Advisory

Federal Health Care Reimbursement Programs for Drug & Device Manufacturers

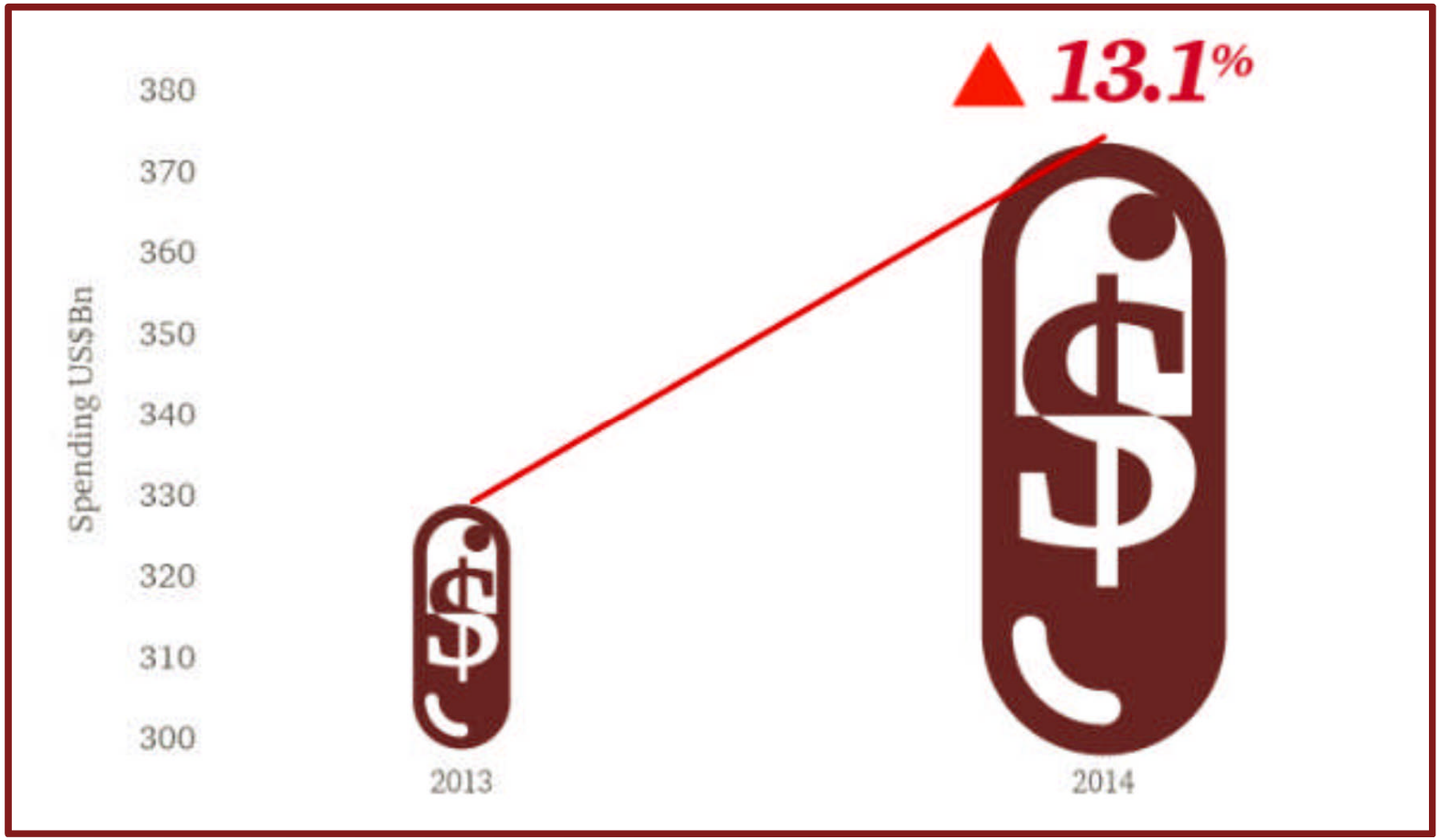
Seton Hall Healthcare Compliance Certification Program

