EPSTEIN
BECKER
GREEN

Coverage, Coding, and Payment for Procedures, Devices, Drugs, and Diagnostics

or

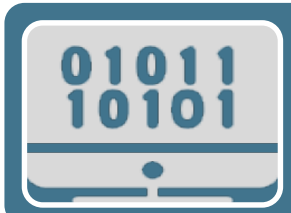
(If you build it, will they buy it?)

Robert Wanerman
Washington, D.C.
rwanerman@ebglaw.com

June 2, 2019

Today's Agenda:
Basic Concepts for Commercialization

Coverage



Coding

Payment

In An Ideal World . . . .

"The F.D.A. is nuts about it."

In Practice, Things Can Be Different

"It's always 'Sit,' 'Stay,' 'Heel'—never 'Think,' 'Innovate,' 'Be yourself.'"

In Practice, Things Can Be Different

The New York Times
nytimes.com

KINSEY

July 6, 2005

When F.D.A. Says Yes, but Insurers Say No

By BARNABY J. FEDER

Medical device makers devote years and millions of dollars to winning regulatory approval for new

how it will wear over decades and the health impact on patients when it fails.

Laboratory tests submitted to the F.D.A. suggested that the disk can last 80 years. But critics say that conclusion does not square with the condition of some disks retrieved from ailing European patients or with X-rays showing relatively rapid deterioration of the disks in some patients.

"The lab tests do not represent what happens in the body," said Dr. Steven Kurtz, a biomechanics expert who has analyzed wear and tear in five failed Charité disks for Exponent, a consulting firm. "Some patients might go 20 years or more with no problems but I wouldn't advise anyone to count on more than 10. And some could be less."

Johnson and supporters of the disk say that nearly all the problems to date have been in cases where the wrong size disk was used or the disk was not properly centered.

The F.D.A. required Johnson to show that the Charité matched spinal fusion in terms of safety and

Medical device manufacturers devote years and millions of dollars to winning regulatory approval for new products. But all that work does not necessarily produce the kind of data that persuades insurers to pay for the products once they hit the market.

In Practice, Things Can Be Different

"We do not see why the Secretary [of Health and Human Services] would be bound . . . by any earlier acceptance of MRI by the Food and Drug Administration"

***Goodman v. Sullivan,* 891 F.2d 449, 451 (2d Cir. 1989)**

EPSTEIN
BECKER
GREEN

A Story of How FDA Labeling Created An Initial Barrier To Successful Coverage

Introduction

Private Payers

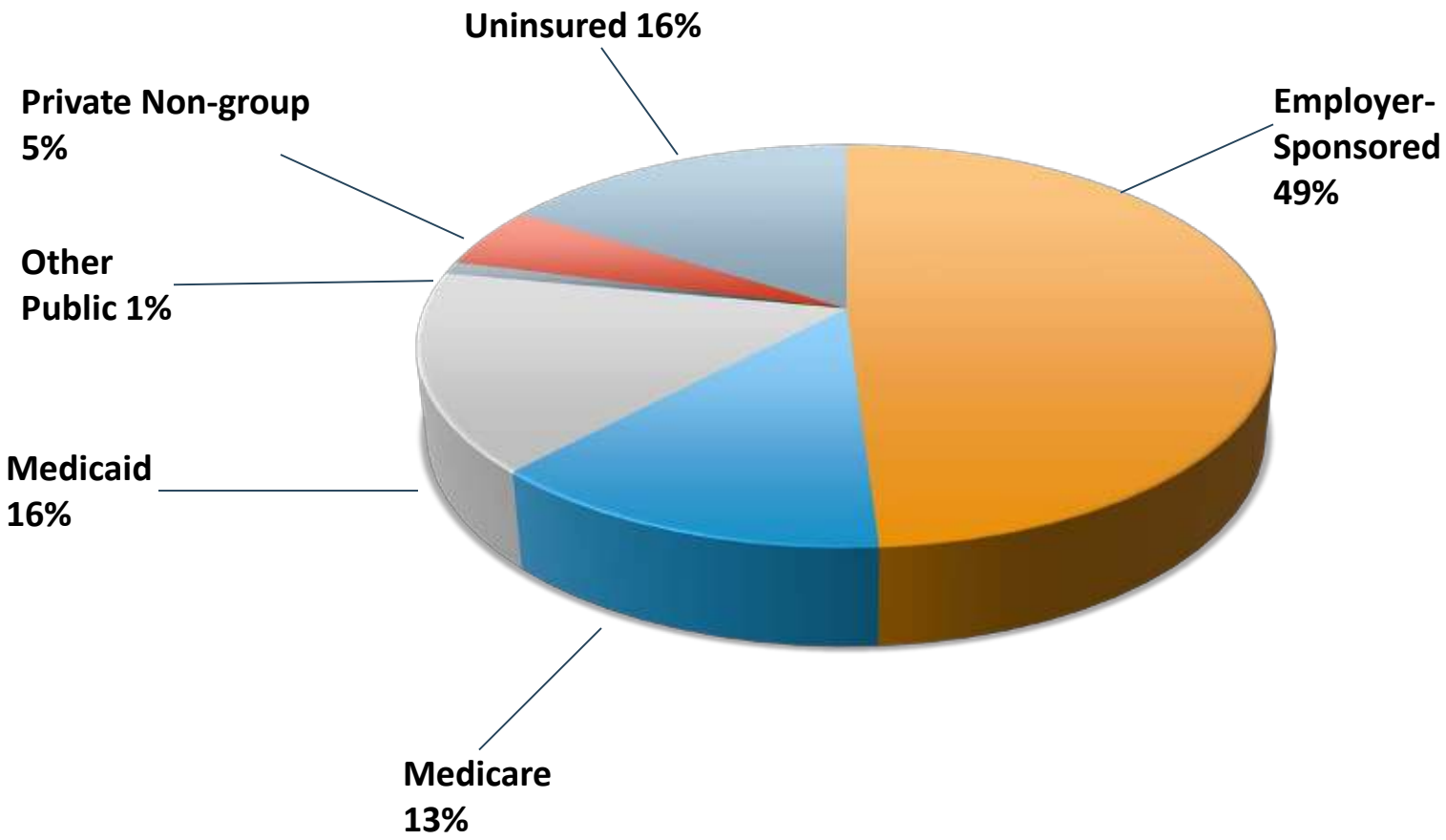
- Employers
  - Self-funded or not
- Unions
- Health Plans
  - Blue Cross/Blue Shield Plans
  - UnitedHealthcare
  - Aetna
  - Anthem
  - Kaiser
  - Others

Public Payers

- Medicare
  - Federal
  - Seniors, disabled, ESRD
  - Traditional Plan and Managed Care
- Medicaid
  - Federal/state
  - Indigent, children, indigent seniors, chronically ill
- TriCare
  - military dependents
- Federal
- SCHIP
  - Federal/state
  - Children
- Others

