
Aligning Incentives and Designing Payment Systems to Promote Excellence in Cancer Care and Innovation

Deb Schrag MD MPH

Dana Farber Cancer Institute

Professor of Medicine Harvard Medical School

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Cancer Drugs FDA Approved: 2012

Drug	Indication	Effect
Axitinib	Met Kidney CA	Median OS=2m>Sorafenib (6.7 vs. 4.7m)
Pertuzumab	Met BrCA	Median PFS=6m> placebo (18.5 vs. 12.4)
Ziv-Aflibercept	Met CRC	Median OS=1m> placebo (13 vs. 12)
Vismodegib	Basal Cell CA	Objective RR% in 104 patients In single arm trial (30%)
Carfilzomib	Refractory M. Myeloma	22% RR
Enzalutamide	Met Prostate	Median OS =6m>placebo (18.4 vs. 13.6)
Bosutinib	Refractory PH+ CML	33% cytogenetic RR
Regorafenib	Met CRC	Median OS=1.4m>placebo (6.4 vs. 5)

Cancer Drugs FDA Approved: 2012

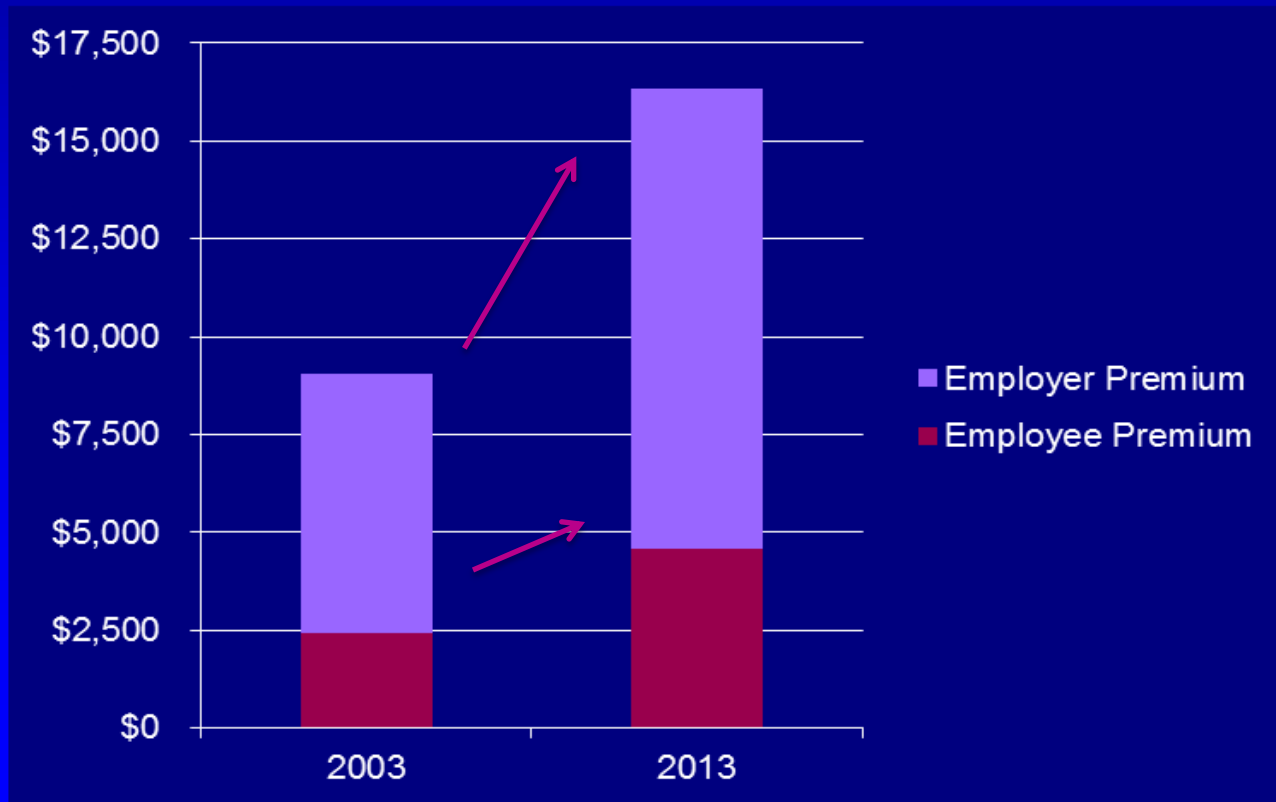
Drug	Indication	Effect	Approximate Cost 1 month of Rx
Axitinib	Met Kidney CA	Median OS=2m> Sorafenib (6.7 vs. 4.7m)	\$9800
Pertuzumab	Met BrCA	Median PFS=6m> placebo (18.5 vs. 12.4)	\$5900
Ziv-Aflibercept	Met CRC	Median OS=1m> placebo (13 vs. 12)	~\$11,000
Vismodegib	Basal Cell CA	Objective RR% in 104 patients In single arm trial (30%)	\$7500
Carfilzomib	Refractory M. Myeloma	22% RR	\$9,950
Enzalutamide	Met Prostate	Median OS =6m>placebo (18.4 vs. 13.6)	\$7,450
Bosotinib	Refractory PH+ CML	33% cytogenetic RR	N/A
Regorafenib	Met CRC	Median OS>1.4m>placebo (6.4 vs. 5)	\$~10,000

