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Preconference II: The Basics of Managed Markets

Compliance in an Era of Value-Based Pricing for Prescription Drugs

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KING & SPALDING

Drug Pricing Methodologies – a Compliance Challenge

- Medicaid – Rebates and modification for "Best Price" (BP)
- Medicare Part D – Negotiated (with rebates) and exempt from BP
- Medicare Part B – "Average Sales Price" and not exempt from BP
  - Hospital Outpatient, ASCs, and "Packaged Payments"
- 340B – driven by Medicaid "Unit Rebate Amount" and BP
- VA and FSS– exempt from BP
- Commercial– not exempt from BP

Drug Pricing Compliance in a New Value-Based World…

So how do compliance and drug pricing rules apply in the emerging "value based pricing" frameworks, and what exactly do we mean by "value based pricing" so we can apply what we know to the framework?

"In late June, Susan DeVore asked an auditorium filled with medical-industry executives if any would be willing to link the prices of the drugs and devices they sell to how well those products work. DeVore, whose company, Premier, helps 3,400 U.S. hospitals make purchasing decisions, recalls seeing about a half-dozen hands go up. 'I think it's a little bit scary for them,' she says. But it's a question they should get used to hearing, she adds. 'Health systems and physicians are more interested in it today than they've ever been.'"

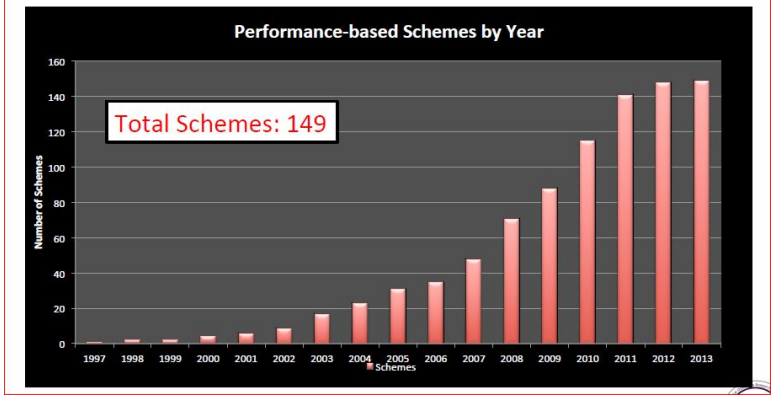
Drugs Could Soon Come With a Money-Back Guarantee
Bloomberg Businessweek, October 8, 2015

…But Not a New Issue

The University of Washington has reported that, as of 2013, there were 149 different value based purchasing models around the world....but did not emphasize that less than 20 of them were in the United States.

UNIVERSITY of WASHINGTON

Performance-based schemes by year



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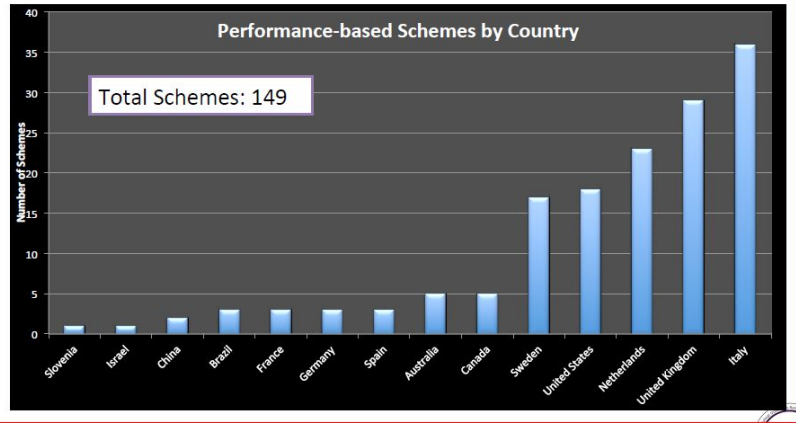
Performance-based schemes by country



An Issue Getting More Attention

"Express Scripts Holding Co., a large manager of prescription-drug benefits for U.S. employers and insurers, is seeking deals with pharmaceutical companies that would set pricing for some cancer drugs based on how well they work.

The effort is part of a growing push for so-called pay-for-performance deals amid complaints about the rising price of medications, some of which cost more than $100,000 per patient a year."