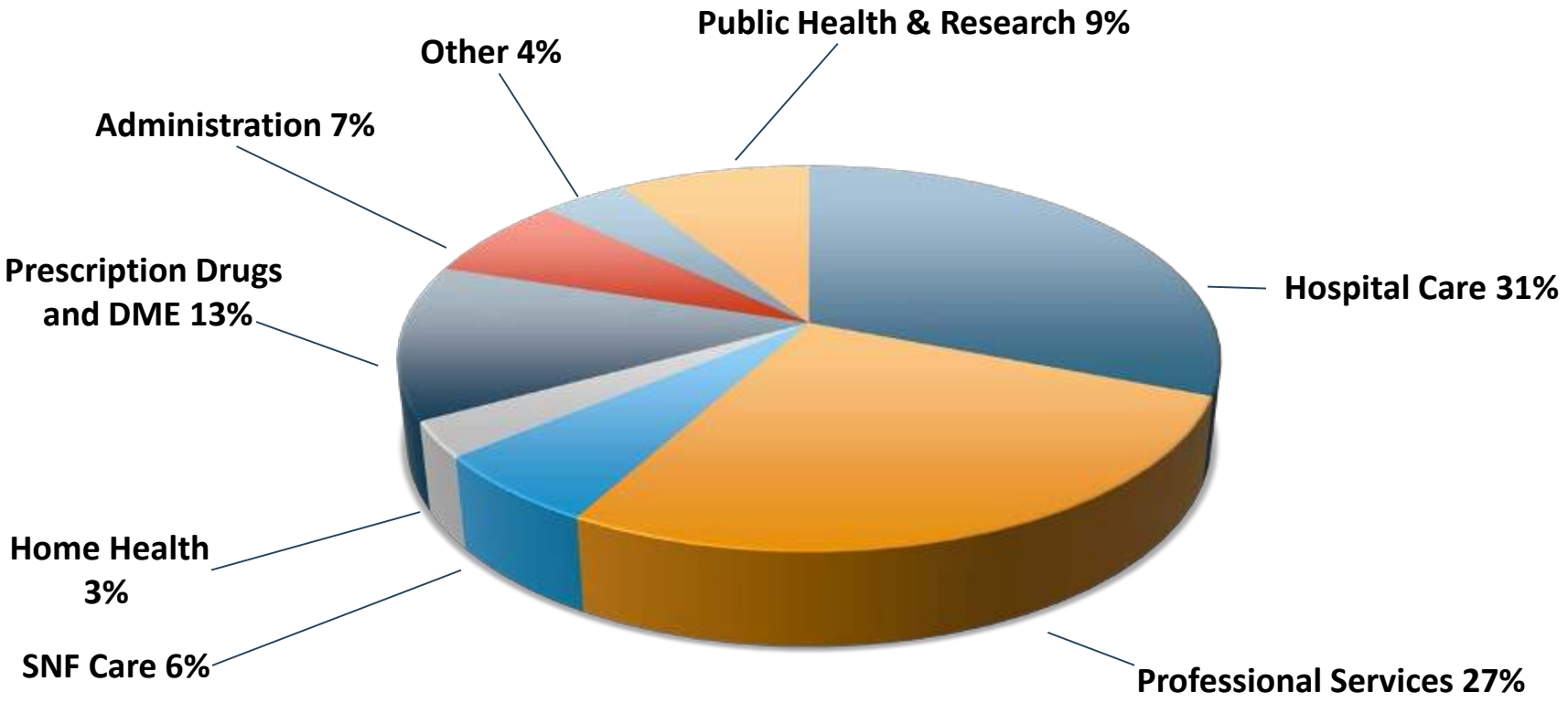
U.S. Health Care Coverage

(Source: Centers for Medicare and Medicaid Services)