Why Do Oncology Drugs Cost So Much?

- Development costs are high
- Products are highly valued
- Products may face limited competition
- Products have small market size
- Limited # of products for any single indication
- FDA approval standard is safety and efficacy
- Patent protection laws
- Cross subsidization of development in global markets
- Biggest payer (CMS) can't negotiate-others payors face pressure to cover cancer treatments
- Moral hazard---health insurance

High Costs Are Passed on To All of Us

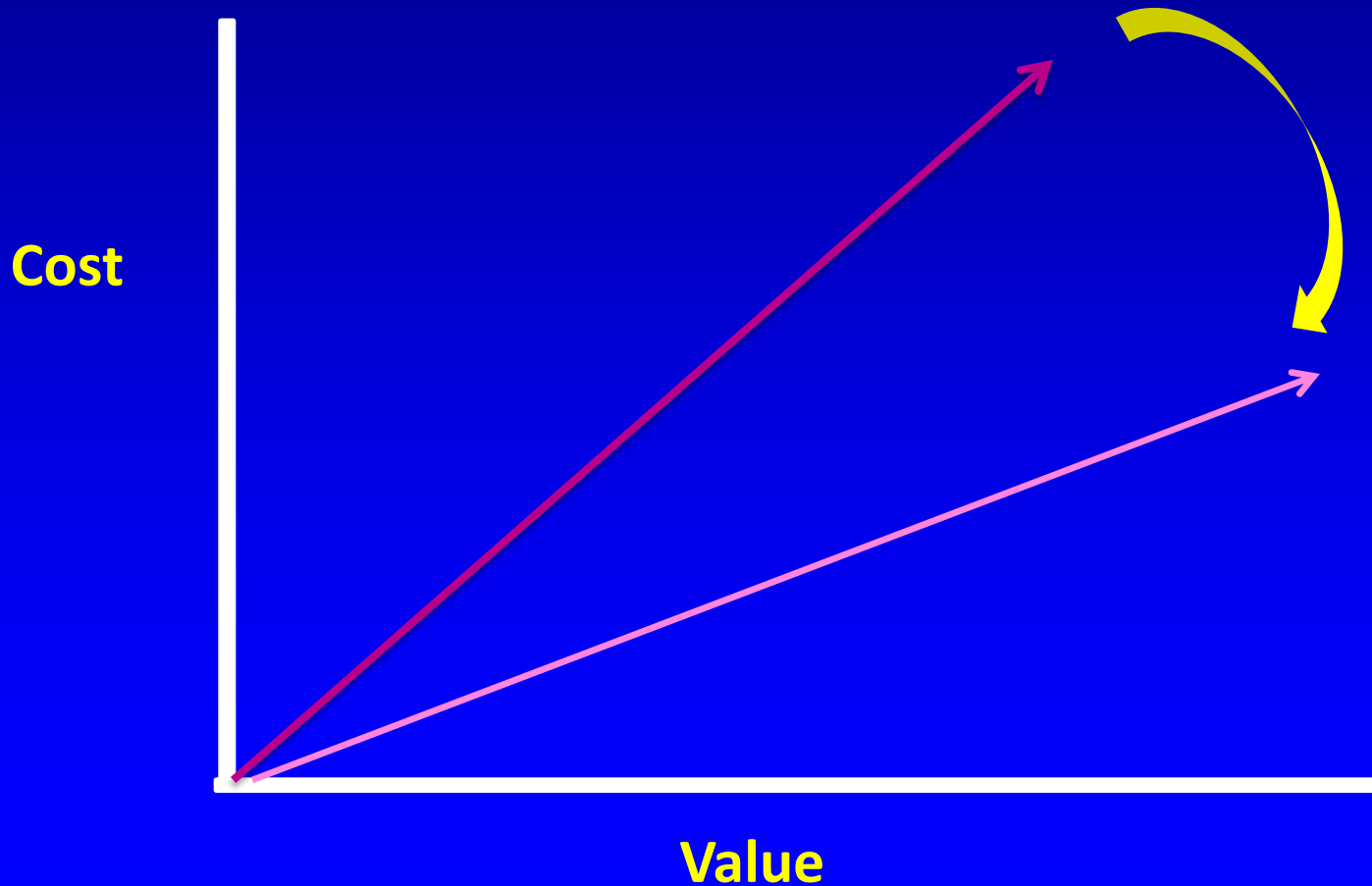
- Health care premiums have not kept pace with wage increases
- The average health care premium for a family of 4 about doubled between 2003-2013



Source: Kaiser Family Foundation from HERT Survey of Health Benefits

What is Value?

