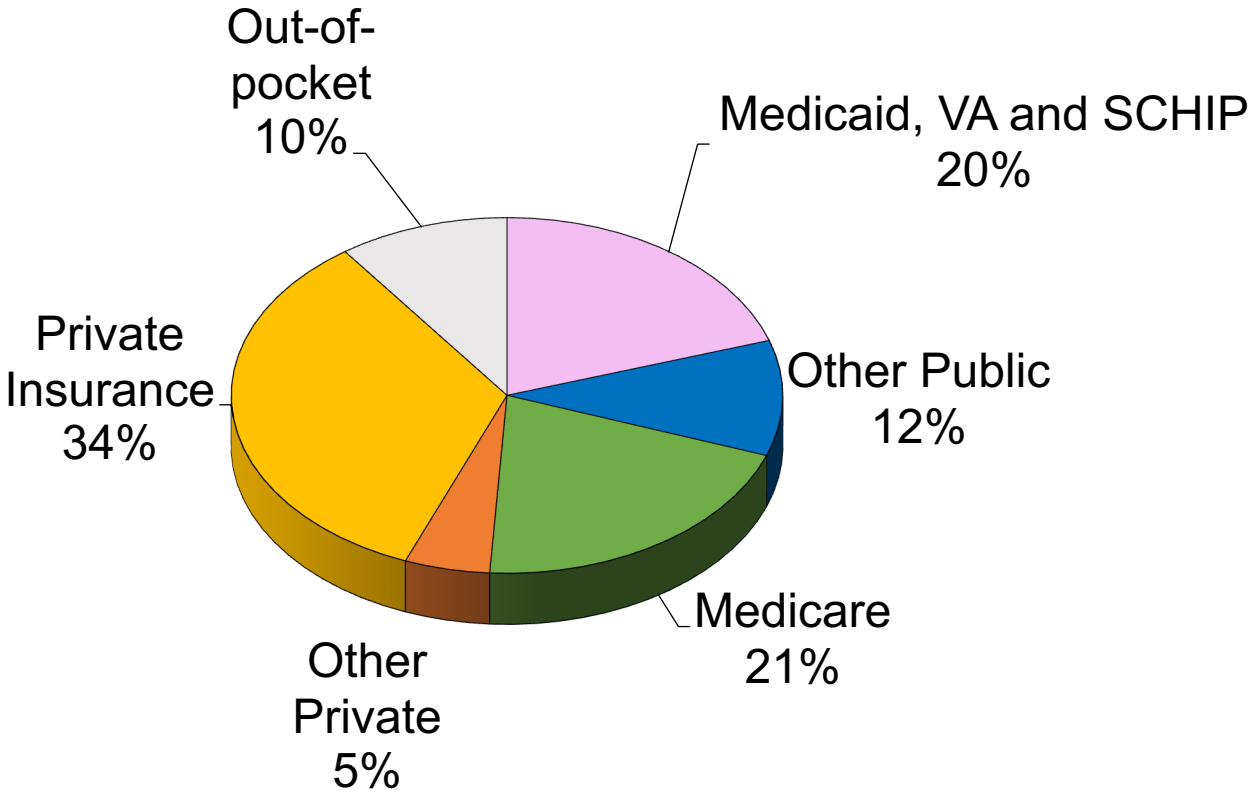


FIGURE 8.3

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

Nation's Health Dollar $3.6Trillion (2018): Where it went

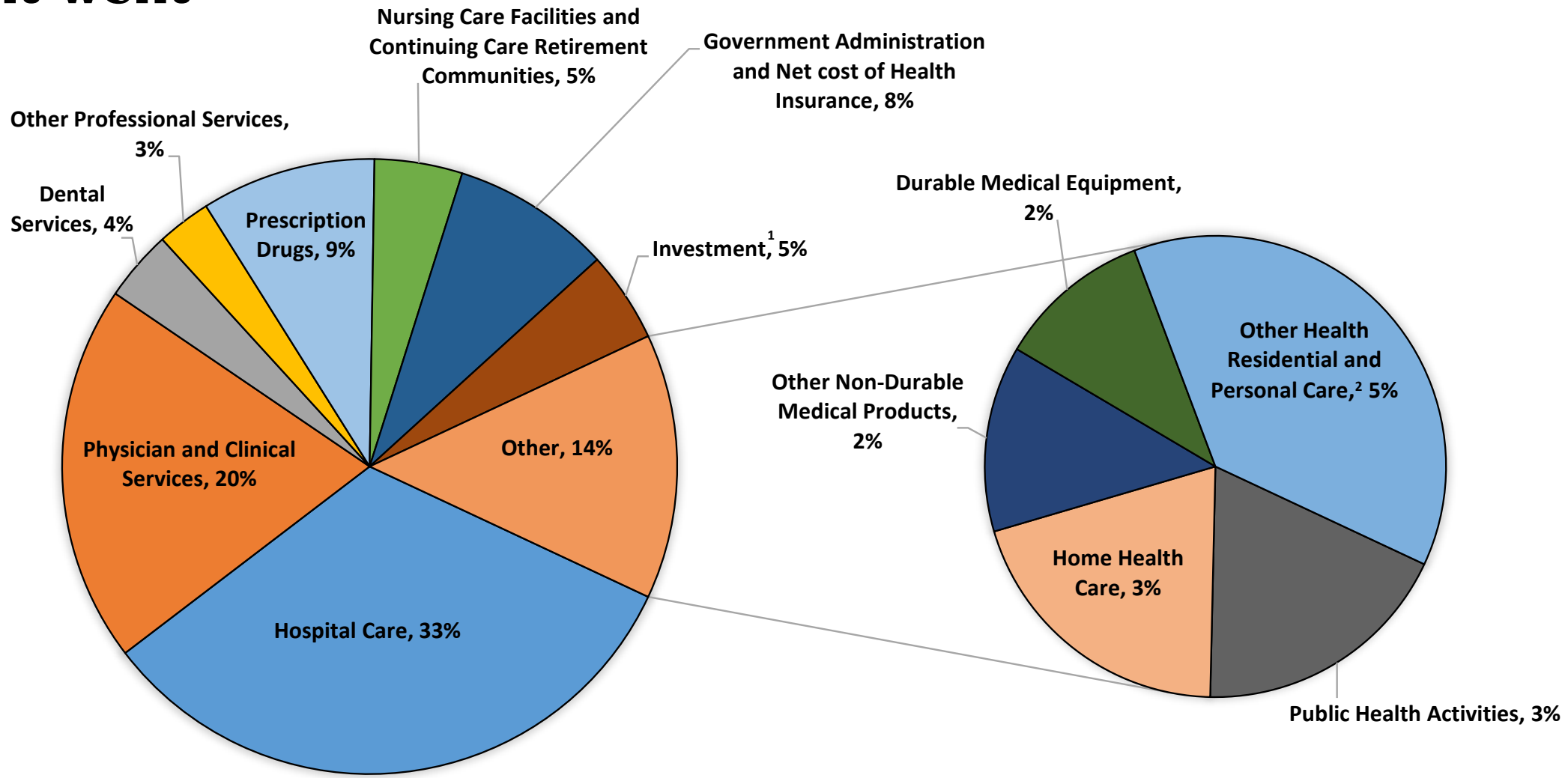


FIGURE 8.5

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

Manufacturers need to address reimbursement

The purchasing decision is influenced by a variety of stakeholders.

Most biomedical product companies will have to market their product's context-specific benefits to different groups at the same time.

Drugs are typically purchased from the manufacturer by wholesalers.