Strictly Private and Confidential
Draft

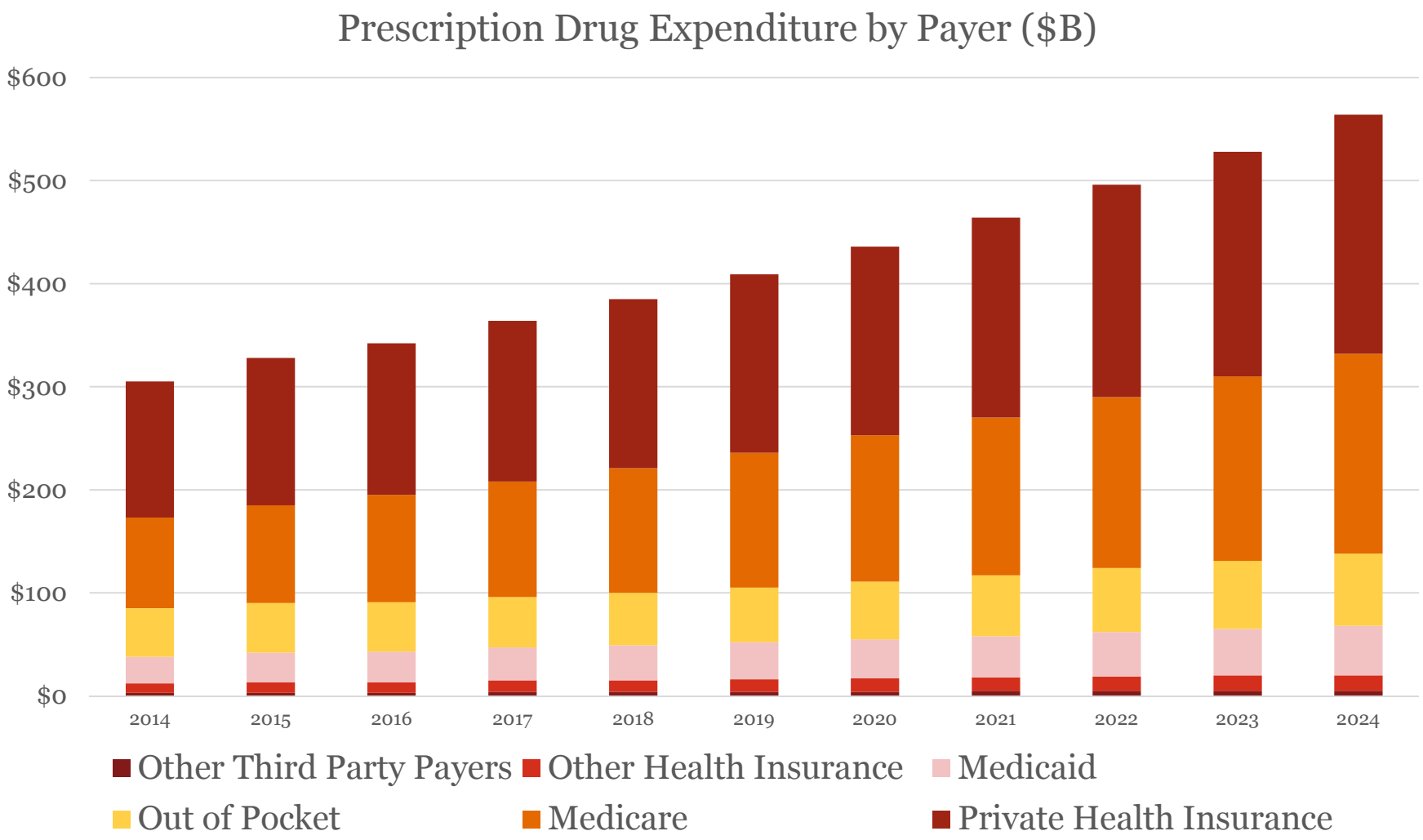
March 21, 2016

pwc

Prescriptions drugs grew 13.1% from 2013 - 2014



Drugs expenditures forecasted to double by 2024



Prescription Drugs Distribution Channels

Flows in the U.S. Prescription Drug Distribution and Reimbursement System:
Guide to Sections II and III in *The 2016 Economic Report on Retail, Mail, and Specialty Pharmacies*