- $\text{Value} = \frac{\text{Quality}}{\text{Cost}}$



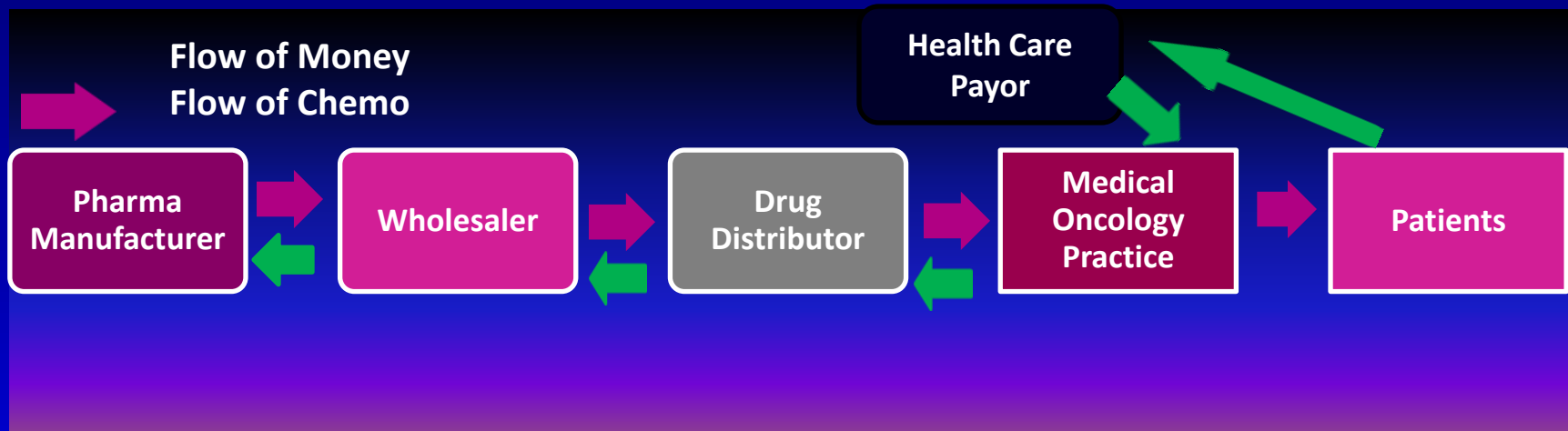
Cost, Cost-Effectiveness and Decision-Making

DECISION MAKERS	INFLUENCE OF COST EFFECTIVENESS
Drug manufacturers in setting price	Perhaps, for global marketplace
Food and Drug Administration in approval	No
Compendia that guide coverage	No
CMS, private payers	No, or at least not explicitly
Clinical practice guideline developers	Limited
Clinicians	Limited, lack of info, misaligned incentives
Patients	No, lack of transparency and information

Existing Strategies to Promote Value in Prescribing Cancer Medicines

- Decrease moral hazard---more “skin in the game”
- Prior authorization requirements
- Tiered formularies---Zofran < Aloxi or MS Contin < Oxycontin
- Quantity limits: Dispense small quantities at a time
- Foster Transparency about costs and benefits of chemo
- “Choosing Wisely” Campaign—Think first, Order Second
- **Better drug development---More alternatives within therapeutic class, more personalized drug regimens**

Buy and Bill Model for Cancer Chemotherapy



Before 2005: 95% AWP

- AWP often \gg than wholesale acquisition costs
- Large profits for oncology
- AWP non-verifiable

After Medicare Modernization Act, from 2005: ASP+6%

- Mandatory manufacturer reporting of quarterly ASP & volume-verifiable
- ASP = volume-weighted average manufacturer sales price net of all rebates to U.S. purchasers
- Excludes sales exempt from Medicaid "best price" calcs & sales to other federal purchasers

April 2014: ASP+4% ---doesn't eliminate incentive to use high cost drugs

Core Functions of Oncology Office Practice

Adequately reimbursed

- Chemotherapy
- Chemotherapy administration (maybe)