The end providers – the hospitals, the clinics, the hospital pharmacies, the retail pharmacy organizations –get reimbursed by the public or private insurers.

Most manufacturers' reimbursement and sales efforts are driven toward making sure the hospitals and providers or direct purchasers get adequately reimbursed for purchasing the drugs or devices.

Flow of payments, services and products

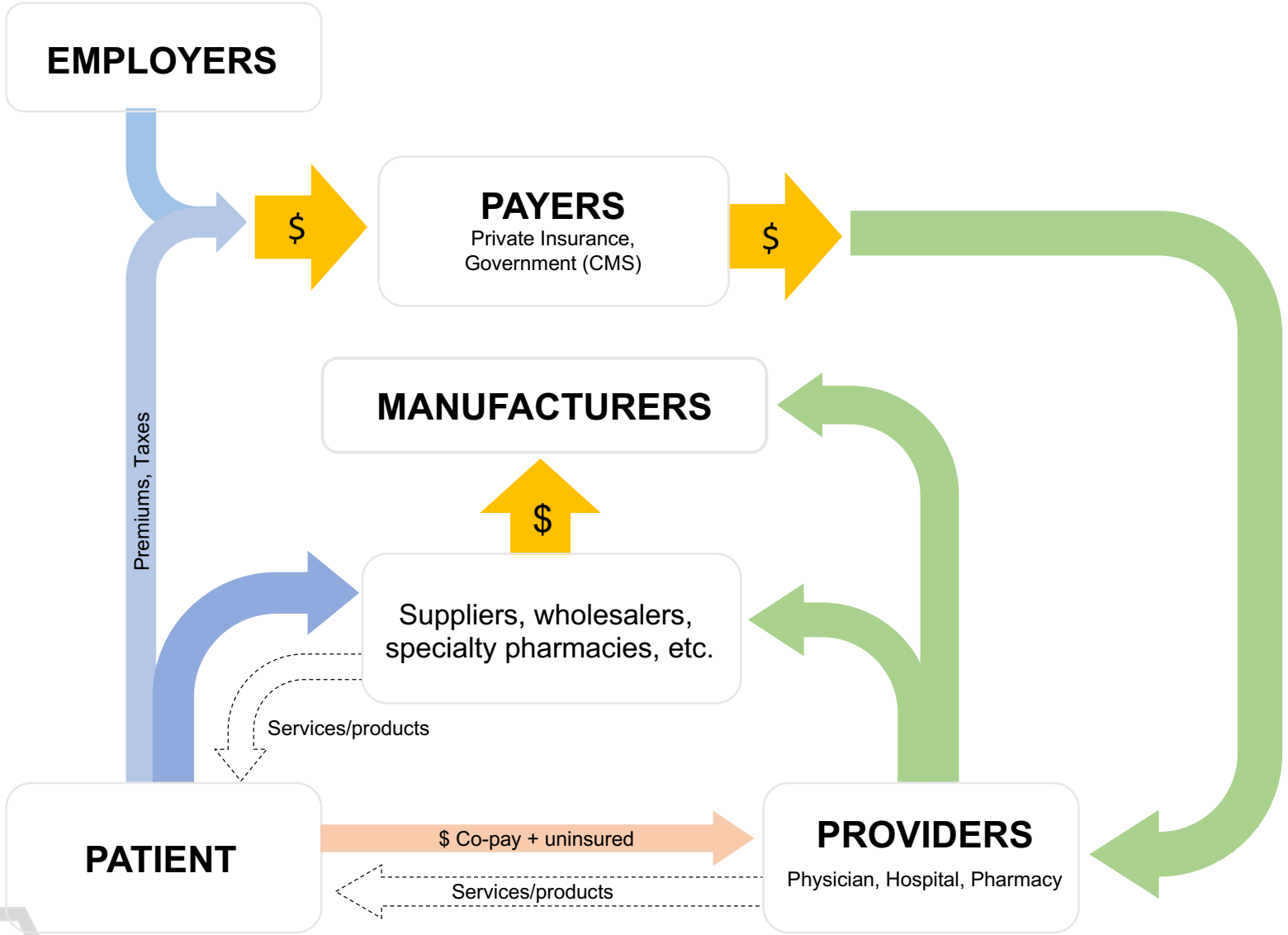


FIGURE 8.4

Drugs /biologics product payment and distribution model

Drugs are distributed to the patient by two means:

I. self-administered drugs delivered through pharmacies.

II. provider-administered or infused drugs delivered through hospital inpatient or outpatient settings or physician's office.