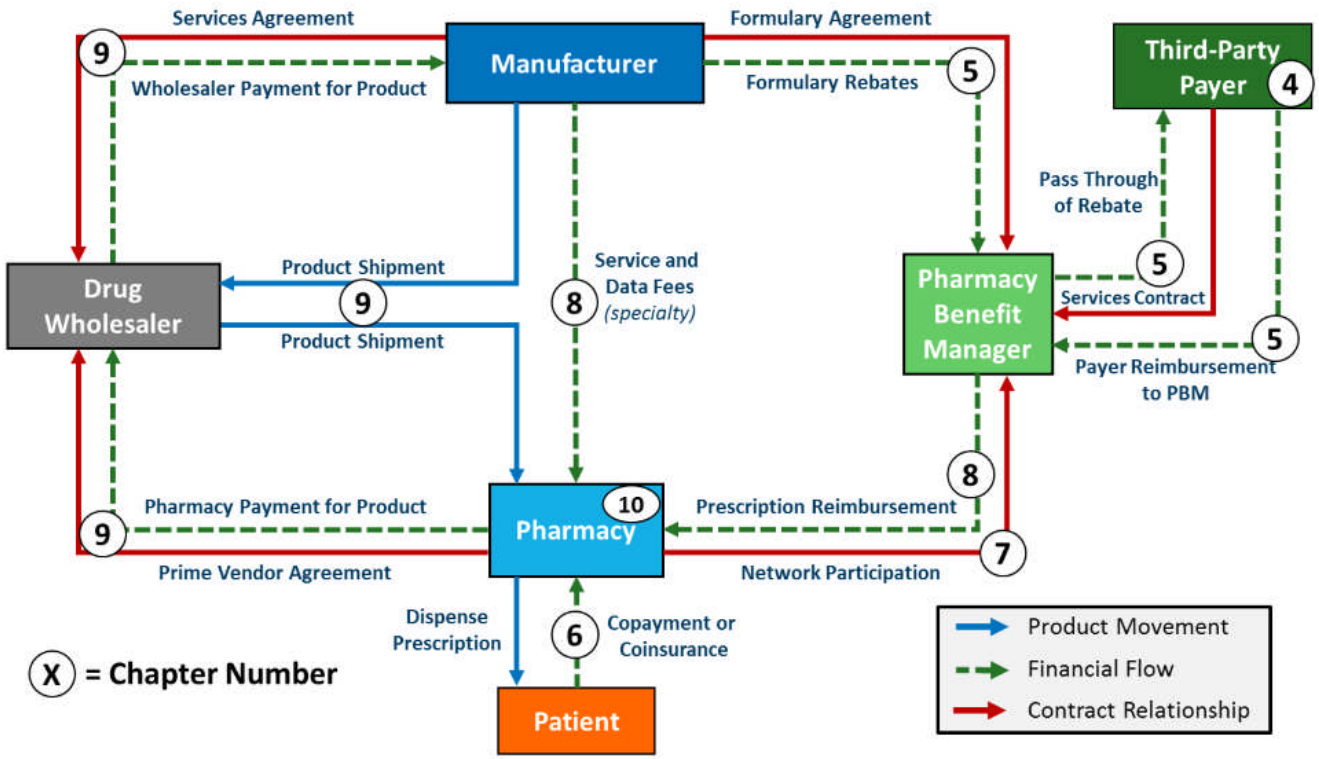


Chart illustrates flows for **Patient-Administered, Outpatient Brand-Name Drugs**. Please note that this chart is illustrative. It is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.
Source: Pembroke Consulting research