Not adequately reimbursed

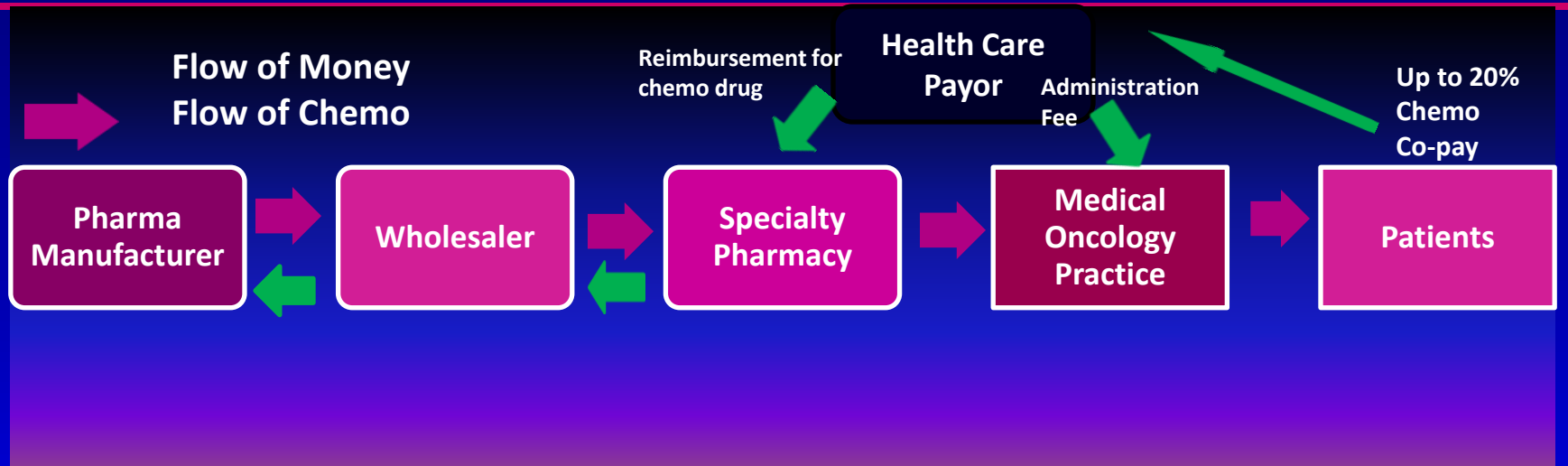
- Counseling about treatment decision making
- Symptom management
- Care coordination
- Phone calls
- Social work and nursing
- Genetic counseling

- Financial counseling
- Survivorship planning

- Research

**ONCOLOGY CARE IS FINANCED
BY CROSS-SUBSIDIZATION**

Specialty Pharmacies and “White Bagging”

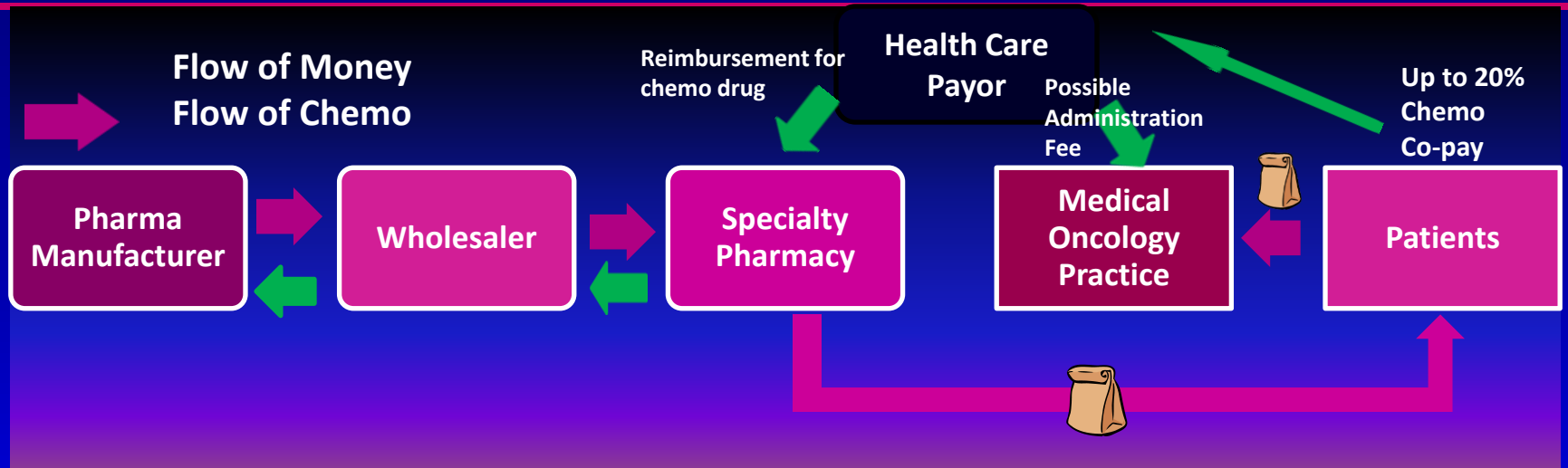


Goal: Take oncologists completely out of the buying/billing business

What Does White Bagging Accomplish?