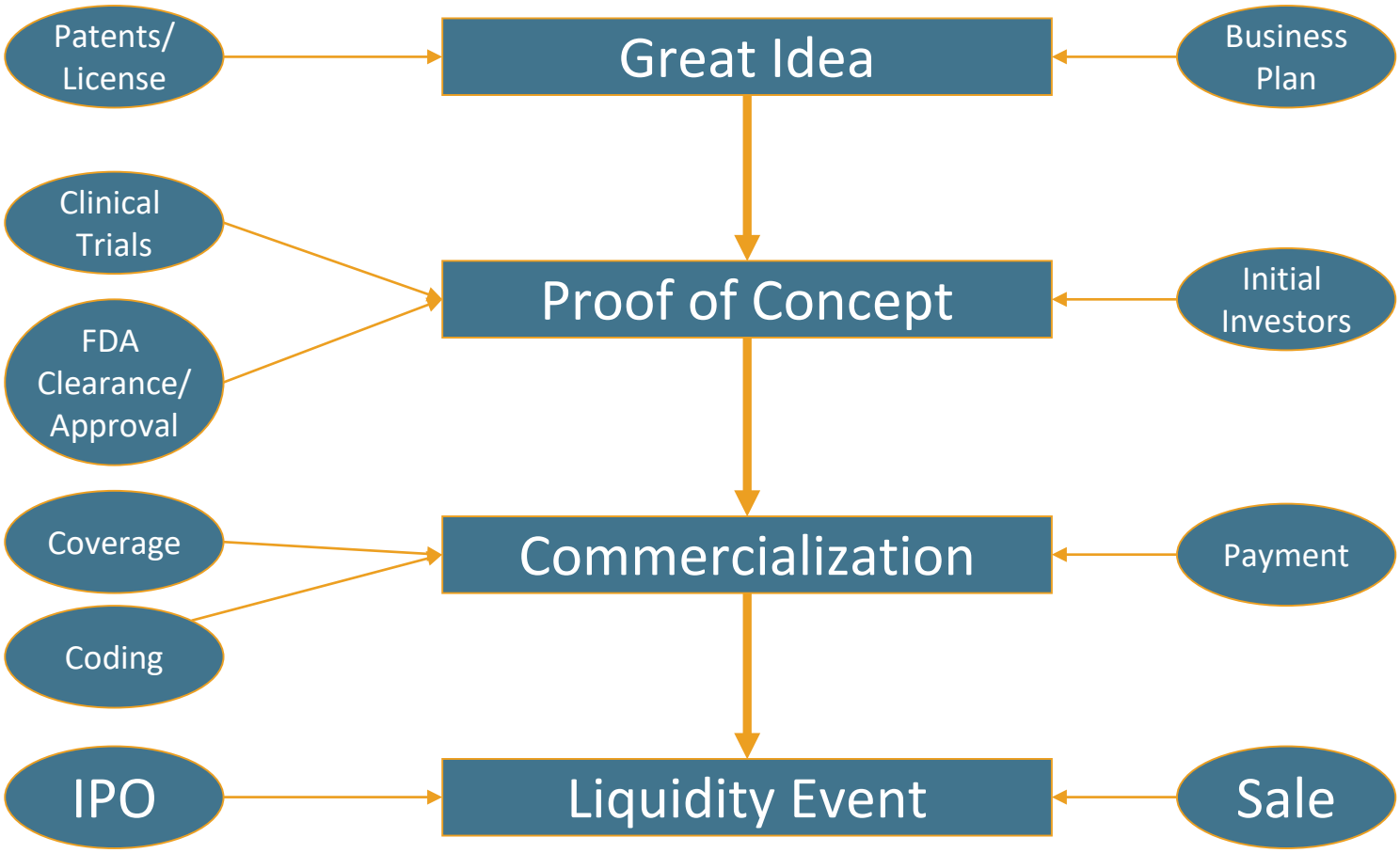


U.S. Health Care Spending - $3.675 Billion

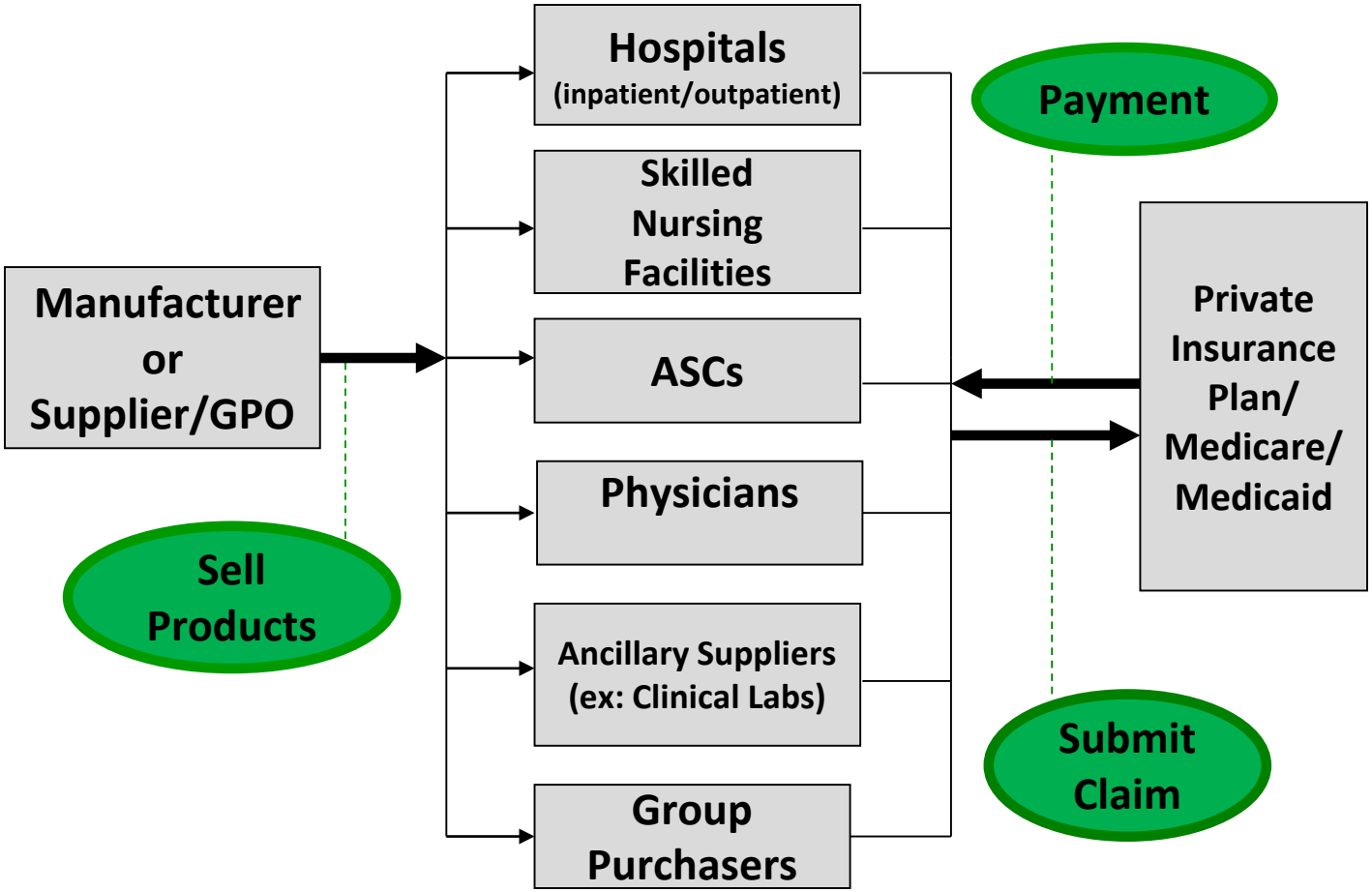
(Source: Centers for Medicare and Medicaid Services)



Critical Milestones In Development



How Does A New Item or Service Fit Into The U.S. Health Care System?



Prescription Drug Distribution Channels

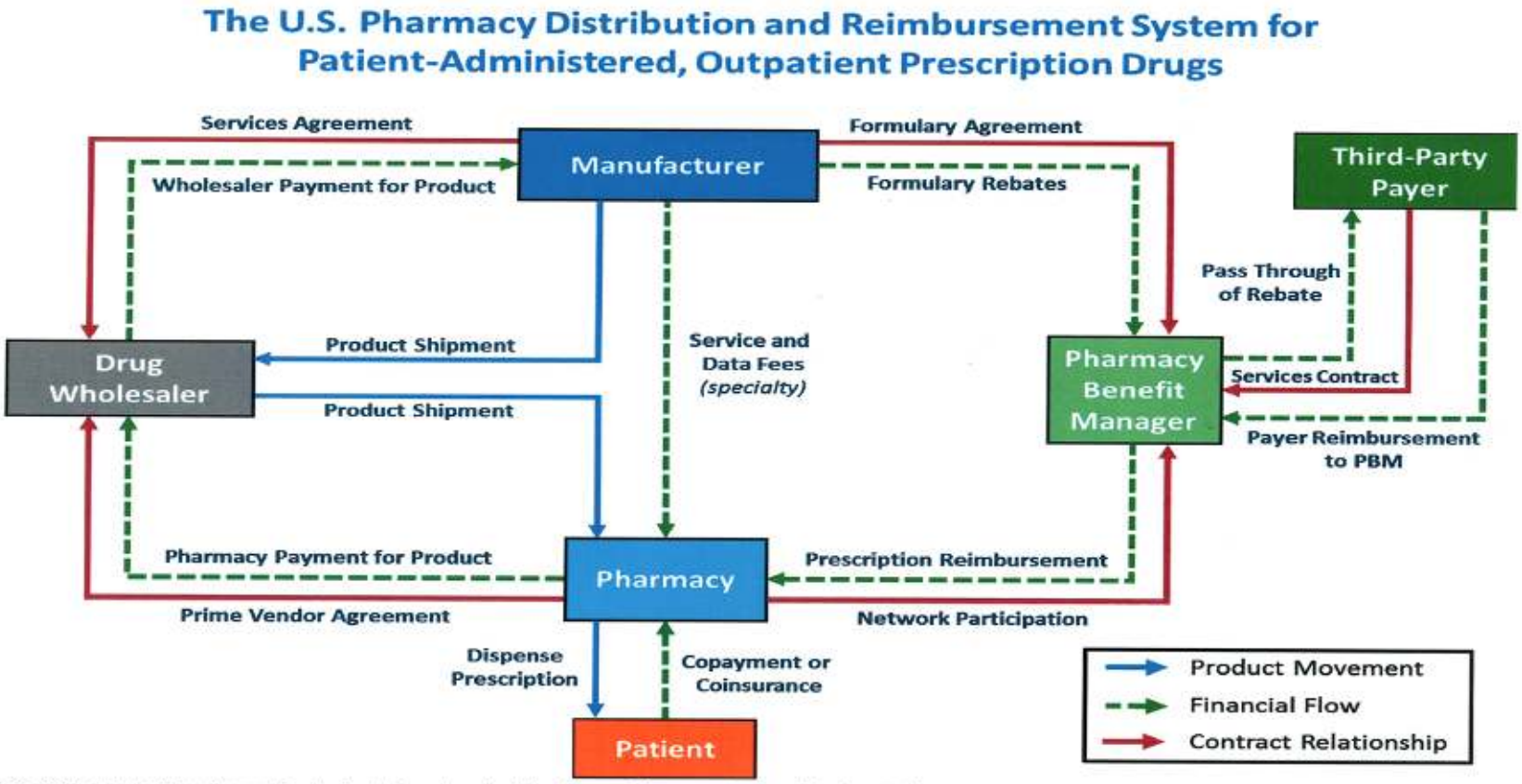


Chart illustrates flows for patient-administered, outpatient drugs. Please note that this chart is illustrative. It is not intended to be a complete representation of every type of financial, product flow, or contractual relationship in the marketplace.
Source: Fein, Adam. J., *The 2016 Economic Report on Retail, Mail and Specialty Pharmacies*, Drug Channels Institute, January 2016.