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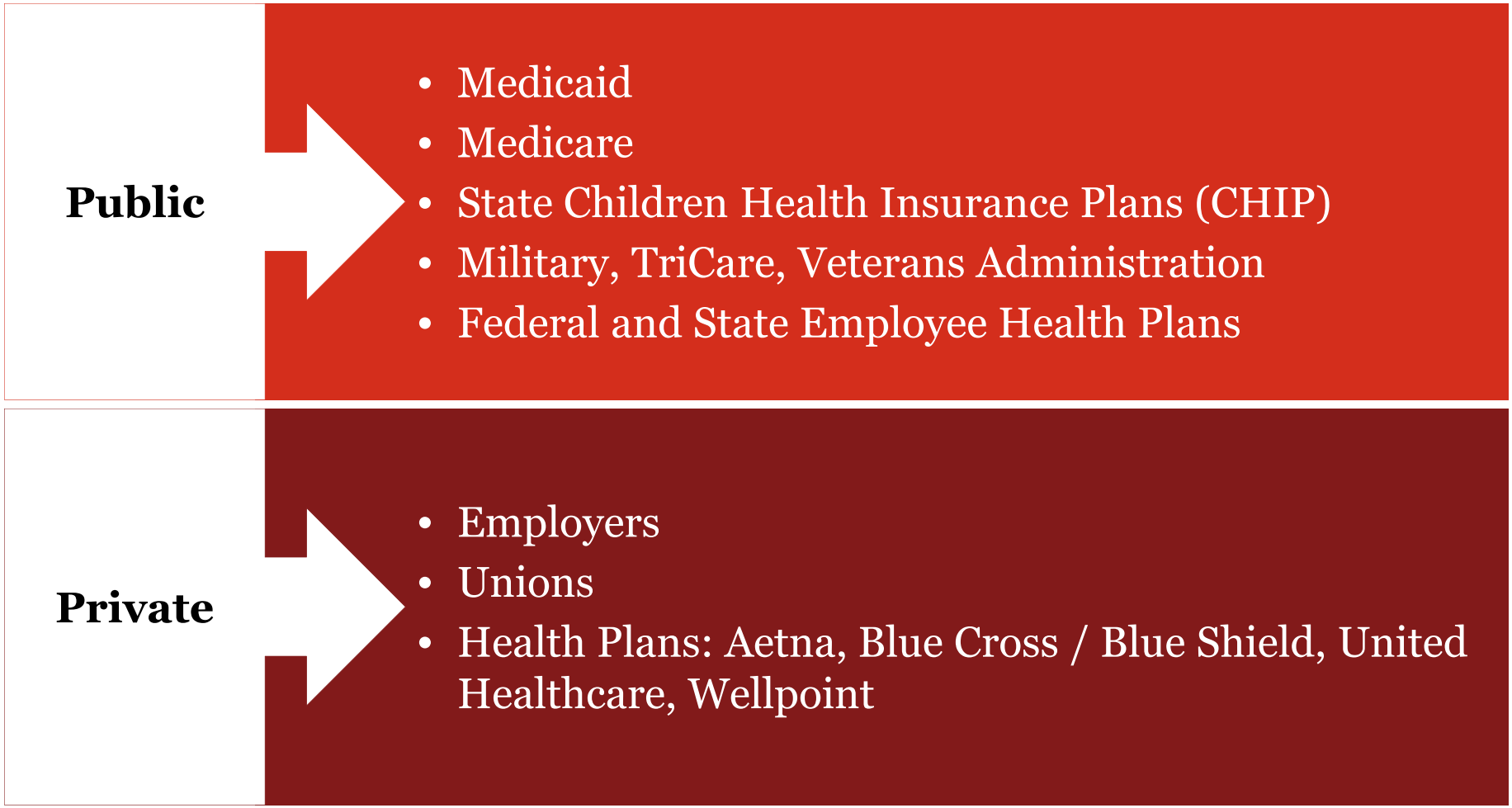
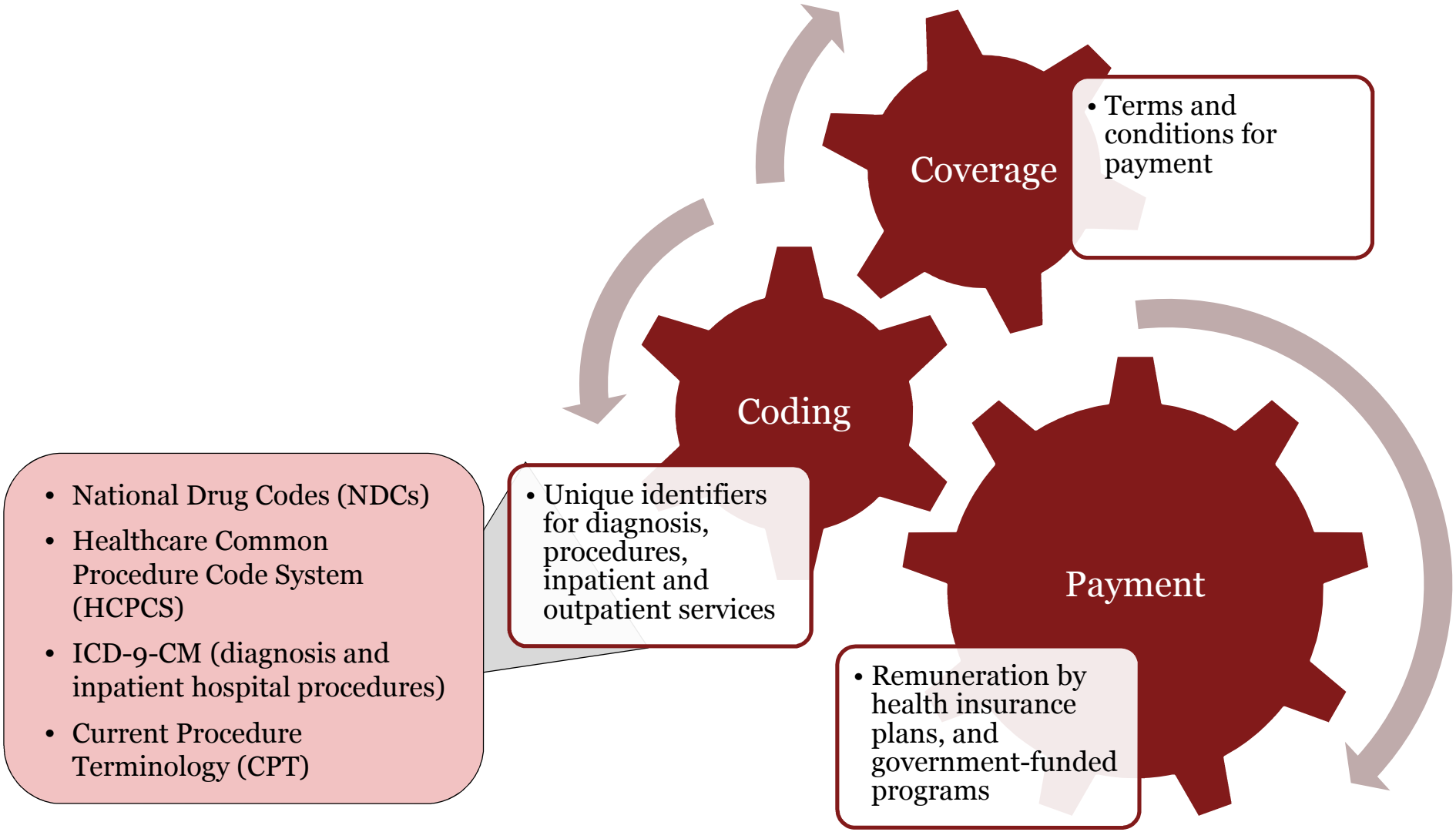
Payer Landscape



Building Blocks of Reimbursement



Coverage, Coding and Payment Basics

Coverage

- Is not guaranteed when FDA approval/clearance is received
- Does not guarantee a new or favorable billing code or favorable reimbursement