- New entity--the specialty pharmacy-- authorized to dispense and bill
- Can be billed either to medical (part B) or pharmacy (Part D) benefit
- Specialty pharmacy can often purchase drugs at a cheaper rate
- BUT: ensuring adequate timely delivery to practices is a challenge
- Not every chemo dose gets used---need a plan to manage inventory

Specialty Pharmacies and “Brown Bagging”



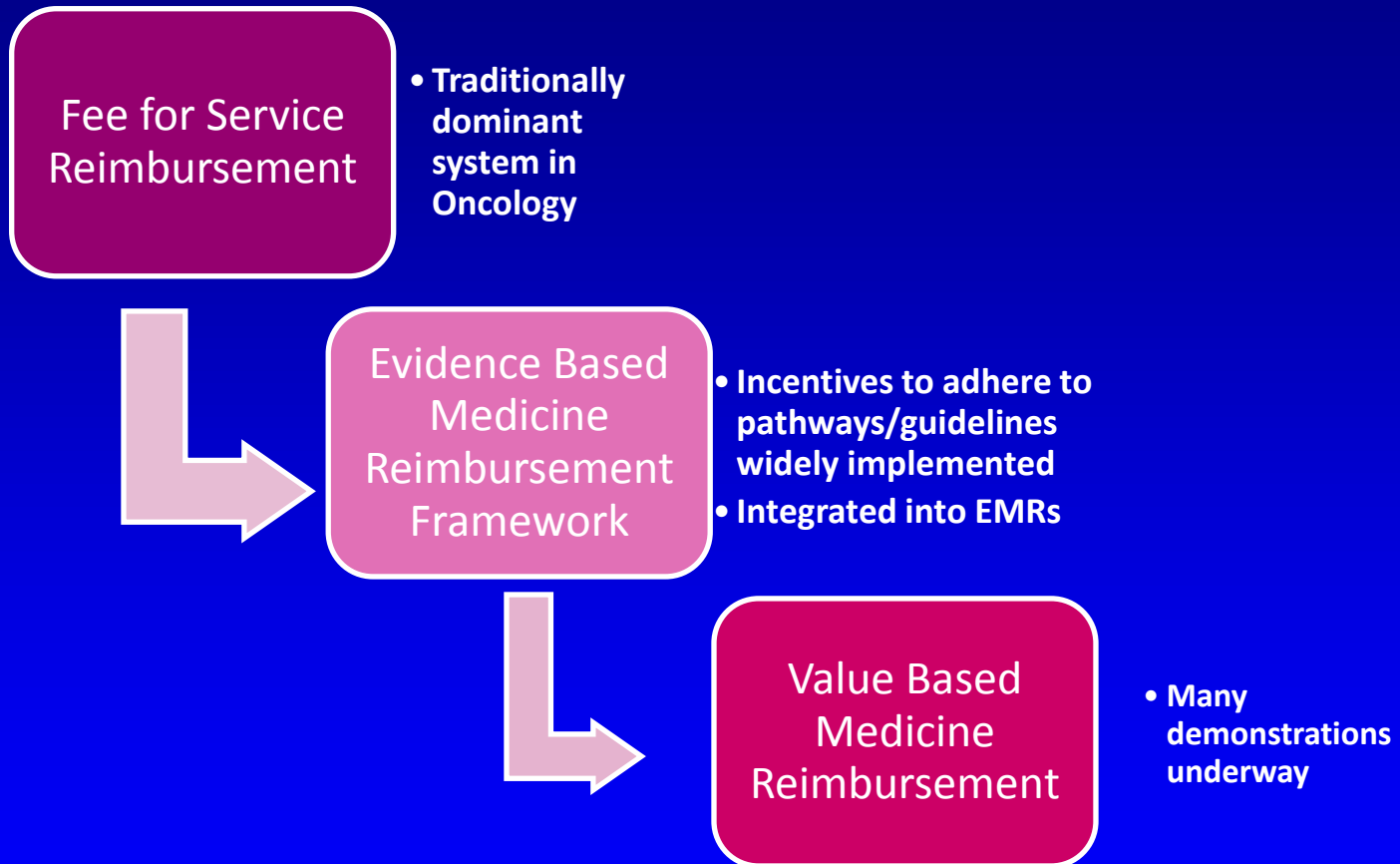
What Does Brown Bagging Accomplish?