New Push Ties Cost of Drugs to How Well They Work
Wall Street Journal, May 26, 2015

Manufacturers Are Interested Too

"Novartis is already discussing flexible pricing models for Entresto with insurers. These would involve the insurer getting a partial refund if the drug didn't produce the promised outcomes and the company getting a bonus payment for exceeding expectations. Mr. Jiminez said some insurers, which he declined to name, were interested in this 'pay-for-performance' model over paying a fixed per-pill cost."

Novartis Looking at Ways to Win Over Cost-Concerned Health Insurers
Wall Street Journal, July 10, 2015

Examples: Diabetes and Cholesterol

- **2009 -- Merck agreement with Cigna regarding Januvia (sitagliptin) and Janumet (sitagliptin/metformin) Tied drug discounts and formulary placement to how well individuals with Type 2 diabetes were able to control blood sugar using drugs**
- **2015 – Amgen agreement with Harvard Pilgrim regarding Repatha -- PCKS9-Inhibitor, providing money back "rebate" in the event patients have heart attack or stroke (which happened to 27% of enrollees in clinical trial)**

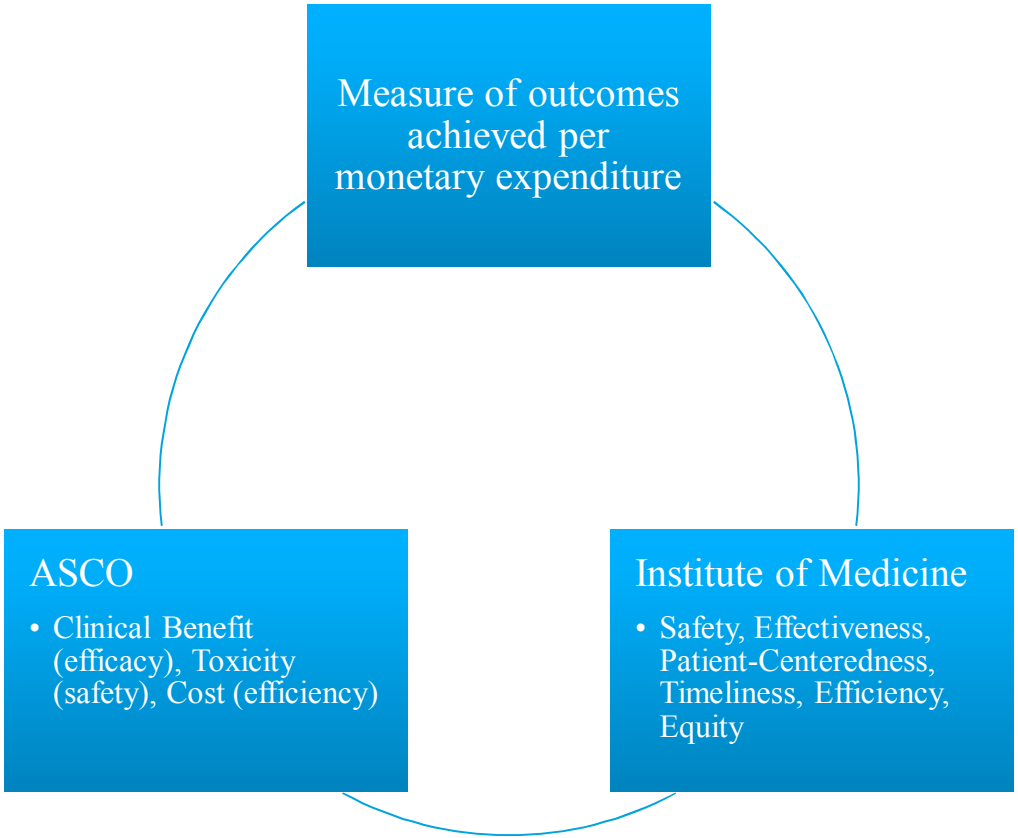
Example: Cart-T Gene Replacement Therapy

August 30, 2017 -- Novartis receives approval for Kymriah for children and young adults with B-Cell ALL. "Novartis also announced a novel collaboration with the United States Centers for Medicare and Medicaid Services (CMS) focused on improving efficiencies in current regulatory requirements in order to deliver value-based care and ensure access for this specific patient population." This approach is intended to include indication-based pricing for medicines and supports payment for a medicine, such as Kymriah for its initial indication, based on the clinical outcomes achieved…"