2

"If there's anything more we can do for you, don't hesitate to fill out the proper forms."

Health Care Is A Highly Regulated Business

Government Entities

- FDA (Approval/Clearance)
- OHRP/ORI (Federally-funded research compliance)
- CMS/State Medicaid Plans (Coverage and Reimbursement)
- SEC (Access to Public Funding)
- DOJ and OIG (Fraud and Abuse)
- States (Fraud and abuse)

Private and Quasi-Public Entities

- IRBs (Research compliance)
- CPT Editorial Panel/HCPCS Workgroup (Coding)
- Health Plans (Coverage and Reimbursement)
- Investors
- Research Subjects

Three Basic and Distinct Concepts

Coverage

Terms and conditions for payment

Coding

Unique identifiers for diagnoses, procedures, devices & diagnostics, inpatient services, and outpatient services

Payment

Remuneration by health insurance plans, government-funded programs

ALL THREE COMPONENTS ARE AN ESSENTIAL PART OF A SUCCESSFUL MARKET ENTRY

How Are These Concepts Different?

Coverage

- Is not guaranteed when you receive FDA approval/clearance
- Does not guarantee a new or favorable billing code
- Does not guarantee favorable payment

Payment

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

Coding

- Links coverage and payment with unique identifiers that can be used for electronic claims processing and health research
- Does not guarantee coverage
- Does not guarantee favorable payment

ALL THREE COMPONENTS ARE AN ESSENTIAL PART OF A SUCCESSFUL MARKET ENTRY

Even CMS Gets Confused

As written, the statute unambiguously authorizes the Secretary to make only a binary choice: either an item or service is reasonable and necessary, in which case it may be covered at the statutory rate, or it is unreasonable or unnecessary, in which case it may not be covered at all. Nothing in the statute authorizes the least costly alternative policy.

***Hays v. Sebelius,* 589 F.3d 1229 (D.C. Cir. 2009)**

Coverage Strategy

Key Coverage Issues

Who will benefit most?

- Seniors, children, women, others?

Where will the benefit be delivered?

- Institutions, outpatient, home care

What are the expected clinical outcomes?

Are there services that are comparable, but inferior or superior?

What is the expected financial impact for the payer/consumer?

Immediate v. long-term benefits?

Coverage Strategy

Process starts well in advance of product launch

- Thinking about coverage at all times beginning with the earliest product R & D discussions as well as when designing clinical trials
- Investors may demand a rigorous coverage and reimbursement strategy

Understanding realistic timeframes is critical

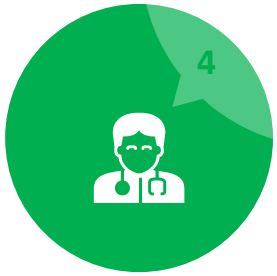
Building a Team

Who Should Be Assisting a Biotech, Medical Device, Diagnostic, or Drug Manufacturer in Developing and Implementing a Commercialization Strategy?

A health lawyer with particular expertise in coverage, coding, and payment procedures for public and private U.S. payers

A coding consultant and, depending upon the circumstances, one or more certified coders

Physician consultants or advisors for assistance with presentations to the payers, to other physicians, or for CPT coding assistance



Health economists and disease management specialists to assist in clinical trial research design so that clinical research data contributes to the Medical Reimbursement Strategy – not just to the FDA Strategy.

Coverage Strategy

Specific Controls for New Drugs or Medical Devices

Limit coverage

- Certain locations, clinical conditions, prior actions (ex: new technology may not be covered unless treatment with existing method tried but failed)

Payers employ Medical Directors who oversee a staff of health professionals and others – both employees and consultants – to help with these decisions.

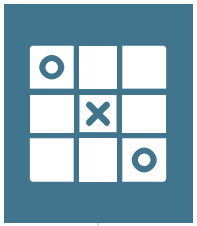
Medical Directors have diverse backgrounds; they may need additional education on specific technologies

Coverage Strategy

Coverage process can range from six months to several years

- Coverage is distinct from FDA approval/clearance
- Must take into account the various coverage standards established for government and private players in the U.S. health system
- Must address indications for “medical necessity”
- May also address coverage limits, such as required site of service as a condition of coverage or frequency of tests (may have a payment impact as well)

Coverage Strategy



Coverage issues should be initiated with major stakeholders

- Professional organizations
  - ex: ACC for cardiovascular, AAOS for orthopedic
- Physician-advocates and thought leaders
  - Scientific advisory boards
- Hospitals, hospital systems, physicians
  - End-users of the items
  - Patient advocacy groups

Build familiarity with the item

- Consult payers during the process
- Cultivate strong physician advocates, institutional and organizational support

Special Coverage Challenges

- Innovative breakthrough for patient health
  - Fills a compelling unmet need
  - Does it replace a health care professional?
- Replacing an existing test/technology
  - Must have superior characteristics (ex: outcomes, speed, quality/quantity of performance or data)
  - Is it less expensive?
- Additive to existing test/technology
  - Fills an information or treatment gap
  - Is it more cost effective when you look at the total cost of the patient's treatment?

Standards for Coverage

Medicare: Section 1862(a)(1)(A) of the Social Security Act ("reasonable and necessary for the diagnosis or treatment of illness or injury.")

- Improved outcomes; including return to regular ADLs
- Benefits outweigh risks
- Does the clinical evidence show outcomes in the relevant population?

Private Plans (BCBS Technology Evaluation Center Criteria):

1. The technology must have final approval from the appropriate governmental regulatory bodies
2. The scientific evidence must permit conclusions concerning the effect of health outcomes
3. The technology must improve net health outcomes
4. The technology must be as beneficial as any established alternatives
5. The improvement must be attainable outside of investigational settings

Comparing the Standards: FDA & CMS

CMS Factors	FDA Factors	Comments
"Reasonable and Necessary"	"Safe and Effective"	No presumption of Medicare coverage; CMS focuses on outcomes and resumption of ADLs for the relevant population (≥ 65 y.o.)
Local standards	Equivalence to device, or new device	CMS emphasizes "standard of practice"
Published articles	Submitted data	CMS relies on peer-reviewed articles, systematic reviews, input from professional societies. It may do its own reviews
Expert consensus	Reasonable expectation of safety (risk/benefit)	CMS seeks to reflect professional consensus
Duration/Frequency	May be irrelevant to label (e.g., PET)	Critical for payors
Indication	May be broad or vague – "off-label" promotion prohibited	Potential for "off-label" use
Compare for available & appropriate alternative	FDA may be more focused on safety	CMS interested in outcomes and comparative effectiveness

Allies and Adversaries

Health benefit plans may not want to cover a new item or service if it would significantly increase costs without superior outcomes

Government programs often use a "budget neutrality" argument to avoid covering expensive new technologies

Hospitals or physicians may not adopt a new product or service if their bundled payment for the same or equivalent procedure is expected to drop if the new product or service is used, or the new technology increases their costs

Be cognizant of potential turf battles between physician specialty groups and among physician groups, ASCs, and hospitals

Avoiding Pitfalls In The Coverage, Coding, and Payment Process

Section 510(k) clearance for devices makes it easier to get on the U.S. market, but more difficult to prove significant difference compared to the predicate device, unless specific indications justify it

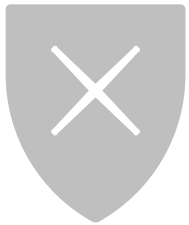
Get articles published in peer-reviewed journals to demonstrate outcomes

Don't argue that a new code is needed to get higher payment – base argument on

- Technological improvement
- Clinical improvement
- Higher and more complex resources

Don't go it alone - link arms with your allies

Why is Coverage Denied?