- Specialty pharmacy dispenses directly to the patient
- May also be a retail pharmacy (coverage must then be under part D)
- Eliminates physician billing
- Pharmacy deals with prior authorization/coverage

What are the problems with Brown Bagging

- Major Safety Concerns—problematic for most oncologists
- Storage of drugs, sterility, safe handling, liability
- 2-stop shopping

Gradual Shift in Oncology Reimbursement Systems

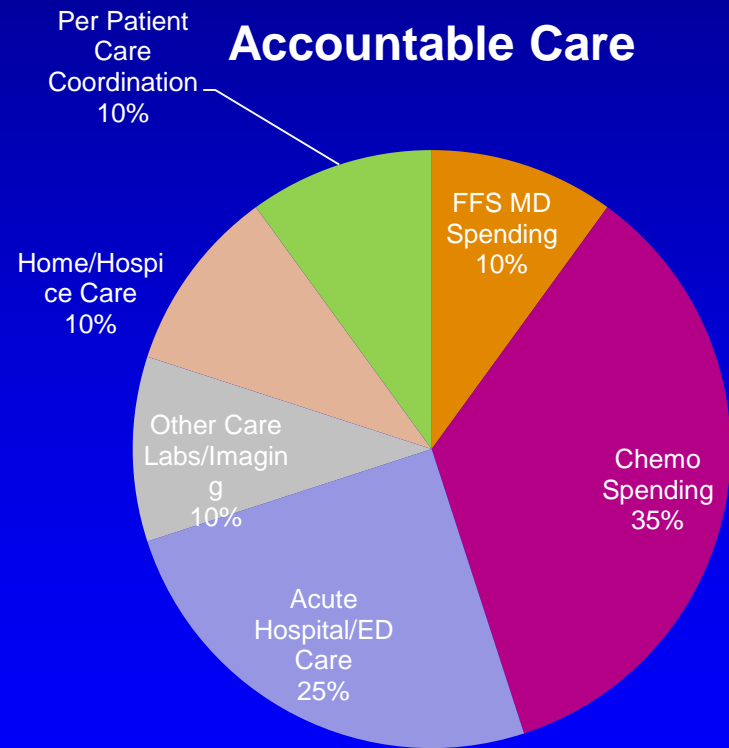
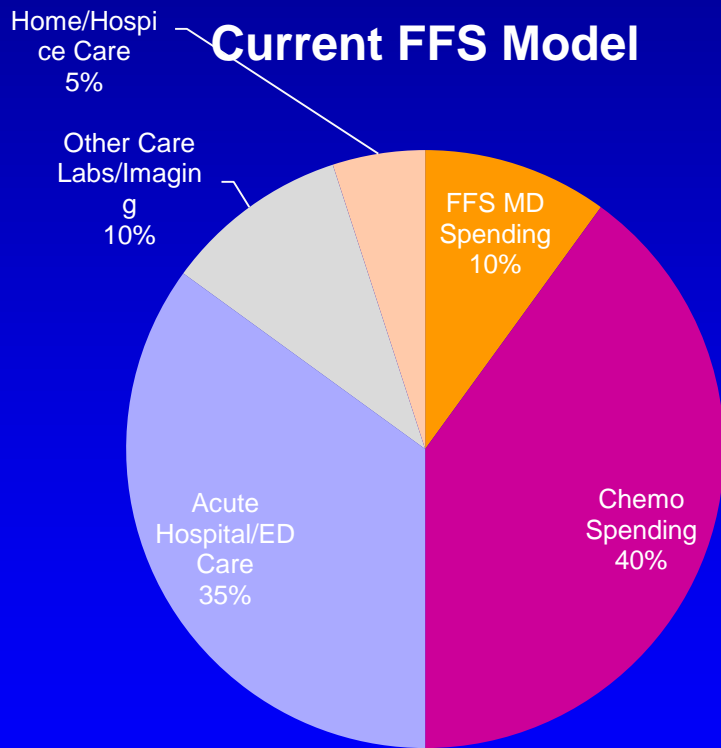