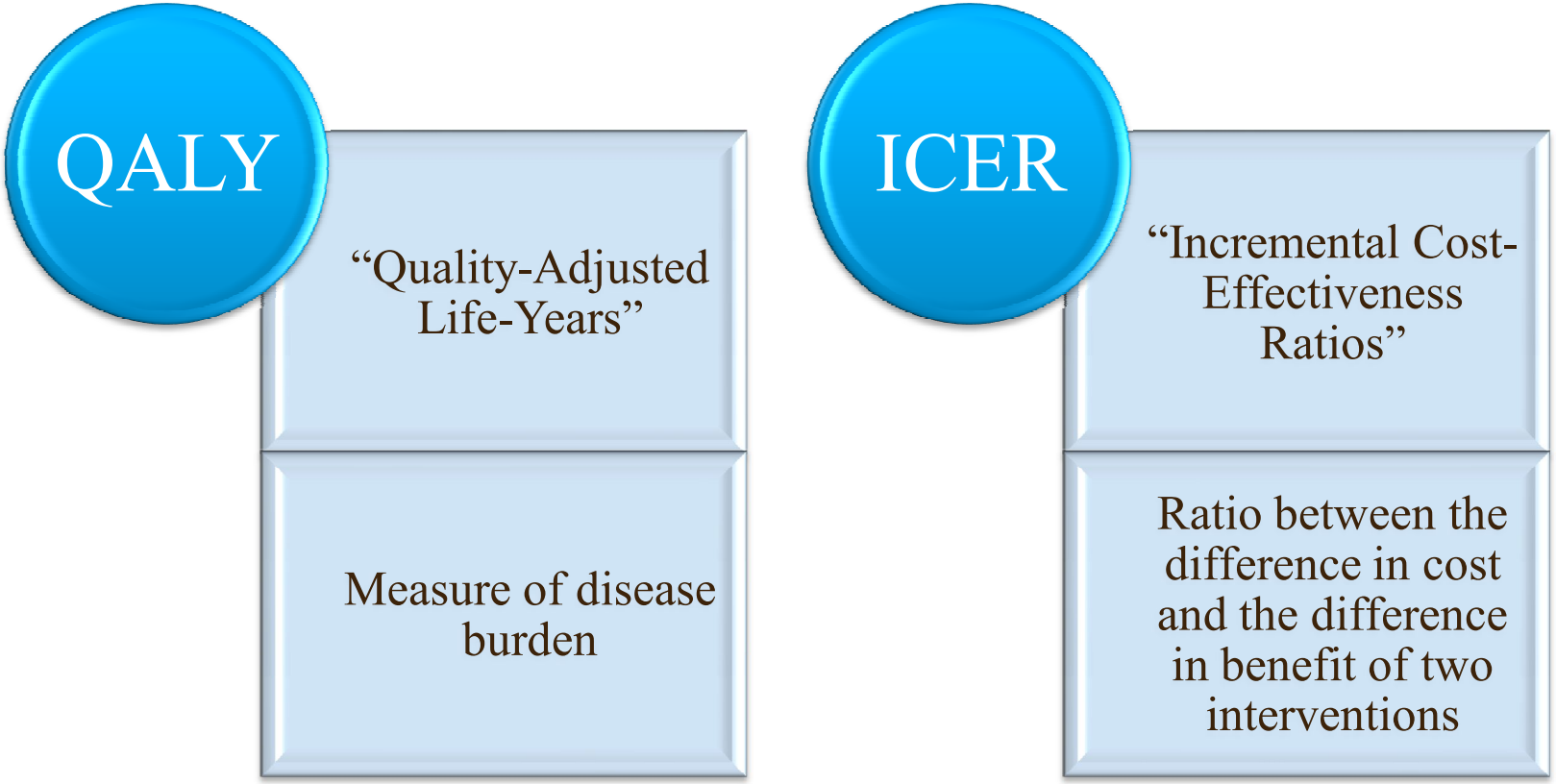
Agreement with CMS relates to payment for outcomes within one month. But to whom and how does it apply?

www.novartis.com/news/media-releases/novartis-receives-first-ever-fda-approval-car-t-cell-therapy-kymriahhtm-ctl019