- Pharmaceutical manufacturers typically sell drugs in bulk to either, wholesalers or large pharmacy groups
- For infused drugs, the purchasers are specialty pharmacies or pharmacies at care-provider institutions or the physician's offices.
- When a prescription is filled at a pharmacy, the pharmacy collects any co-pay and then bills the insurance company/payer to get reimbursed for the drug.
- Manufacturers offer discounts and rebates to the pharmacy benefit manager (PBM) companies that manage formularies and drug reimbursement programs for many different payers.

Self-Administered Drug payments to PBMs and Manufacturers

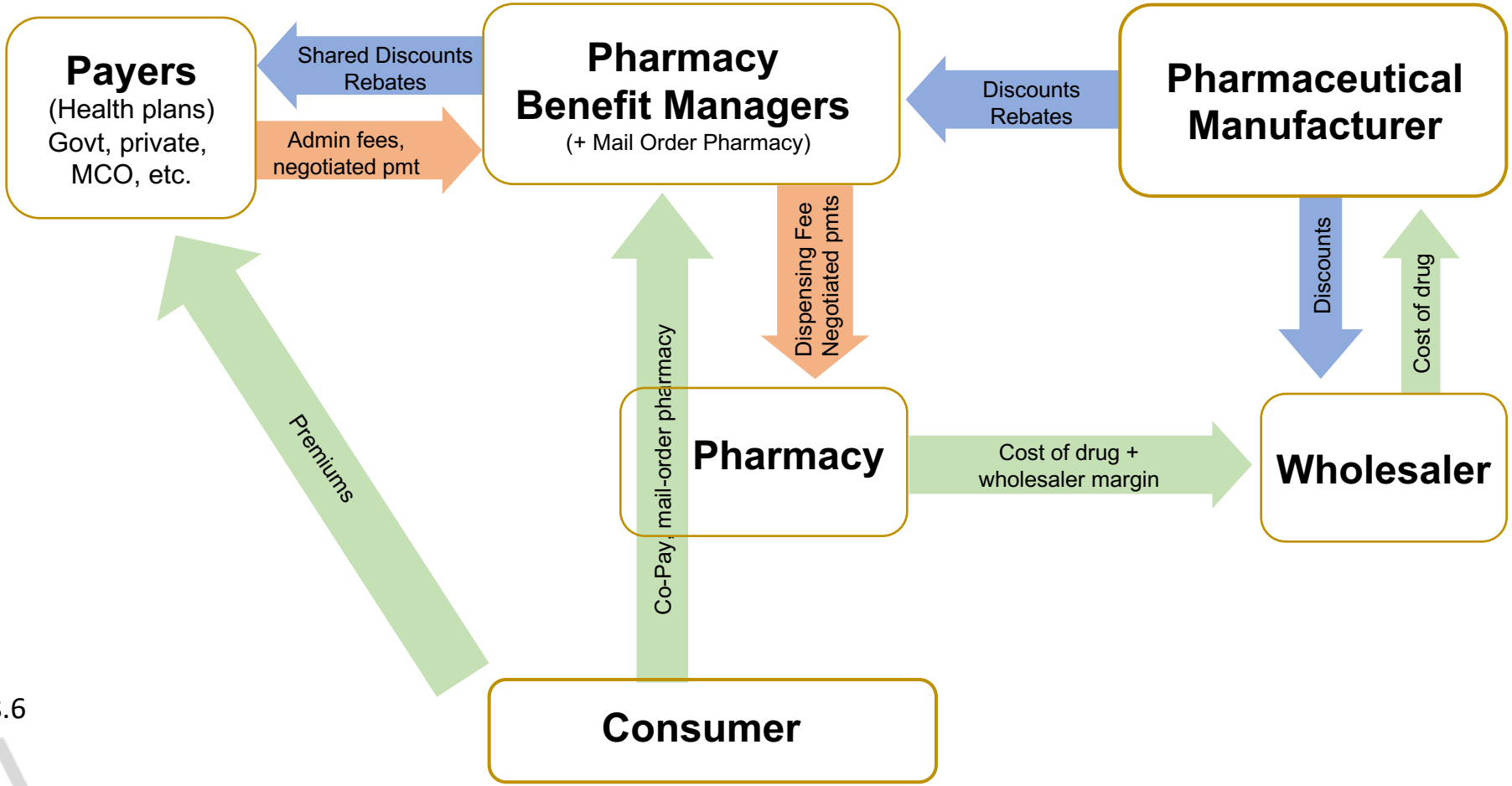


FIGURE 8.6

Infused Drugs (Biologics) Payment flow to Manufacturer

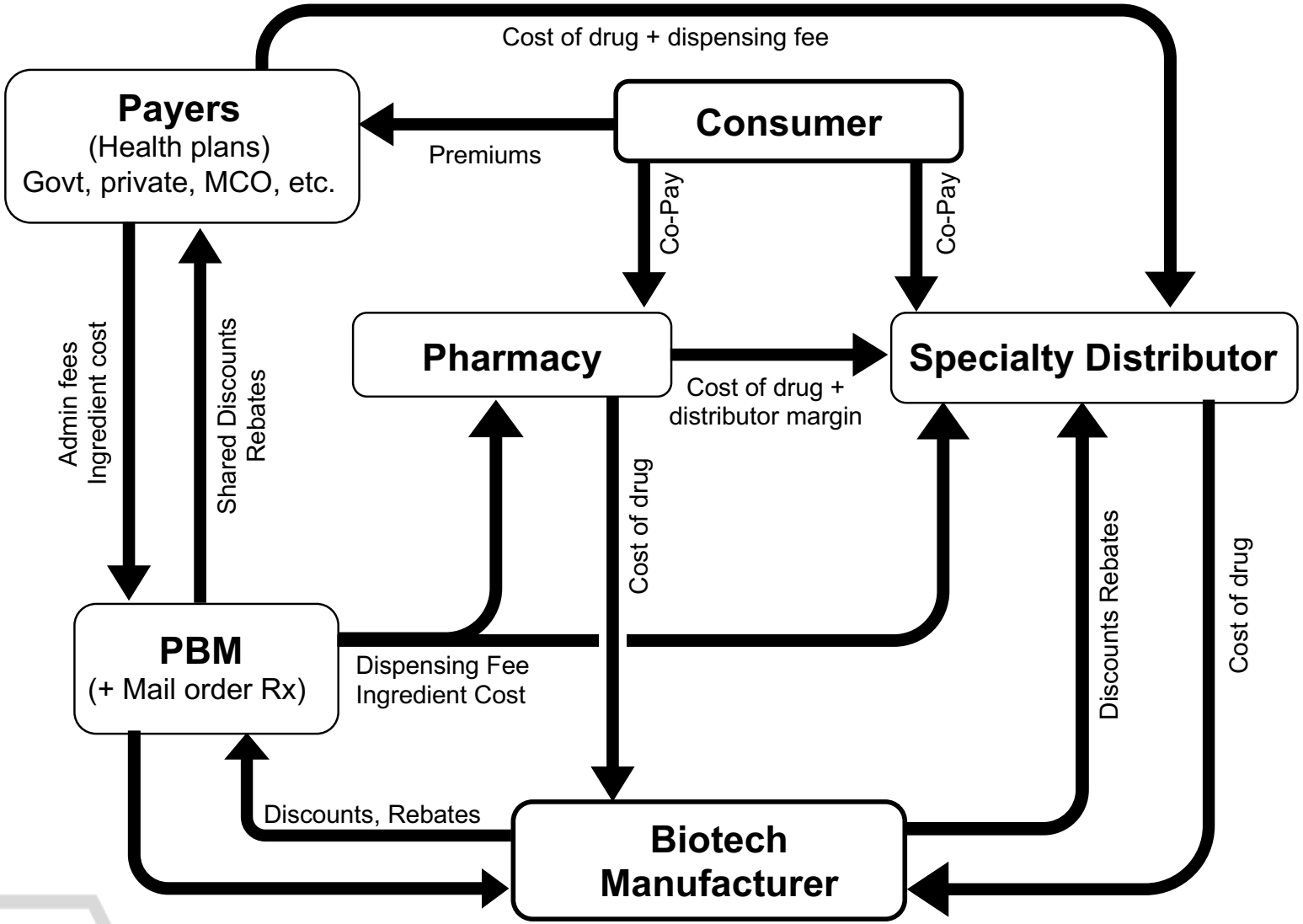


FIGURE 8.7

Devices and diagnostics payment / distribution

- 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.
- *Device reimbursement is usually bundled with the overall procedure reimbursement and payment level is dependent on site of delivery,*
- Sold through specialized distributors or through a direct sales force to hospitals or clinics or to their purchasing consortia.