- Experimental / investigational
- Not approved by the FDA
- Insufficient or inconclusive evidence
- Not within a defined benefit category
  (ex: some preventive services, some applications of AI)
- Reliable evidence not available for target population
  (ex: >65 for Medicare)
- Inconsistent with existing professional practice guidelines
- Humanitarian device
- Unproven services

Integrating Coverage Issues Into Clinical Trial Design

- Coverage is driven by evidence of improved outcomes, clinical efficiency, and cost effectiveness
- Clinical trial design should incorporate these factors
- Study design should include gathering data comparing study item to existing treatments or technologies
- Consider factors relied on by the Agency for Healthcare Research and Quality in their evaluations (www.ahrq.com)

Evidence-Based Medicine ("EBM")

Relies on published and unpublished studies, expert opinions, technology assessments, opinions of professional societies, recommendations from Medicare Coverage Advisory Committee ("MCAC")

Key areas of focus include:

- Study design, implementation, analysis
- Applicable to Medicare population
- Assessment of risks and benefits
- Does the item add value (lower costs, improved outcomes, less follow-up, etc.)

What Kind of Evidence Is Needed?

- Meta-analysis of individual patient data
- Large, random, double-blind studies
- Meta-analysis of grouped data
- Small, single-site random clinical trials
- Cohort studies
- Non-U.S. studies
- Poorly controlled studies
- Anecdotal information

Comparative Effectiveness Research

Research designed to inform health-care decisions by providing evidence on the effectiveness, benefits, and harms of different options.

The evidence is generated from research studies that compare drugs, medical devices, tests, surgeries, or ways to deliver health care.

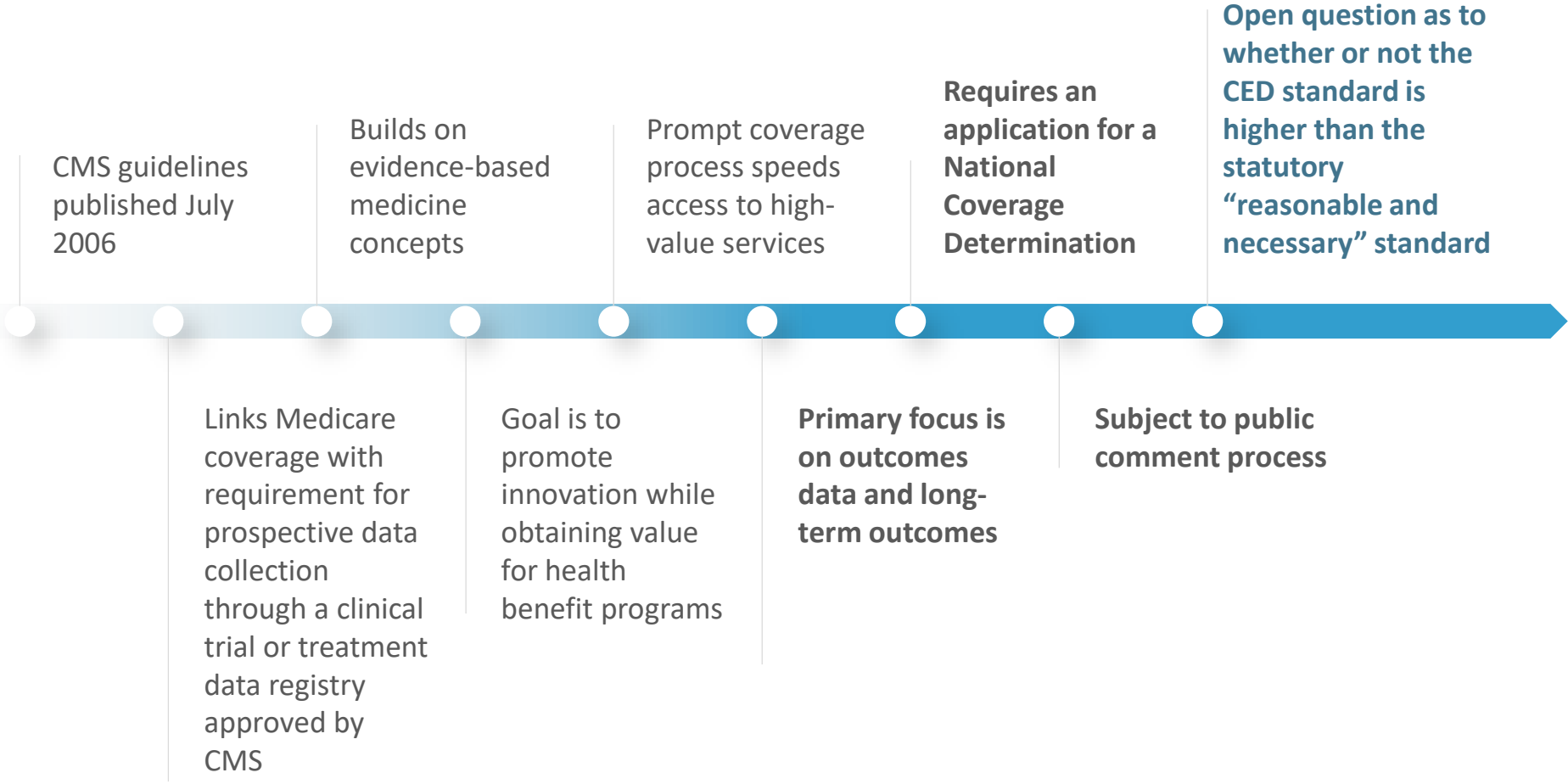
What are your “competing” treatments?

Comparative cost vs. clinical effectiveness

Potential ethical issues in designing trials

Strategy, approach, timing and engagement are critical

Medicare Coverage With Evidence Development ("CED")



EPSTEIN
BECKER
GREEN

CED Case Study: Autologous Platelet-Rich Plasma For Chronic Wounds

Coding Basics: Types of Codes

CPT:
Procedures, Diagnostic Tests – HCPCS Level 1 – Approved by AMA

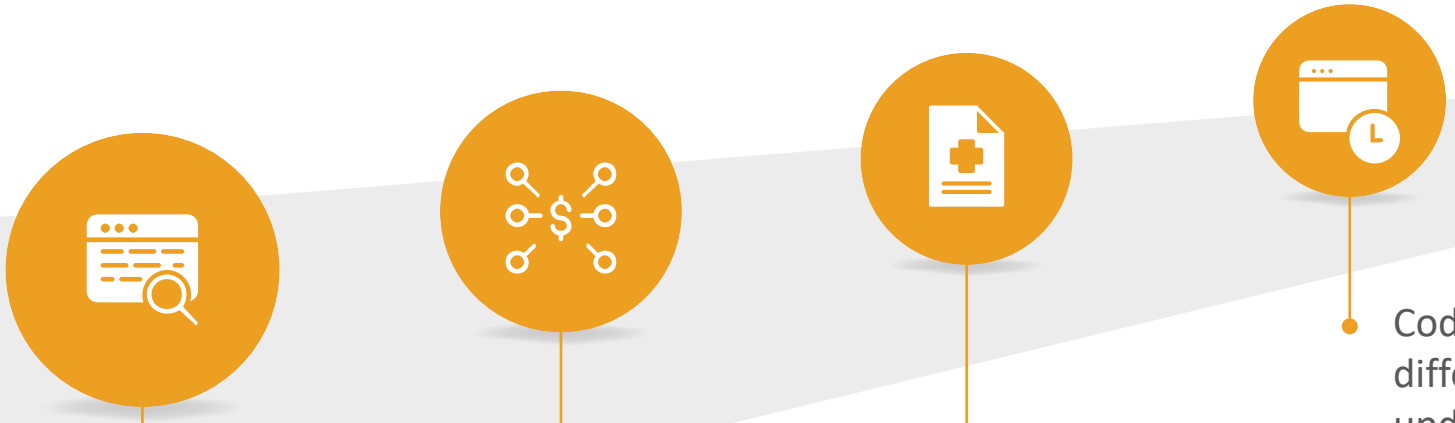
HCPCS:
Drugs, Devices, DMEPOS – HCPCS Level 2 – Approved by CMS Workgroup