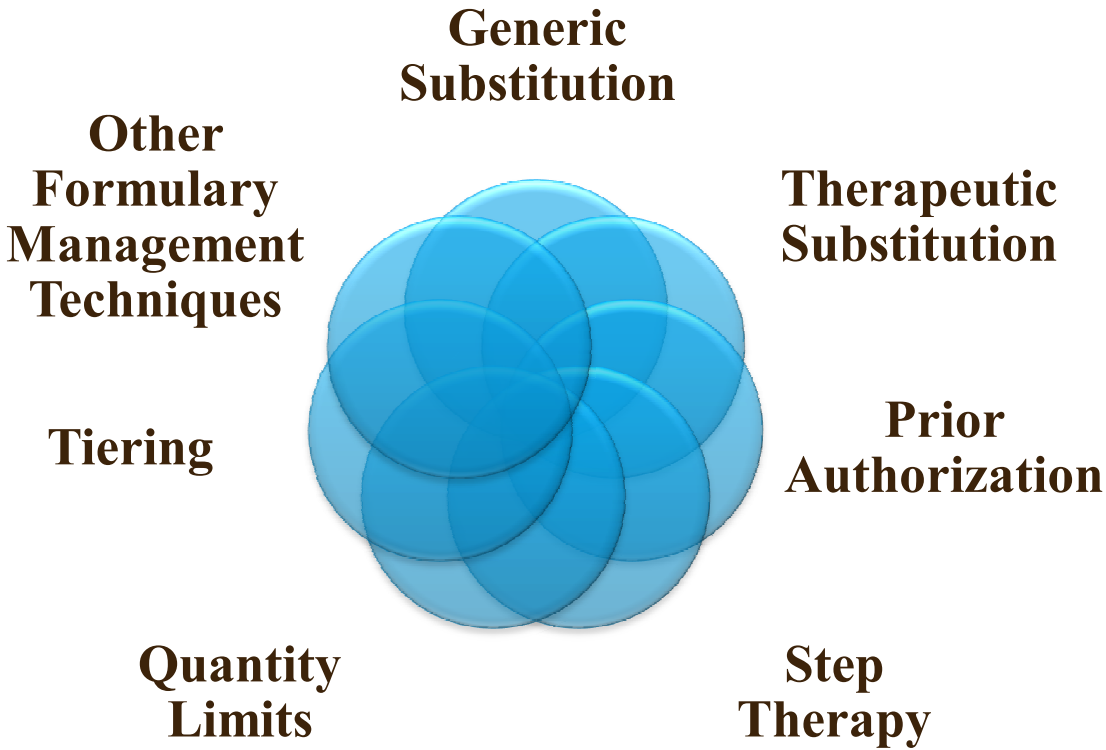
What Is "Value"?



Metrics to Assess Value



Value-Based Pricing is NOT:



Value-Based Pricing Models

ASCO Value Framework

Tool to assist physician and patient in shared decision making

Designed to compare new treatments with prevailing standard of care using data derived from a prospective randomized trial

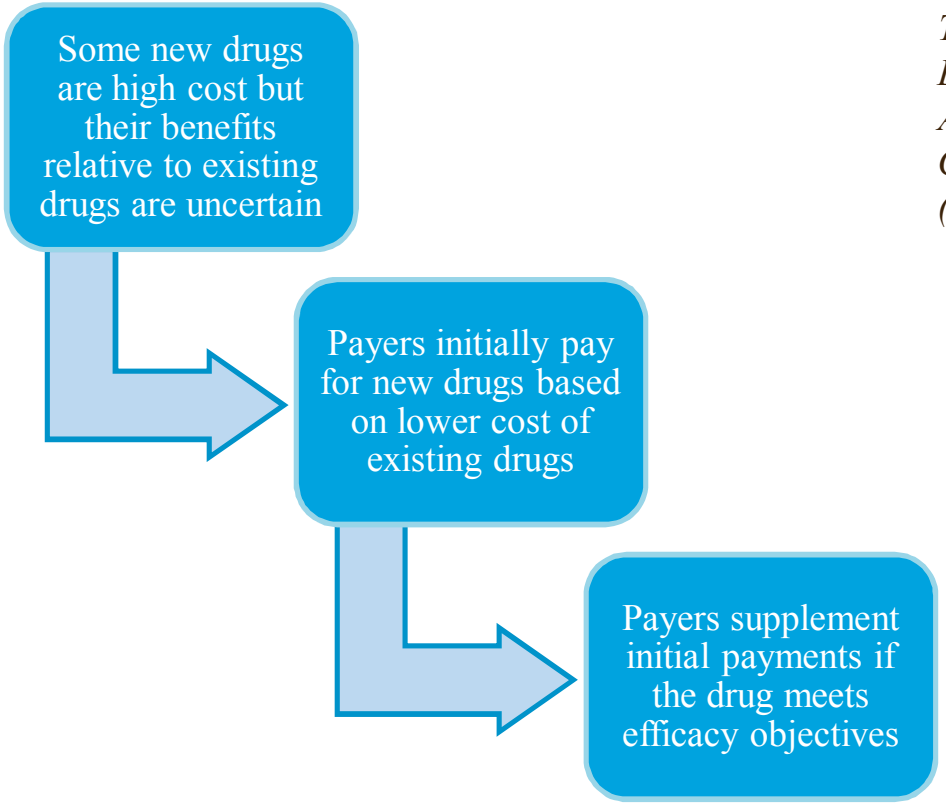
Two versions (advanced cancer and potentially curative treatment)