Alternative Payment Models to FFS

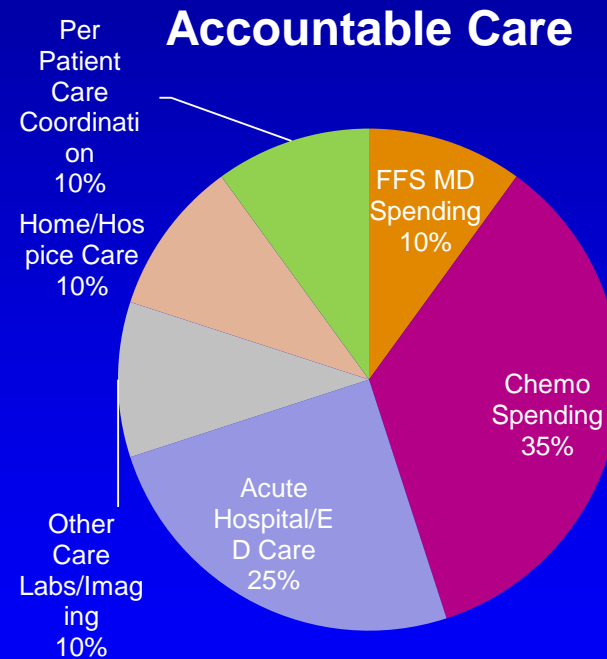
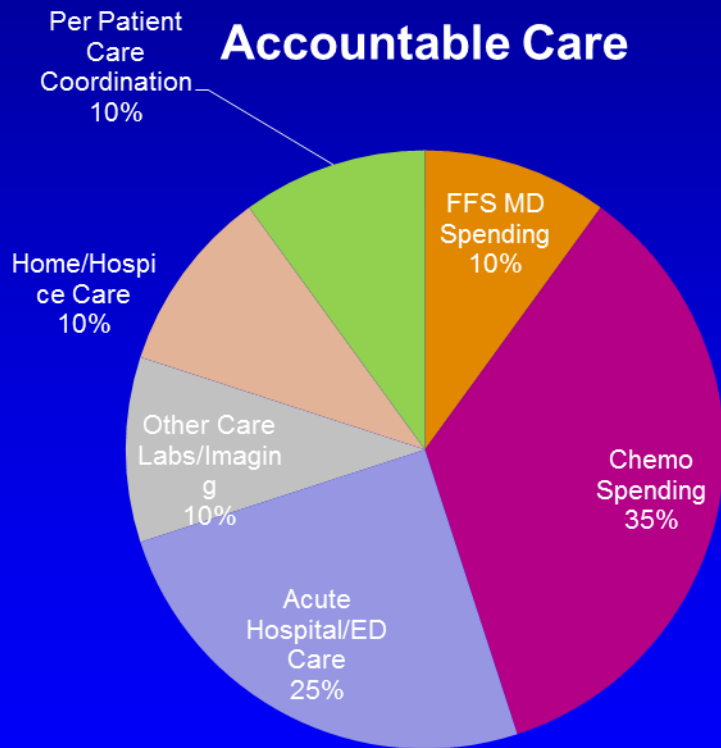
Alternative	Potential Advantages	Potential Disadvantages
Capitation/ Gatekeeping	Highly effective at controlling costs	Curtails freedom of choice May restrict access to care
Pathway Adherence	Promotes evidenced based practice, high quality	Constrains choices Challenging to maintain
Accountable Care Organizations	Foster teamwork and efficiency Promote quality	Constrains choice
Episode Bundling	Predictability Incentivizes teams to work together to get good outcomes	Easier to construct for short episodes and a well-specified team. Outliers expose providers to risk