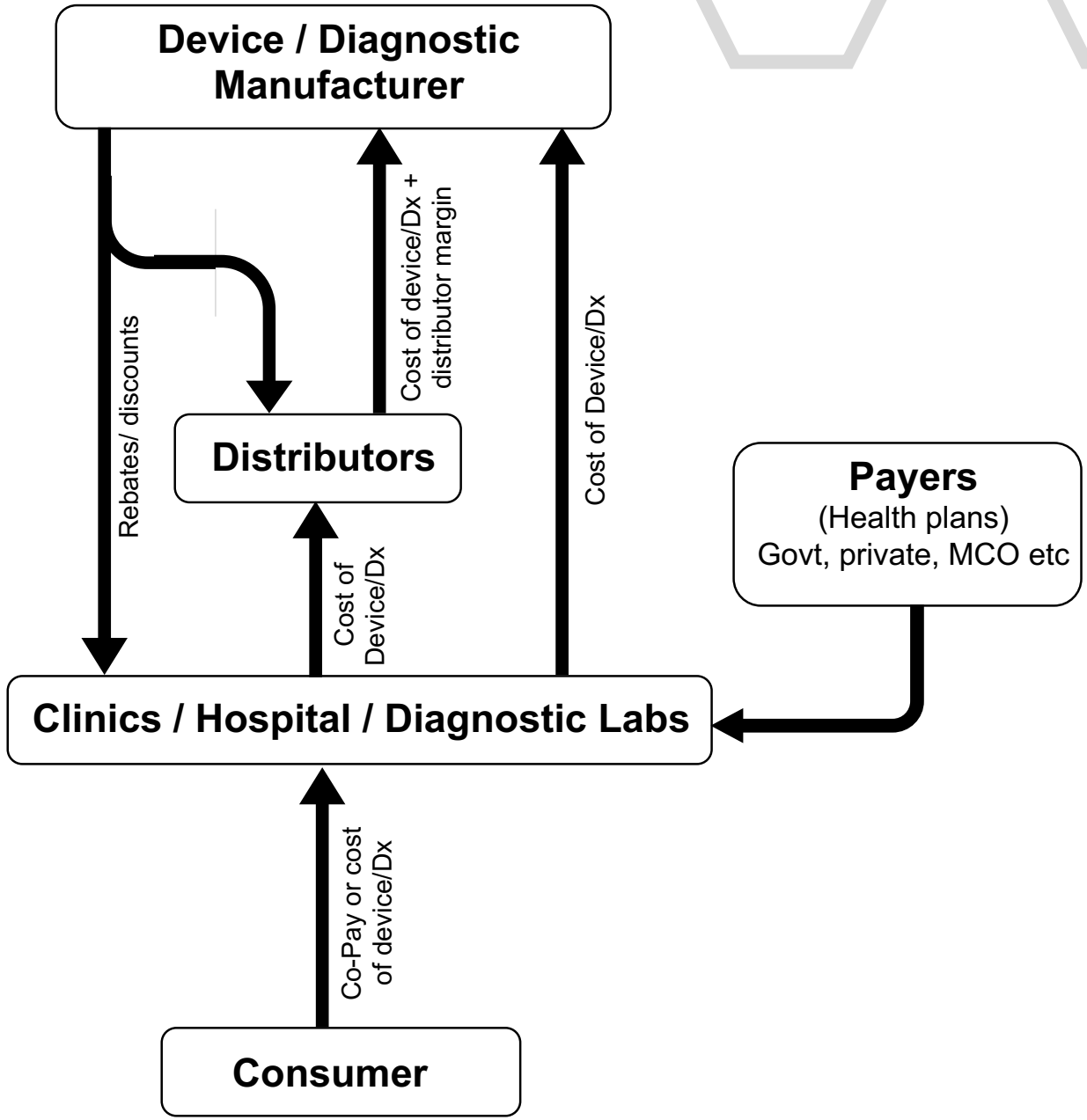


FIGURE 8.8

Clinical diagnostic tests distribution and payments

- Clinical diagnostic tests that are cleared through the 510(k)/CLIA process, or approved via the PMA process, are usually sold to large, centralized laboratories or to one of thousands of local clinical or hospital-based diagnostic labs.
- These products (reagents, diagnostic kits, etc.) are purchased by the laboratory or service provider organization within which the laboratory is housed (e.g. hospital)
- 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).

Components of the reimbursement process

- **Reimbursement** is the key to healthy sales revenues in the biomedical marketplace.
- Three components must be in place for adequate reimbursement:

1. **Coverage** ➢ *Will the payer cover the product?*
2. **Coding** ➢ *Is there an appropriate code that the provider can use to bill the payer?*
3. **Payment** ➢ *Is the payment rate in the reimbursement adequate for the provider / manufacturer?*

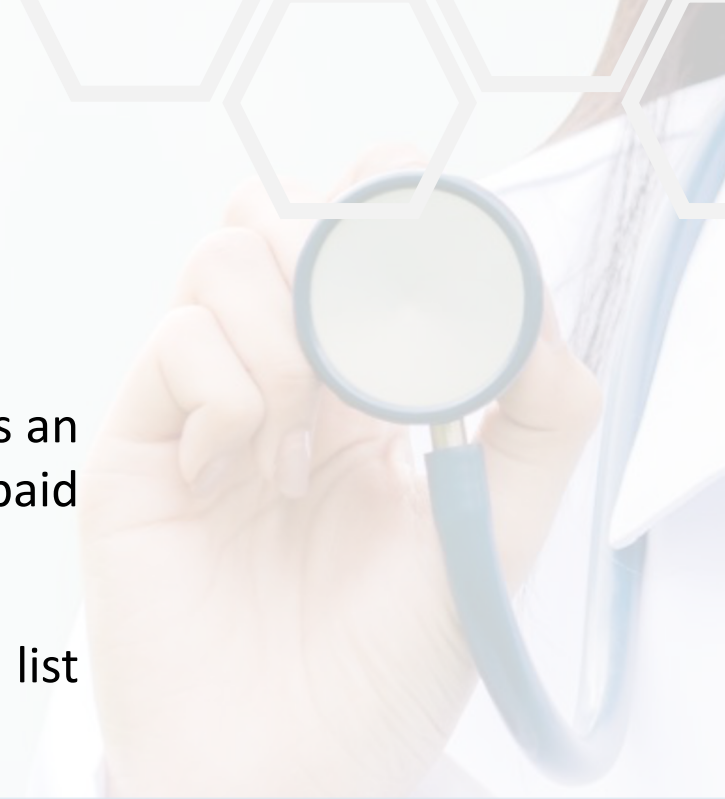
Coverage

- *Coverage* refers to a payer's decision to provide program or plan benefits for a specific product or service.
- Evaluation for coverage is usually on basis of clinical outcomes (i.e. patient benefit), technical, and (depending on the payer) economic value of an FDA-approved product or technology.
- CMS is a purchaser that pays for services and products and heavily weighs the outcomes of clinical usage when making coverage decisions.
- The main criterion for coverage by Medicare is medical benefit to its beneficiaries, and the most commonly used gold standard to determine benefit is the randomized clinical trial
- CMS continues to consider the impact of coverage decisions on healthcare costs.

Coverage

Payers do consider cost in making a reimbursement decision.

- In the UK, the National Institute for Health and Clinical Excellence (NICE) is an independent organization, responsible for deciding which medicines are paid for on the National Health Service (NHS).
- NICE has been issuing recommendations for taking drugs off the NHS list based largely on cost-effectiveness evaluations.
- A common measure of effectiveness of a medical intervention is through Quality-adjusted life years, or QALYs, based on the number of years of life that would be added by the intervention.
- The cost per QALY is typically used as a comparator or threshold to review a novel medical treatment or new intervention against the existing treatment paradigm.