Mathematical model to determine "Net Health Benefit" score that is compared to cost to assess drug's value

- Clinical Benefit Score (1 to 5)
- Toxicity Score (add or subtract up to 20)
- Bonus Points (for palliation or treatment-free intervals)

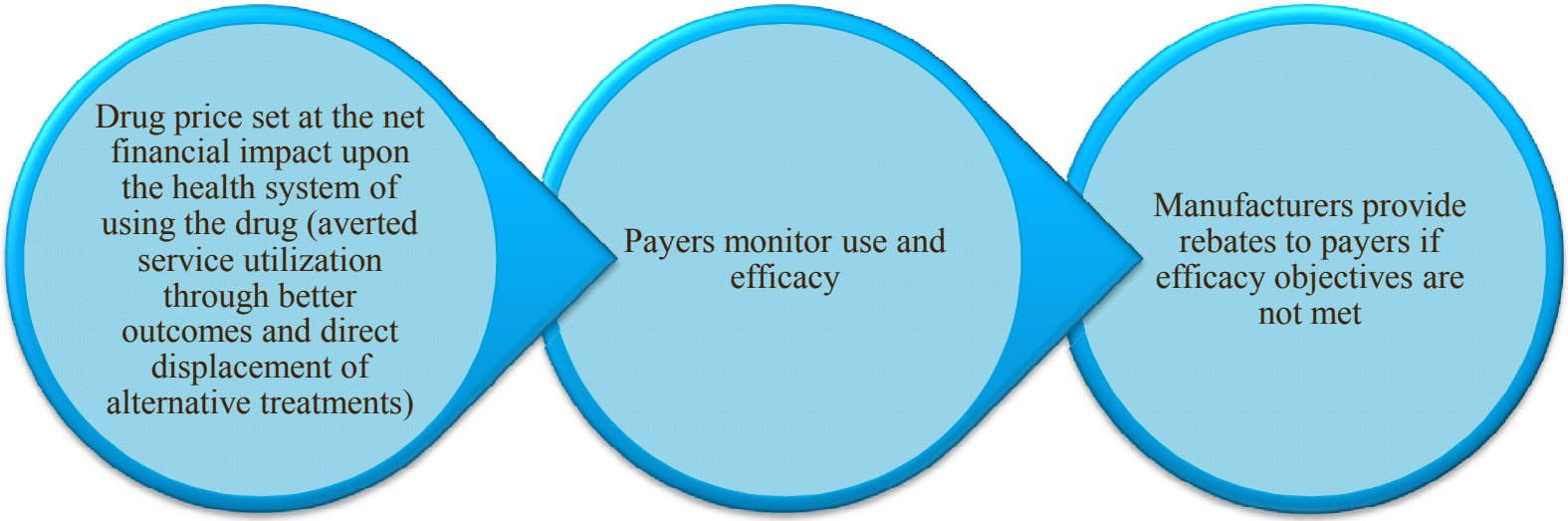
American Society of Clinical Oncology Statement: A Conceptual Framework to Assess the Value of Cancer Treatment Options, Journal of Clinical Oncology (August 10, 2015)

Pay for Performance (Drug Efficacy)



Topher Spiro, et al., "Enough Is Enough, The Time Has Come to Address Sky-High Drug Prices," Center for American Progress (September 2015)