Alternative Payment Models: Aligning Spending and Value

Changing Distribution of How We Spend Money on Cancer Care



Alternative Payment Models: Shrinking the Pie



THE #1 PRIORITY is RESEARCH TO IDENTIFY BETTER CANCER TREATMENTS

More value-based insurance design experiments

Data sharing platforms and learning health care systems

Research to discover better treatments is CRITICAL

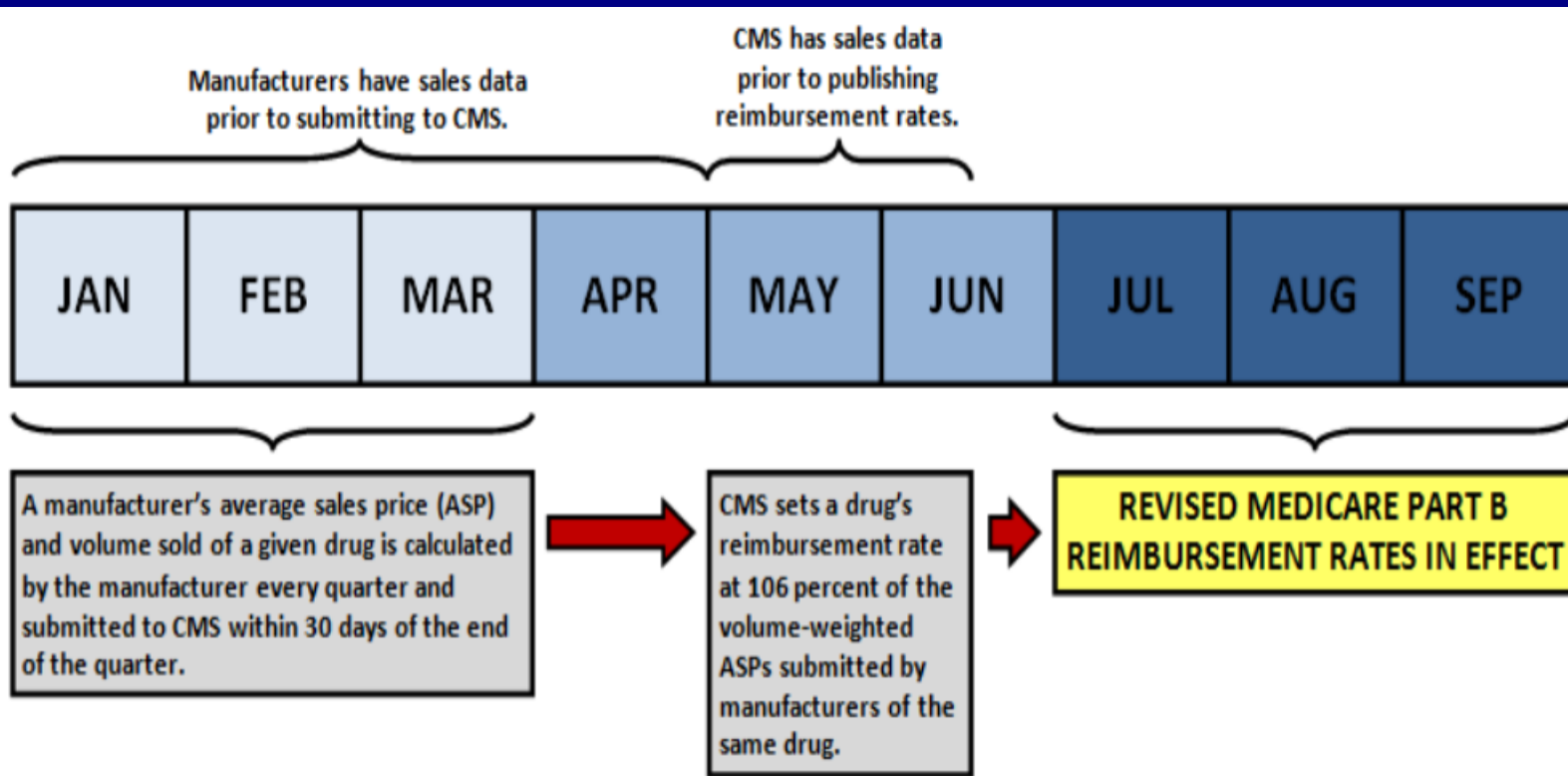
Reimbursement systems must incentivize research

THANK YOU!!!!

Deb_Schrag@dfci.harvard.edu

QUESTIONS?

CMS Approach to Calculating ASP+6%



ASP+6% still aligns incentives with use of high cost drugs

\$1000 drug=\$60 vs. \$10,000 drug=\$600

A compromise to preserve practice revenue

Onyx Stock Price and Regorafenib Development Time Line

ONYX Pharmaceuticals, Inc.

■ ONXX



■ Volume



A More Competitive Marketplace is Emerging

- **7 drugs have been FDA approved for kidney cancer since 2005**
 - **Sorafenib: 2005**
 - **Sunitinib: 2006**
 - **Temsirolimus: 2007**
 - **Everolimus: 2009**
 - **Bevacicumab: 2009**
 - **Pazopanib: 2009**
 - **Axitinib: 2012**

Clinical Trials Remain the Linchpin

- **We must do better at accrual**
- **Design studies with meaningful endpoints/effect sizes**
- **Embed molecular correlatives to specify mechanisms**
- **Distinguish little benefit for many vs. big benefit for few**
 - **crizotinib for alk mutated lung cancer**
- **Invest in publicly funded clinical trials**
- **Align CMS/FDA/CDC/AHRQ and NCI**

Align Incentives to Promote Teamwork and Coordination

- **If you give chemotherapy, you need a plan to minimize ED/hospitalization use**
- **Value based design: reward good behavior**
- **Incentivize accessibility outside routine hours**
- **Incentivize communication strategies**
 - **Patient to Clinician**
 - **Clinician to Clinician**
 - **Waiting room/group education**
 - **Across systems**

Treatment Pathways/Guidelines

- Works when there are choices
- If similar efficacy choose least \$\$ option
- Resource intensive to develop and curate
- Challenging to keep free from commercialism
- Need tracking systems for molecular profiling
- Need interoperability
- Proprietary vs. open access
- Challenging for providers with multiple payors each subscribing to different pathways