Coverage decision factors

- The quality of the data given by the manufacturer to the payer
- Rigorous randomized clinical trials with additional data to satisfy CMS or private payer coverage review, to prove cost-effectiveness during the clinical trials.
- The manufacturer could also meet with CMS' Coverage and Analysis Group or other payers, early during product development to receive input on trial design and the data to be collected

Cost effectiveness evaluations by payers are growing globally

- **USA -** The Institute For Clinical and Economic Review (ICER) is an independent research organization that objectively evaluates the clinical and economic value of prescription drugs, medical tests, and other healthcare delivery innovations. Their output is used by many insurance companies to determine whether or not to pay for specific treatments.
- **Japan** - Central Social Insurance Medical Council (Chuikyo), a sub-committee of the Ministry of Health, Labour and Welfare.
- **Germany -** Institute for Quality and Efficiency in Healthcare (IQWiG) is an independent advisory body that reviews the efficacy and quality of the healthcare

Coding

- Codes are used on insurance claim forms by purchasers/providers to get reimbursed.
- Getting a code is not a guarantee of coverage, nor is there any guarantee that the payment rate assigned to the code will be reasonable.
- Use of specific codes on claim forms is always at the sole discretion of the provider.
- CPT / HCPCS codes: The Current Procedural Terminology codes (CPT codes: a numeric coding system maintained by the American Medical Association [AMA]) identify specific services carried out by physicians.
- CPT codes are also synchronously published by the CMS, and in their system, CPT codes are called Level 1 HCPCS (Healthcare Common Procedure Coding System) codes.
- Products and services not included in the Level I HCPCS codes are in a group of Level II HCPCS.
- The International Classification of Disease Ninth Edition, Clinical Modification (ICD11) numeric codes classifies disease diagnoses (volumes 1 & 2) and procedures (volume 3).
- The ICD codes are managed by the World Health Organization (WHO)

Payment codes and calculations of reimbursement amount vary by setting of health care delivery

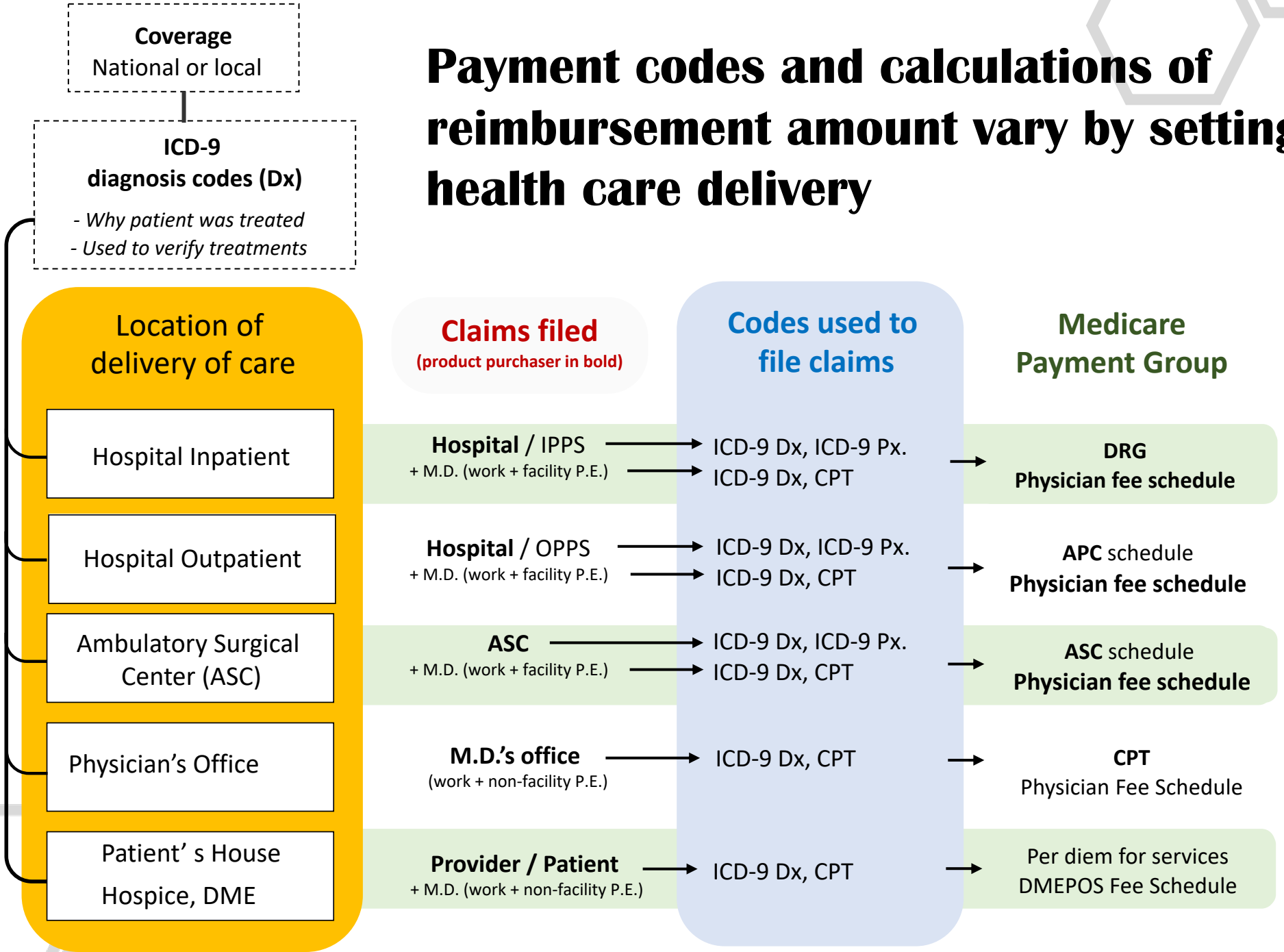


FIGURE 8.9

Payment

Drug reimbursement

- Pricing is communicated by the manufacturers and negotiated by the payers (insurance companies, CMS), and payments are calculated from either AWP (average wholesale price) or ASP (average sales price).