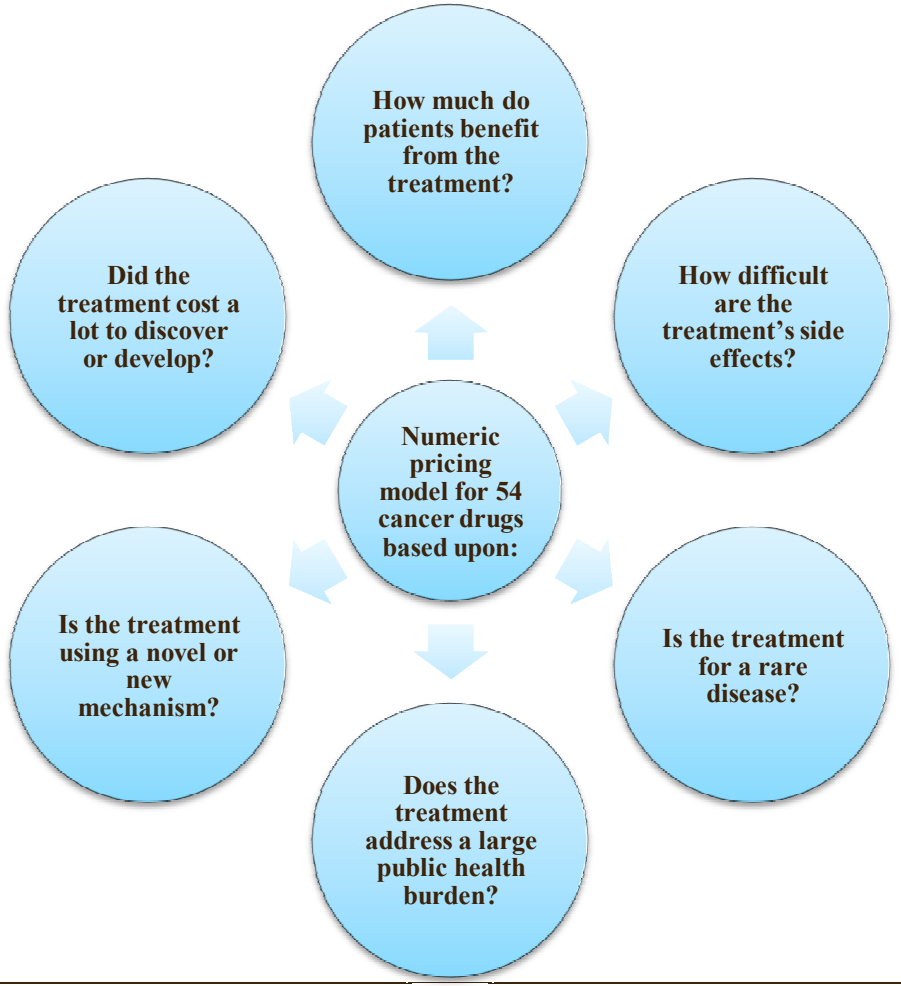
Pay for Performance (Care Cost Reduction)



Richard Fuller and Norbert Goldfield, Clinical and Economics Research, 3M Health Information Systems

DrugAbacus

Memorial Sloan Kettering Cancer Cancer's "Interactive Exploration of Drug Pricing"
(www.drugabacus.org)



Profit Limit Model

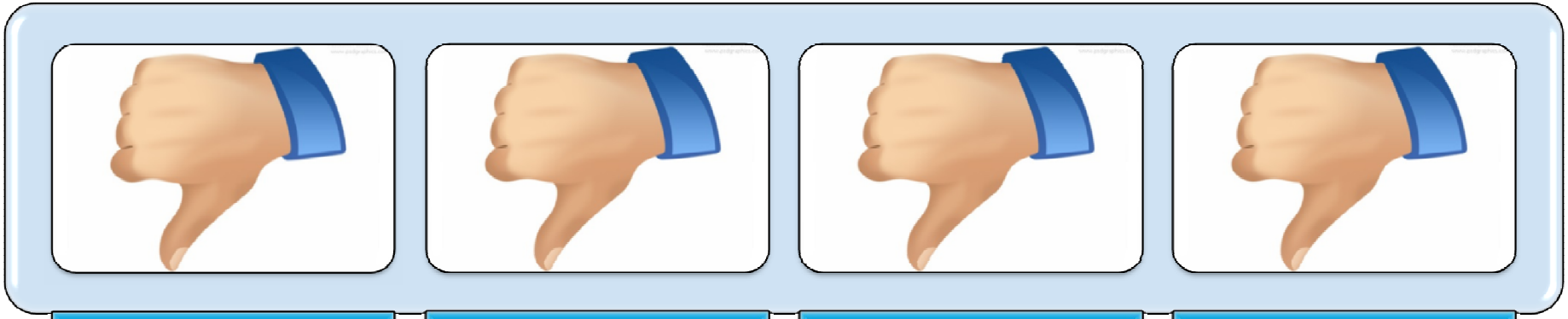
Limit manufacturer profits to 120% of the cost of market capital (net of production, marketing and current R&D costs)