ICD-10:
Diagnoses & Inpatient Hospital Procedures

Reimbursement codes that aggregate items and services in a particular setting:

- DRG (inpatient hospital)
- APC (outpatient hospital/ASC)
- RUG (skilled nursing)

Coding Basics



Coding is an identifier for a diagnosis, drug, device, or procedure

Coding connects coverage and payment

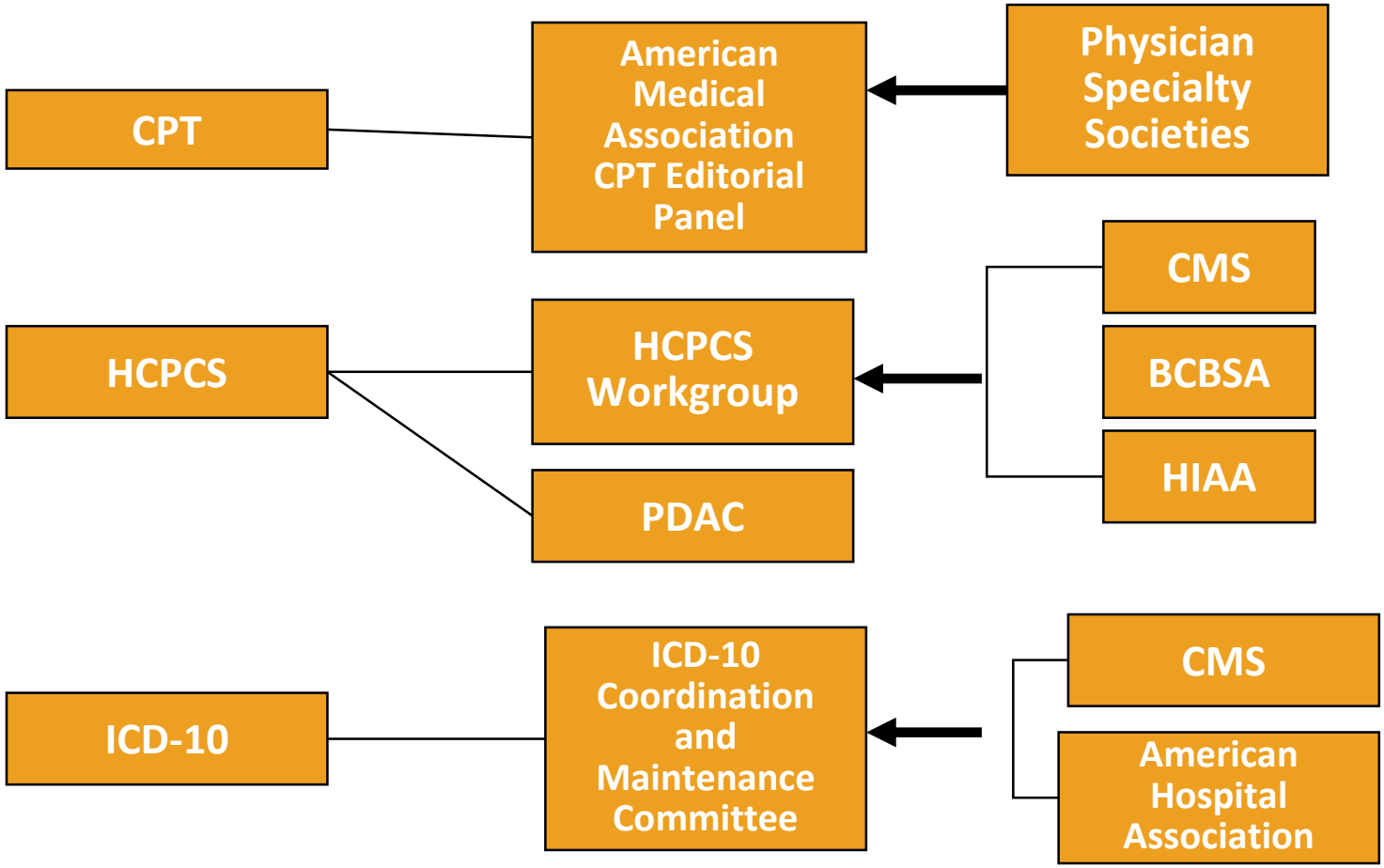
Codes allow for rapid claims processing and health policy research

Coding systems have different timetables for updates and revisions

Coding Basics

KEY CODING ISSUES FOR BILLING CODES

How Are New Codes Established?



Comparing the Code Sets

	CODE SET COMPARISON CHART						
	Timing			Volume	Transparency		
CODE SET	Application Deadline	Effective Date	Length of Cycle	Average Number of Applications in Cycle	Provide Detailed Application Summaries	Publish Preliminary Decisions	Public Input
HCPCS II	January 3	January 1 of the following year	12 months + Quarterly Updates	150	Yes – published at least 4 weeks prior to Public Meetings	Yes	Public Meetings Spring of each year
CPT	3 months prior to May, October, or February meeting see www.ama-assn.org	Cat. I: codes released Fall, eff Jan 1 ---------- Cat I vaccine, MoPath, or III codes: Jan 1 or July 1 ---------- Cat II codes: Feb 15, Jun 15, or Oct 15	15 months + Quarterly Updates	200 (Review is divided into committees and sub-committees, who report back to 1 group)	No	No	Public may attend voting meeting. Votes are silent.
CDT	November 1	Jan 1 of second year following receipt of application	14 to17 months	120	Yes	No	Public may attend voting meeting. Votes are known.
ICD-9 And ICD-10	January (2 months prior to meeting)	October 1 of the following year	7 months	CMS processes 10 – 25 procedure applications NCVHS processes 25 diagnosis applications	Yes – provided at public meeting	No	Public Meeting March
	July (2 months prior to meeting)	October 1 of the following year (codes for New Tech can be implemented in following April)	13 months	CMS processes 10 – 25 procedure applications NCVHS processes 25- 35 diagnosis applications	Yes – provided at public meeting	No	Public Meetings September

Source: CMS Innovators' Guide to Navigating Medicare, Version 3 2015, *available at*: https://www.cms.gov/Medicare/Coverage/CouncilonTechInnov/Downloads/Innovators-Guide-Master-7-23-15.pdf

Overview of Payment Methodologies

Hospitals

- Part A – inpatient – reasonable costs → DRGs
- Part B – outpatient – reasonable costs → APCs

Other Part B Services

- Fee Schedules
- Average Wholesale Price "AWP"
- Average Sales Price "ASP"

Skilled Nursing Facilities

- Reasonable costs → Resource Utilization Groups ("RUGs")