- Rebates and discounts given through wholesalers and group purchasing organizations, pressure by state formularies, and negotiated discounted pricing or rebates to pharmacy benefit managers (PBMs).

Payment structures for (devices, diagnostics, physician-administered drugs)

Reimbursement for services and products is made as a bundled payment, composed of:

(1) Facility payment for services and supplies *provided*

(2) Physician payment for services provided

(3) Sometimes, a specific extra payment is made for (very few) new products that are deemed to result in “substantial clinical improvement”.

The final calculated reimbursement level depends largely on the setting in which the product or service is applied and then on other case-specific factors such as the complexity of procedures.

Prospective payments (most commonly used method)

- Pre-negotiated prices that Medicare uses to reimburse hospitals for inpatient and outpatient services, as well as skilled nursing facilities.
- DRG grouping is based on the diagnoses for which the patient is admitted
- Outpatient Payment System (OPPS), based on the Ambulatory Payment Classifications (APC) which cover groups of procedures or services provided in outpatient settings.
- New technologies that meet the CMS criteria and are shown to deliver substantially improved clinical outcomes, become eligible for “transitional pass-through” payments.
- The physicians’ payment is based on a relative value assigned to the specific procedure code and is based on the location Physicians are paid separately from the hospital for the procedures they performed and their specific practice.
- For diagnostic products, the clinical laboratory payment environment is largely based on Medicare published schedules that use CPT codes.
- CMS has established the Laboratory Fee schedule, which is a schedule of CPT (PLA) codes and corresponding payment rates.

Reimbursement planning activities

- Identify patient population- (target) for the new product. Based on the population demographics, the payer mix can be identified and reimbursement strategy planning can start.
- Data collected in clinical trials should satisfy the value proposition that will be evaluated by the payers.
- Market research during product development to assess market perceptions of pricing, acceptance, awareness of product and possibility of reimbursement/coverage by payers.
- Educating payers is part of marketing efforts – e.g. meet with payers in informal and formal meetings
- Economic usage or additional clinical outcome data requested by payers may be collected during clinical trials for quicker acceptance of coverage, coding and appropriate pricing.
- Economic and clinical outcomes data could also help in achieving a suitable pricing level for the product.

Reimbursement planning in product development

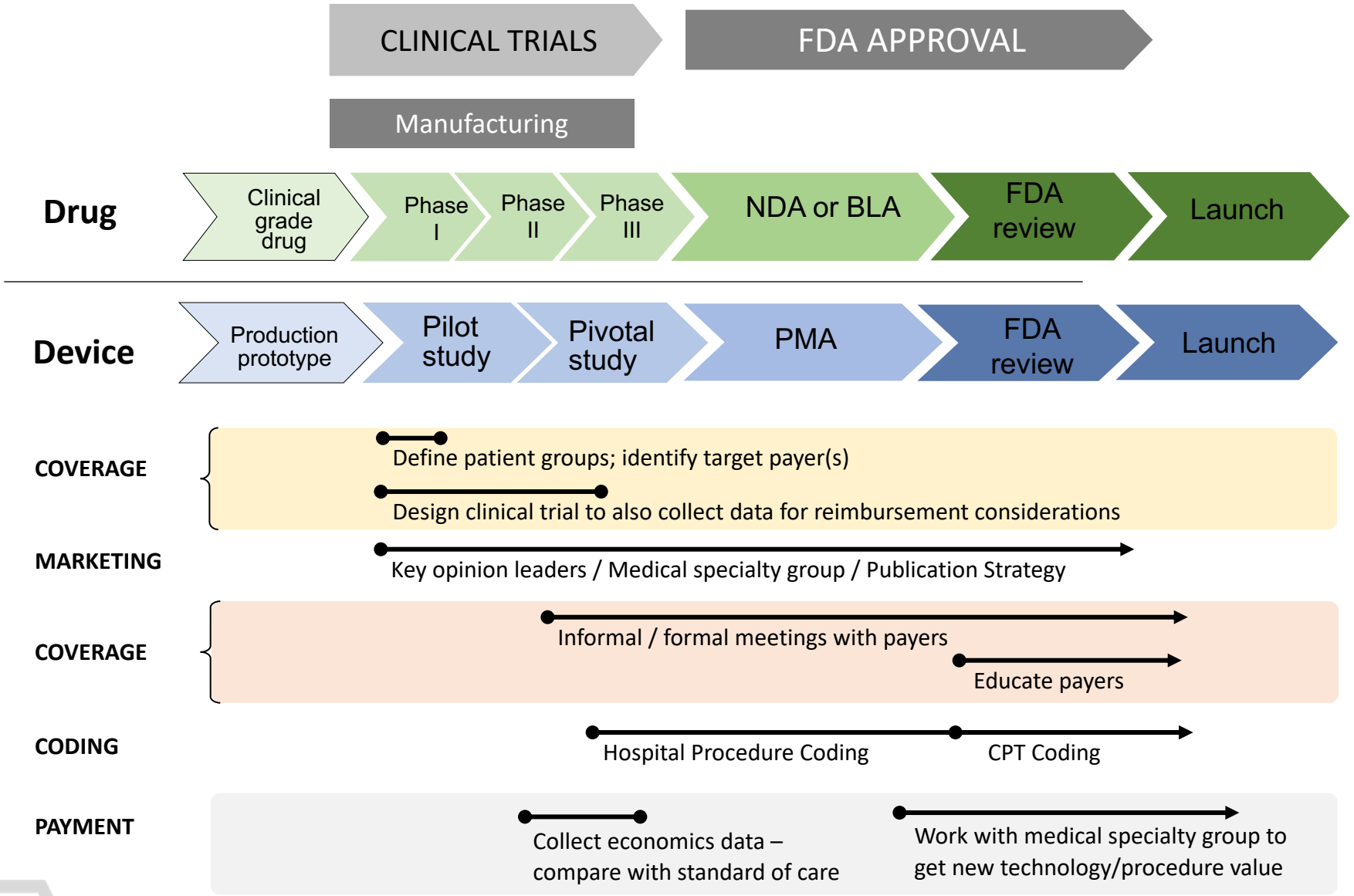


FIGURE 8.9

Reimbursement for self-administered and infused drugs

Self-administered drugs (pills)

- Manufacturers approach various providers with relevant clinical trial data proving value proposition of their drug
- Establish a price point for their drugs in negotiation.
- The bulk of efforts by manufacturers relate to positioning their drug in the preferred group in the formularies.