- Limit profits for breakthrough drugs to 140%
- Limit profits for new manufacturers of new treatments to 150%

If manufacturers exceed limits, lose Hatch-Waxman exclusivity

Len M. Nichols, Ph.D., "What Price Should We Pay for Specialty Drugs?" Center for Health Policy Research and Ethics, College of Health & Human Services, George Mason University (May 15, 2015)

Practical Barriers to Implementation



High Implementation Costs

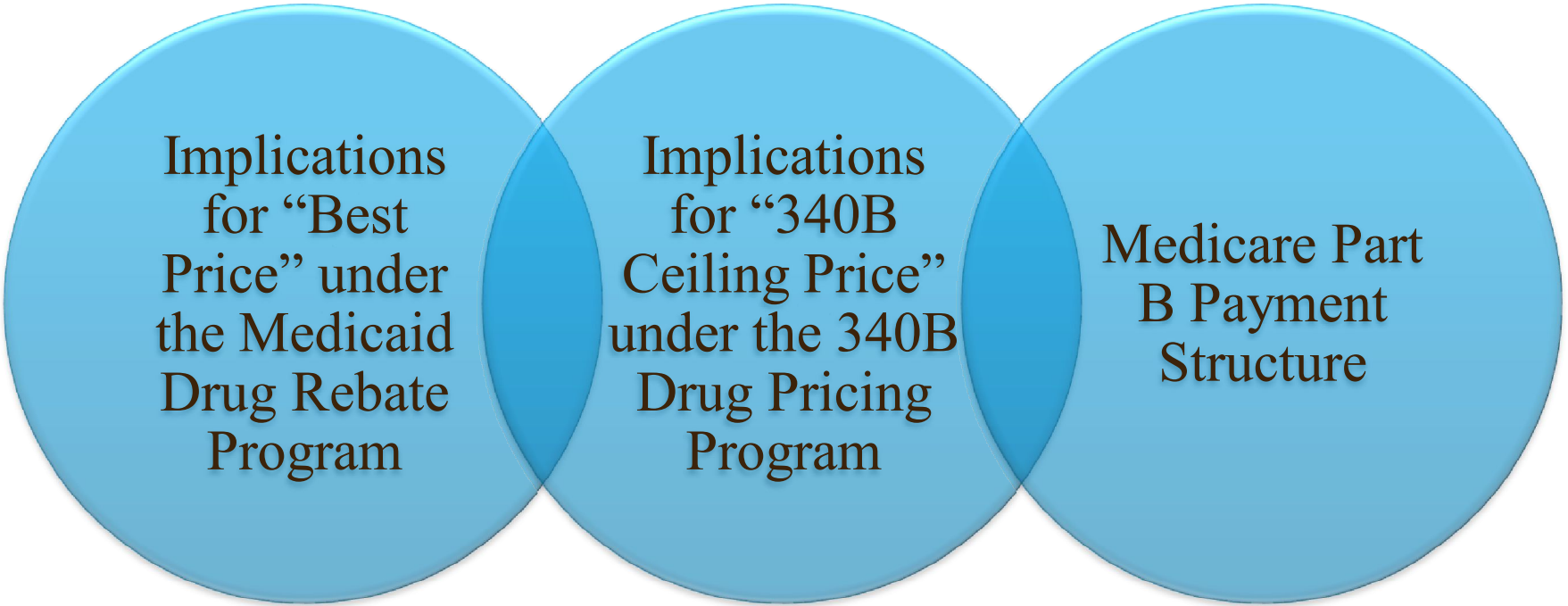
Measurement Challenges

Suitable Data Infrastructure

Incentives

- Manufacturers
- Payers
- Patients/ Beneficiaries

Compliance Issues Specific to VBP -- Pricing



Medicaid Best Price

"Best Price" for an innovator drug is the "lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States" with certain exceptions (e.g., Part D prices)