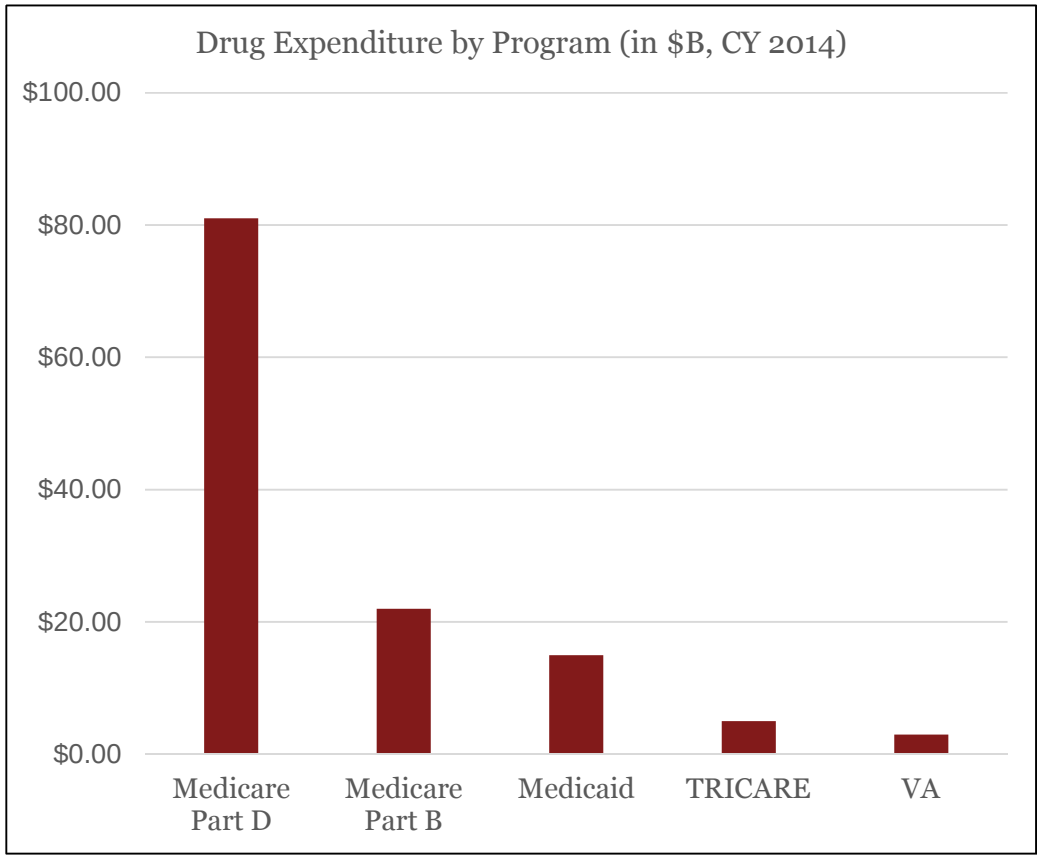
Coding

- Links coverage and payment but does not guarantee coverage
- Does not guarantee favorable reimbursement
- Allows rapid claims processing and health policy research
- Different timetables

Payment

- Link to coverage and coding
- May be subject to limits
- May be stand-alone or bundled
- May be driven by breakthrough or existing technologies

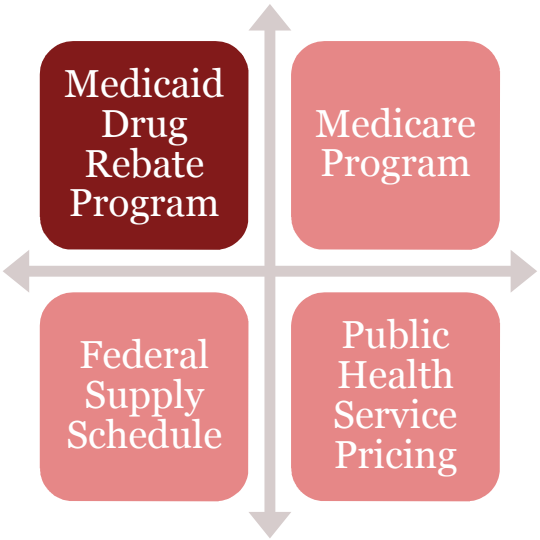
Federal Health Care Programs



Medicaid Drug Rebate Program

What is Medicaid?

- Federal-State health insurance program for low-income and needy people.
- Covers children, the aged, blind, and/or disabled and other people who are eligible to receive federally assisted income maintenance payments.
- Pays health-related bills, including prescription drugs.
- Manufacturers who enter into Medicaid drug rebate agreements with CMS are required to **pay rebates to the states based on their product's utilization within** the various State Medicaid programs.



Medicaid Reimbursement

States use a variety of benchmarks to determine the Estimated Acquisition Costs (EAC)s:

- Average Wholesaler Price - %
- Wholesale Acquisition Costs + %

Other reimbursement considerations:

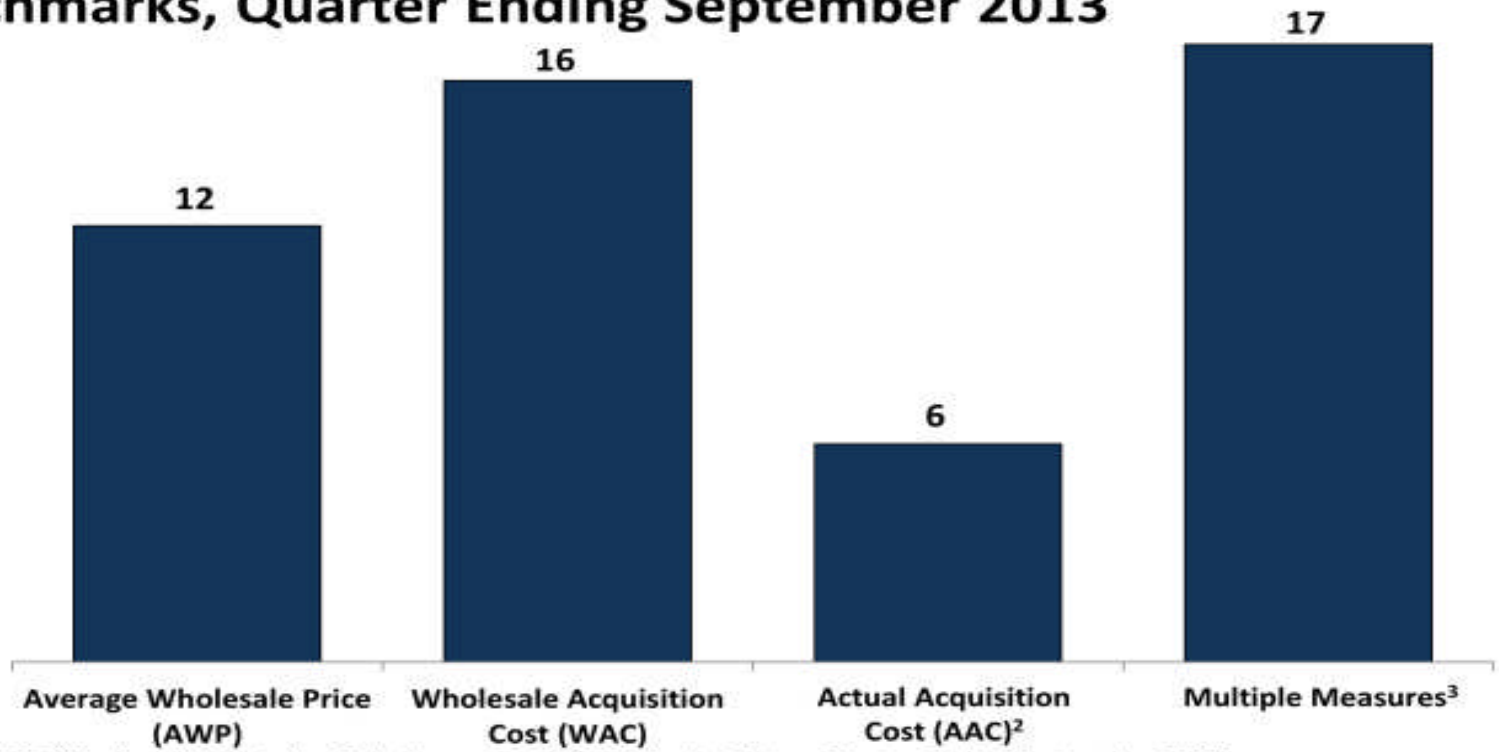
- Average Manufacturer Price (AMP)
- Federal Upper Limit (FUL)
- Maximum Allowable Cost (MAC)

Dispensing fees range from $2 to $10, with an average of $5 or less per prescription

State Medicaid Programs use a variety of Reimbursement Benchmarks

Figure 1

Numbers of State Medicaid Programs Using AWP, WAC, AAC, or Multiple Measures as their Primary[1] Drug Reimbursement Benchmarks, Quarter Ending September 2013



SOURCE: CMS, "Medicaid Prescription Reimbursement Information by State – Quarter Ending September 2013".

NOTES: 1. Numbers reflect the primary benchmark used. For example, if a state uses AWP minus a percentage, but will substitute WAC plus a percentage when there is no AWP, then it is listed as an AWP state.

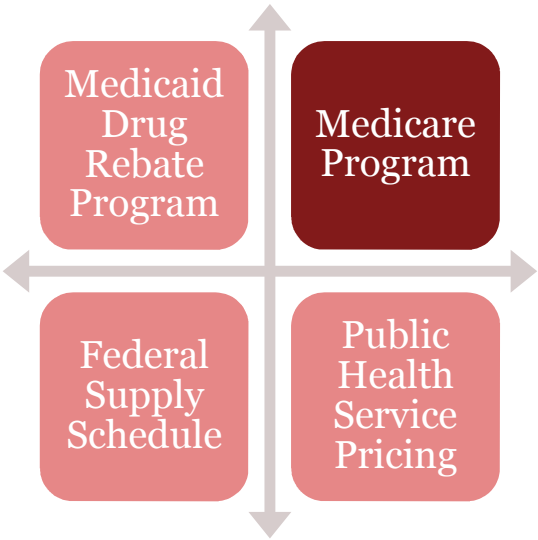
2. All states currently using AAC use WAC as the alternative when AAC is not available.

3. States using multiple benchmarks typically have "lesser of" formulae that may include both AWP minus a percentage and WAC plus a percentage.

Medicare Program

What is Medicare?