Ambulatory Surgical Centers

- Nine payment groups → Multiple APCs

Physicians – Part B

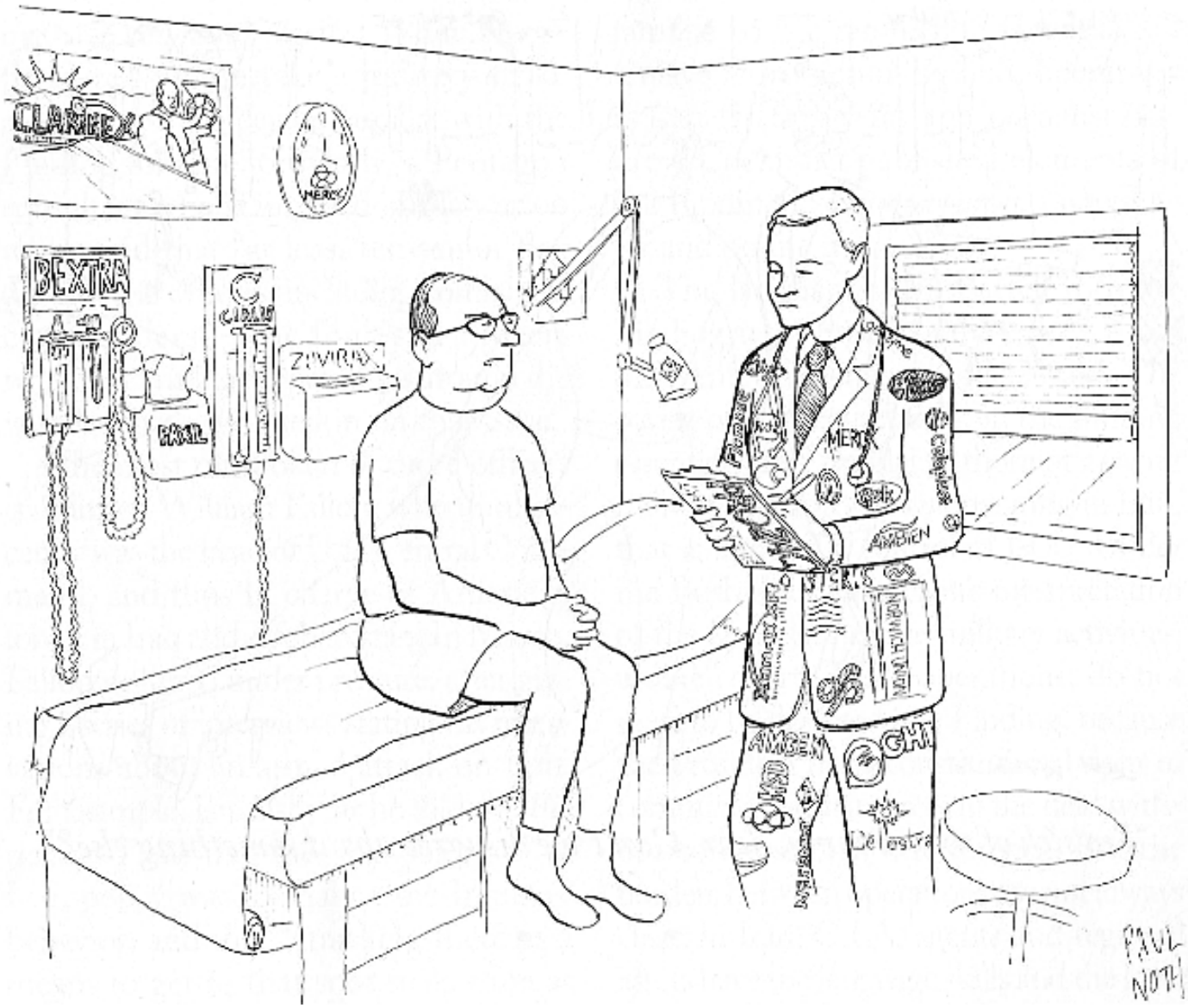
- Reasonable charges → RBRVS based on CPTs

Payment Methodologies

GENERAL RULE:

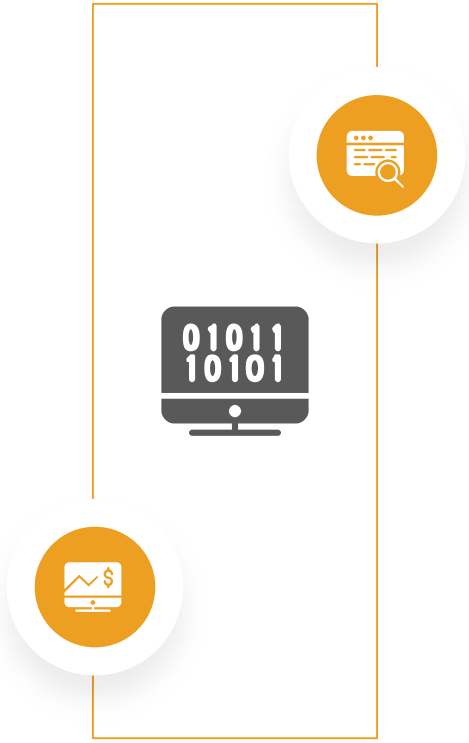
Payment for Procedures, Devices, and Drugs Will Turn On:

- Site of Service
- Enumerated Benefits
- Enumerated Exclusion
- Coverage determinations (nationally/locally)
- Bundled items and services, or stand-alone


CLARITIN
MERCK
BEXTRA
CIPRO
ZYVIRAX
PAXIL
MERCK
AMBIEN
AMBEN
Celestra
PAUL NOTH

Coordinating Coverage With Coding & Payment

Coverage determinations can have an impact on coding and payment



Analysis of competing or similar items in the same coding category:

- What are the codes used for those items?
- What is the range of payment?
- Is the prevailing payment range acceptable?
- If not, what evidence justifies either a new code or higher payment?

"Never, ever, think outside the box."

EPSTEIN
BECKER
GREEN

Questions?

EPSTEIN
BECKER
GREEN

Coverage, Coding & Payment Case Studies

Case Study: Coverage for Virtual Colonoscopy ("VC")

- As of January 2009, VC covered by many private health plans in the U.S. for patients > 50 years old when there has been a failed traditional colonoscopy; two cover VC for screening in all patients > 50 years
- Medicare (CMS) focused on two questions:
  - Is the evidence sufficient to determine that CT colonography is a valuable screening test for colorectal cancer for average risk Medicare individuals compared to optical colonoscopy?
  - Is the evidence sufficient to conclude that the use of CT colonography improves health outcomes for colorectal cancer screening in average risk individuals compared to optical colonoscopy?

Case Study: Coverage for Virtual Colonoscopy

- Published studies had a mean age of 57-58 years
- Studies found lower sensitivity and specificity for polyps < 6mm with VC compared to optical colonoscopy
- May 2009: CMS concluded that the current evidence is inadequate, and Medicare will not cover virtual colonoscopy
  - CMS found that no published study has focused on a population more representative of the Medicare population.
  - CMS could not determine if the published study results are generalizable to the Medicare target population (> 65 years).
  - CMS concluded that there is "insufficient [clinical trial] evidence to determine that CT colonography is a valuable screening test for colorectal cancer for average risk Medicare individuals compared to optical colonoscopy."