Reimbursement planning

- Reimbursement planning begins in the preclinical phase, where the target patient population is identified.
- Patient demographics will dictate the mix of payers.
- For example, Product A targets patient population (payer mix): *15% >65 yrs (Medicare) 70% <65 years of age (private payers e.g. Cigna, United Health Care, Blue Cross/Blue Shield) and others 15% (Medicaid)*

Physician-administered drugs

- Physician-administered drugs are typically reimbursed under a J-code in the CPT.
- Takes 18 months to get a new permanent code.
- Payment for physician-administered drugs provided in a physician's office is primarily based on the price of the drug.
- Drugs administered in the hospital to inpatients are paid (reimbursed) under a DRG (IPPS system) payment which reflects the total cost of administering the drug in the inpatient system.
- Similarly, payments for drugs administered in the outpatient setting are paid through the APC (CPT J-codes) schedule in the OPPS system.
- The provider typically makes a profit from the reimbursement payment they receive.

Reimbursement path for devices

- Identify if an existing CPT code will apply to this procedure (if applied in the inpatient setting, identify an ICD-10/ 11 procedure code also).
- Simultaneously determine the ICD-10/11 diagnosis code used to describe the patient indication/problem.
- Combinations of these various codes will point to the specific payment grouping code that will be used to pay the providers in the various payment systems.
- The combination of the diagnosis code and the procedure codes will be used by the payers' grouping software to determine the DRG group code.
- From the DRG code, the manufacturer can determine the specific payment that the hospital receives for carrying out the procedure.
- Devices paid for as part of the bundled payment for overall procedure covered under a DRG.
- Hence, if the DRG payment is not adequate to cover the increased cost of a new improved device, there is a disincentive for the hospital to purchase or continue to use the device unless it helps in improving efficiency and increases savings overall.

An argument could be made to CMS for higher-valued payment by grouping into a new DRG – by an initial appeal (with assistance from the medical specialty group) to the CMS, followed by review by CMS - and could take several years for CMS to collect the data on payments

Getting a new code

OPPS: Outpatient Setting:

- The CPT codes for the procedures involving the device are used to identify the APC group code and determine the APC payment level.

Physician's Fee Schedule: Based on CPT procedure codes

- File an application for new code
- Work with the appropriate medical specialty society/ AMA committee to get a value assigned to the CPT code for reimbursement basis
- A reimbursement relative value scale is used to assign values to the new CPT code depending on the complexity of the procedure
- For clarity, note that the cost of the device to the hospital is covered under the bundled procedure DRG or APC payments

Final Steps

- Set up customer service at the company to assist providers / patients with reimbursement process.
- Publish educational materials describing appropriate billing codes, coverage rules, and payment rates and policies.

Sales

Drug Sales

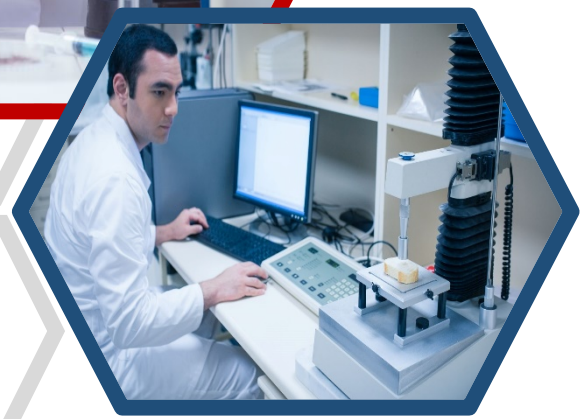
- Sales personnel : trained by the company and are able to explain complex clinical results to physicians.
- Medical Science Liason (MSL) : typically a trained physician or scientist, engages thought leaders
- MSLs play an important role in between marketing and sales.

Device Sales

- Sales positions in the device industry are also highly specialized jobs
- Most salespeople have a bachelor's degree in biological sciences or biomedical engineering
- Often the sale of a new device will include one or more training sessions, as the procedure of usage of the device is very important for performance
- In the device industry in particular, salesforce feedback can play a vital role in new product design and development as they come back with insightful observations from their participation in the product application and usage training process.

Product liability

- Once a medical product is approved by the FDA for sale in the market, the company is generally protected against wrongful use of the product
- As long as the product is used in the manner and indication for which it is approved, and it works as claimed, the manufacturer in general is not liable for faulty usage.
- Product liability lawsuits have as their basis one of three claims – negligence, strict liability, or breach of warranty.
- **Negligence cases**, the burden is on the plaintiff (patient) to prove negligence
- **Strict liability or product liability cases** focus on the product.
- The critical focus in a strict liability suit is whether the product is defective and unreasonably dangerous or whether the manufacturer failed to adequately warn of hazards
- **Breach of warranty cases** assert that the manufacturer breached the warranty or representations made about the product.
- **Product liability cases** that typically blame faulty or unsafe design, the cases have to be introduced into the state judicial system, and often come up against the fact that state law cannot preempt (a device approved under) federal law, thus providing some liability protection for FDA-approved devices.



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