- For people who are 65 and older, people under the age of 65 with certain disabilities and people of all ages with end-stage renal diseases (kidney failure).
- Consists of four parts:
  - Part A – Hospital Insurance helps cover Hospital care, Skilled nursing facility care, Nursing home care (as long as custodial care isn't the only care you need), Hospice, and home health services.
  - Part B – Medical Insurance helps cover doctor's service, outpatient care and home health care and this is the reimbursement program for eligible products.
  - Part C – Medicare Advantage program refers to private plans that provide Medicare benefits to enrollees
  - Part D – Voluntary outpatient prescription drug benefit available to everyone with Medicare



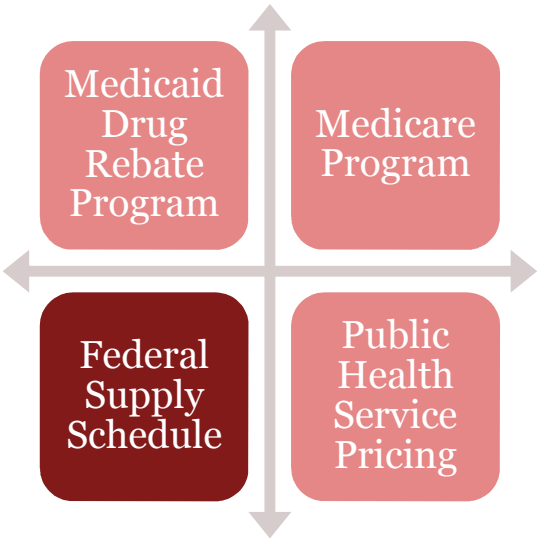
Medicare Part B and D Reimbursement

- **Medicare Part B**
  - Medical Insurance helps cover doctor's service, outpatient care and home health care and this is the reimbursement program for eligible products
  - Reimbursement is based on 106% of Average Sales Price
- **Medicare Part D**
  - Coverage is provided through private drug plans offered by plan sponsors.
  - Under Federal guidelines, Part D sponsors independently negotiate pharmacy reimbursement and price concessions with manufacturers and pharmacies.
  - Beneficiaries enrolled in Medicare's voluntary drug benefit typically obtain drugs from pharmacies.
  - Pharmacy reimbursement under Part D is based on negotiated prices. Negotiated prices are made up of three elements: ingredient cost, dispensing fee, and sales tax.
  - Ingredient costs are usually based on the average wholesale price (AWP) discounted by a specified percentage or maximum allowable cost set by the plan sponsors.

Federal Supply Schedule (FSS)

What is the Federal Supply Schedule?

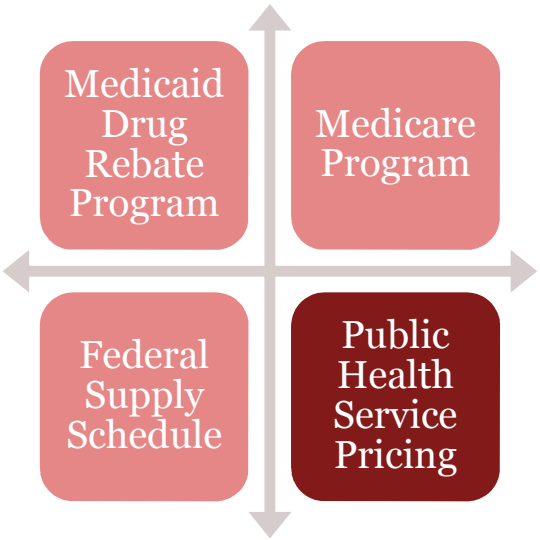
- Relevant law related to the FSS contract is the Veterans Healthcare Act of 1992.
- The largest purchasers of pharmaceuticals via FSS pricing within the federal government are the VA, DoD, Indian Health Service, and Coast Guard (the Big 4).
- The federal ceiling price is the maximum price manufacturers can charge the Big 4 for federal supply schedule (FSS) listed brand name drugs, even if the FSS price is higher. FCP must be at least 24 percent below the non-federal average manufacturer price (NFAMP).



340B Entity Pricing

What is the 340B program?

- Allows eligible federally funded grantees and other safety net health care providers to purchase prescription medication at significantly reduced price
- Administered by the Office of Pharmacy Affairs (OPA) within the Dept. of Health & Human Services
- Healthcare Reform expanded eligible facilities to include
  - ✓ Children's Hospitals, Free Standing Cancer Hospitals, Critical Access Hospitals, Rural Referral Centers, and Sole Community Hospitals