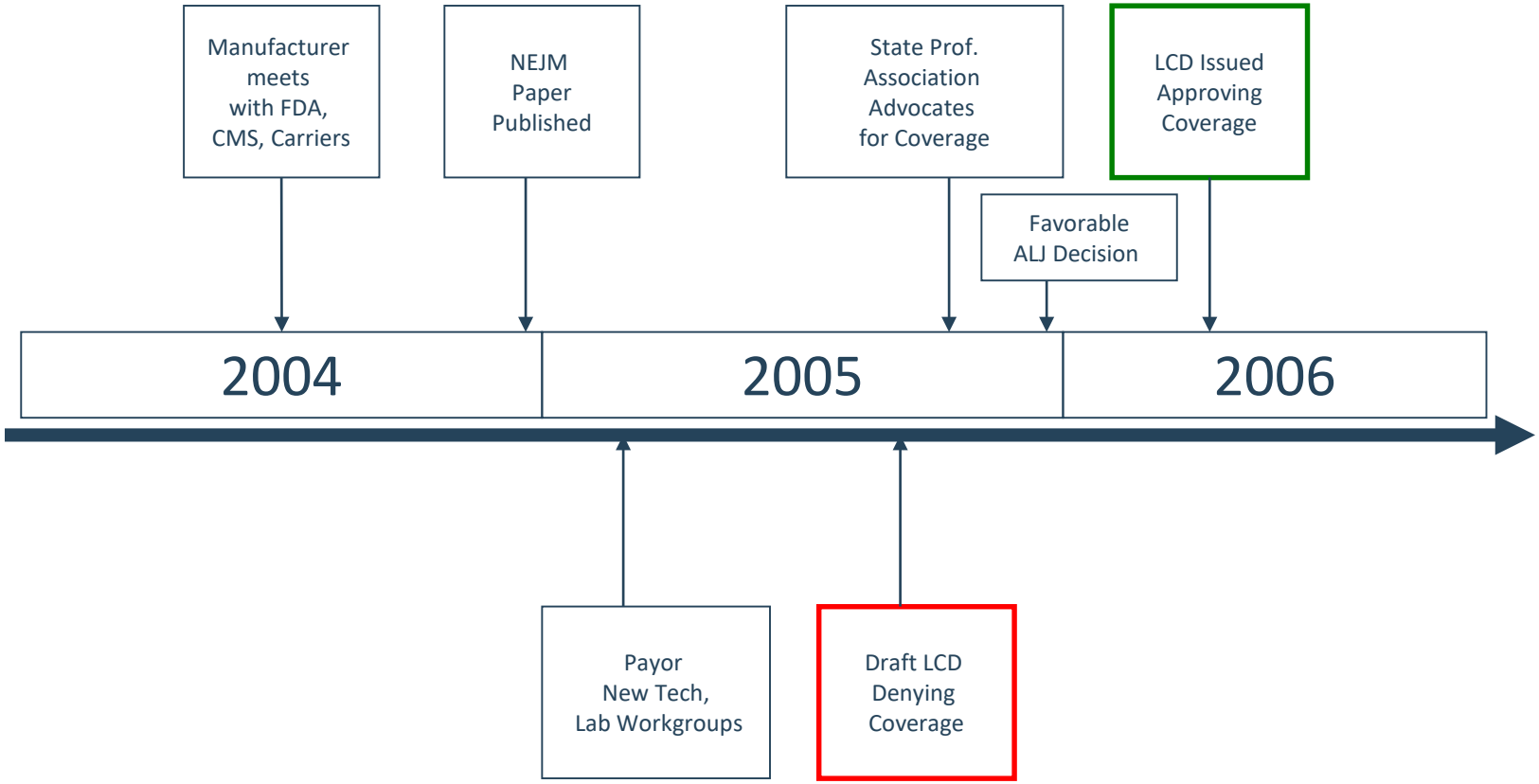
Case Study: Artificial Disk Replacement

- October 2004: FDA approves artificial disk for sale, but requires that manufacturer provide data on long-term performance of the device
- July 2005: New York Times reports that several private insurers question clinical outcomes compared with spinal fusion
- February 2006: CMS proposes national noncoverage determination
- May 2006: CMS issues national coverage determination that artificial disk will be covered for beneficiaries under age 60 if local carrier medical director concurs.
- August 2007: CMS denies coverage for all artificial disk replacements
  - Agency explained that none of the clinical trial data submitted involved patients over age 60, and that as a result there was no basis on which CMS could conclude that the device is reasonable or necessary for the Medicare population

Case Study: Oncotype DX

- Oncotype DX first marketed in 2004
- Diagnostic test uses RNA from paraffin-block tissues as an early predictor of the risk of breast cancer recurrence by measuring levels of specific genes
- Pivotal publication: 10-year retrospective study on 668 node-negative, estrogen receptor-positive patients.
  - Extremely high correlation with course of the malignancy
  - Correlation is higher than “traditional pathology”
- Results consistent with several large, independent patient cohorts
- Close collaboration with NSABP/NCI
- Professional association strongly recommended coverage upon December 2004 NEJM publication
- Draft Local Coverage Determination was unfavorable
- Final Local Coverage Determination was favorable, following ALJ decision and input of professional organizations

Case Study: Oncotype DX



Case Study: Coverage of MTWA

- Microvolt T-Wave Alternans ("MTWA") is a non-invasive diagnostic test for identifying patients who are at risk of sudden cardiac death from arrhythmia
- MTWA was covered by a few Medicare carriers
- Manufacturer met with CMS to request a national coverage decision

Case Study: Coverage of MTWA

- CMS reviewed peer-reviewed literature and conducted its own technology assessment
- Focused on 12 of 1028 citations in support of MTWA
- CMS conducted its own literature review
- March 2006: NCD approved coverage for MTWA

Case Study: Coverage of MTWA

- BCBS TEC had previously concluded that MTWA did not meet its criteria for coverage
- CMS focused on the Medicare-eligible population
- Only spectral analytic method is covered – not all methods
- Aetna, a large commercial health insurer, followed CMS's policy

Case Study: Natrecor®

- Natrecor® was approved by the FDA in 2001 for treatment of acutely decompensated heart failure (ADHF) in patients who have dyspnea at rest or with minimal activity
- Risks include renal complications, hypotension, increased mortality
- FDA approval followed concerns about safety
- Drug typically used in the inpatient setting
- Medicare accounts for approximately 85% of the market

Case Study: Natrecor®

- Manufacturer had its scientific advisory board study safety issues regarding use of the drug in outpatient settings
- Questions about safety appeared in newspaper articles and in medical journals
- TrailBlazer Health Enterprises, a large Medicare carrier, requested a national coverage determination review in May 2005

Case Study: Natrecor®

- Utilization data showed a rapid increase in number of services allowed and dollars paid by Medicare Part B contractors
- Trailblazer attributed increased volume to off-label use in the outpatient setting
- The NCD request also referenced reports indicating serious adverse consequences associated with Natrecor®

Case Study: Natrecor®

- CMS review resulted in a revised national coverage determination in March 2006 that Natrecor would not be covered for "Chronic" CHF
- CMS acknowledged that some studies suggested Natrecor may reduce days of hospitalization and improve symptoms of chronic CHF
  - However, CMS found that this was not a consistent finding in the clinical literature
- CMS weighed the weaknesses of the literature against "substantial" safety concerns
  - Determined that the benefits of Natrecor for the treatment of chronic CHF benefits do not outweigh the risks in the Medicare population
- CMS' decision applies only to off-label use of Natrecor as a treatment for chronic CHF
  - Does not address current FDA indication of ADHF

Case Study: Natrecor®

- Trailblazer Health Enterprises issued a Local Coverage Determination ("LCD") to define coverage further in its jurisdiction
- The LCD defines the five ICD-9-CM diagnosis codes for which Natrecor will be covered as reasonable and necessary:
  - 428.0 – congestive heart failure unspecified
  - 428.21 – acute systolic heart failure
  - 428.23 – acute on chronic systolic heart failure
  - 428.41 – acute combined systolic and diastolic heart failure
  - 428.43 – acute on chronic combined systolic and diastolic heart failure
- If one of the above ICD-9-CM diagnosis codes does not appear on the claim form, Natrecor will not be covered