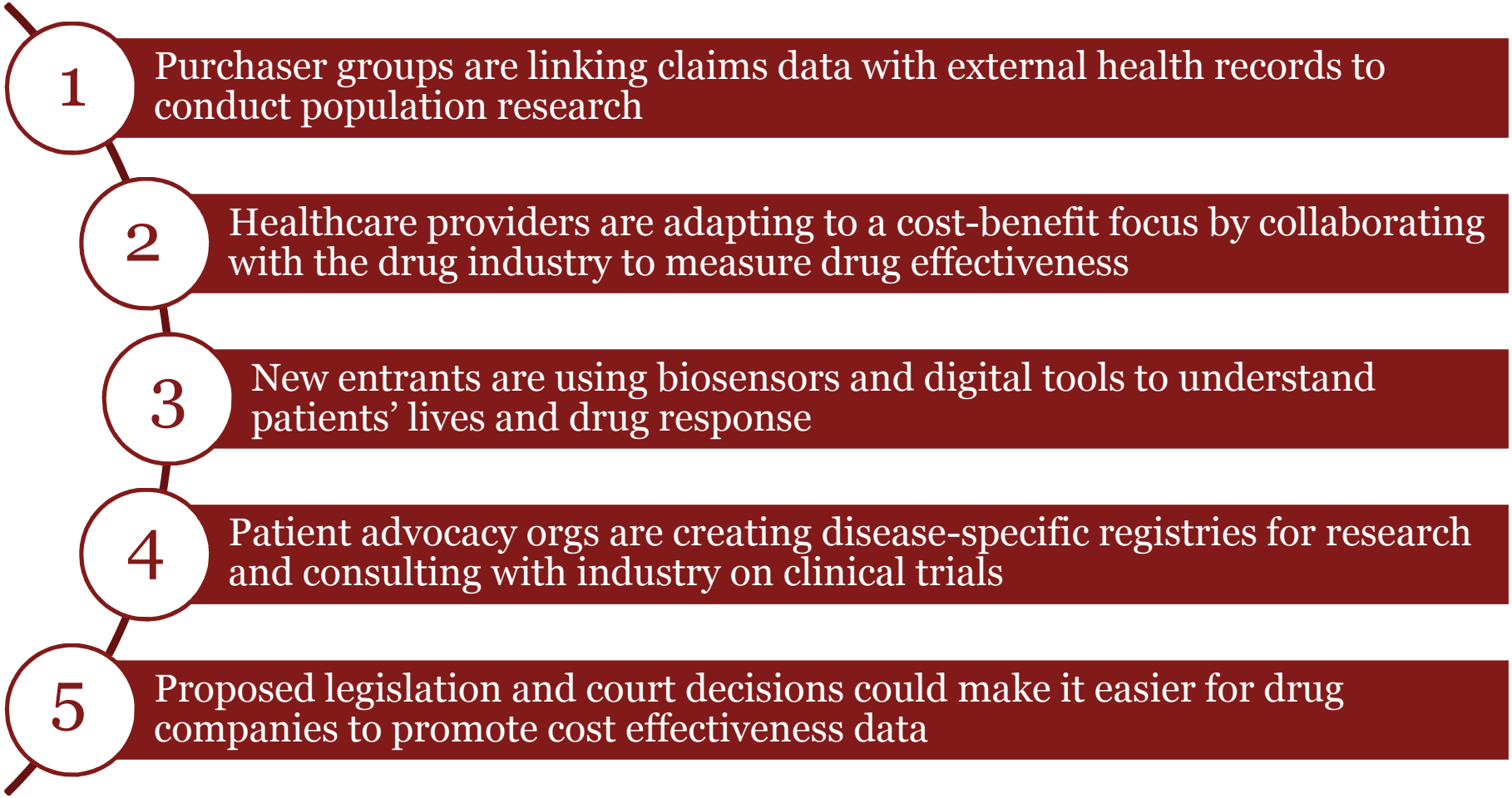
Reimbursement Trends: Specialty Drugs

- Dispensed through specialty pharmacies because of unusual distribution or handling requirements (e.g., cold chain, REMS)
- Products require consultation with or monitoring of patients prior to or after administration of the medication
- Provider requires coordination of benefits, payments and rebate collections
- Specialty products tend to be more expensive than traditional drugs
- High costs and rapid growth means managing specialty drugs will be critical to federal programs

Reimbursement Trends: Evolving Payer Expectations

- How well does it work in real life practice?
- What treatment will it replace?
- What is the risk of it being used off-label?
- Is it more cost effective than current treatment/diagnostic methods both in the short and long term?
- The value of key opinion leaders has been declining. It is now all about the evidence.

Reimbursement Trends:
21st Century Collaborations: The Value Convergence



Public-private partnerships demonstrate the government's commitment to collaboration

Accelerating Medicines	• is a public-private partnership between the National Institutes of Health (NIH), the U.S. Food and Drug Administration (FDA), 10 biopharmaceutical companies and multiple non-profit organizations • transform the current model for developing new diagnostics and treatments by jointly identifying and validating promising biological targets for therapeutics
Precision Medicines Initiative	• will seek to extend precision medicine to all diseases by building a national research cohort of one million or more U.S. participants
ClinGen	• is a National Institutes of Health (NIH)-funded resource dedicated to building an authoritative central resource that defines the clinical relevance of genes and variants for use in precision medicine and research

Appendix: Ingredient Cost Glossary

EAC: Estimated Acquisition Cost; EAC is a benchmark used by many state Medicaid programs to set payment for drug ingredient costs

AWP: Stands for "Average Wholesale Price," but is more akin to a sticker price; AWP is one benchmark used to calculate EAC

WAC: Wholesale Acquisition Cost; WAC is one benchmark used to calculate EAC

AAC: Actual Acquisition Cost

NADAC: National Average Drug Acquisition Cost; NADAC can be used to calculate AAC

FUL: Federal Upper Limit; FUL sets a reimbursement limit for some generic drugs

MAC: Maximum Allowable Cost; MACs are reimbursement limits set by states in addition to the FUL

AMP: Average Manufacturer Price; AMP is used to calculate drug rebates. The ACA also established that it would replace list prices as the basis for FULs, but this has not yet been implemented