A lower Best Price can increase the Medicaid Unit Rebate Amount (URA) paid by manufacturers under the Medicaid Drug Rebate Program

In a drug market that is 30% Medicare, 30% Medicaid, 40% private payer, a "price concession" to address value concerns may create a lower Best Price and increase Medicaid rebate liability

Returning funds to Medicaid in the event "value" is not achieved could be effectuated through a "bundle" methodology or through state supplemental rebate agreements (ratified by CMS)

340B Ceiling Price

Manufacturers that participate in Medicaid are required to participate in the 340B Drug Pricing Program, which limits drug prices under the program to the 340B Ceiling Price

The 340B Ceiling Price is equal to the quarterly Average Manufacturer Price (AMP) minus the Medicaid URA

A lower Medicaid Best Price can increase the Medicaid URA, which can reduce the 340B Ceiling Price, lowering drug prices under the 340B Drug Pricing Program

Medicare Part B Payment

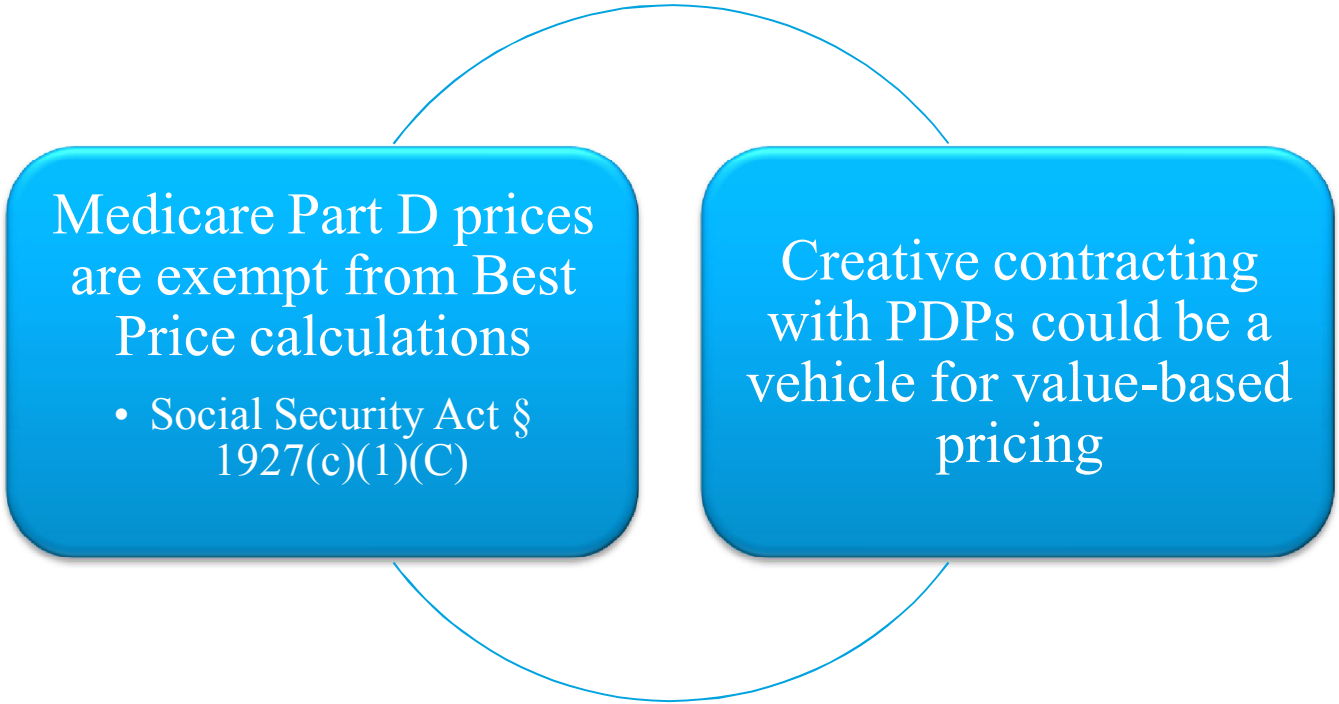
Medicare Part B reimbursement for drugs is based on the "Average Sales Price" (ASP) + 6% methodology

Price concessions as part of a "value" arrangement may reduce the ASP payment limit for "valued" products in the future

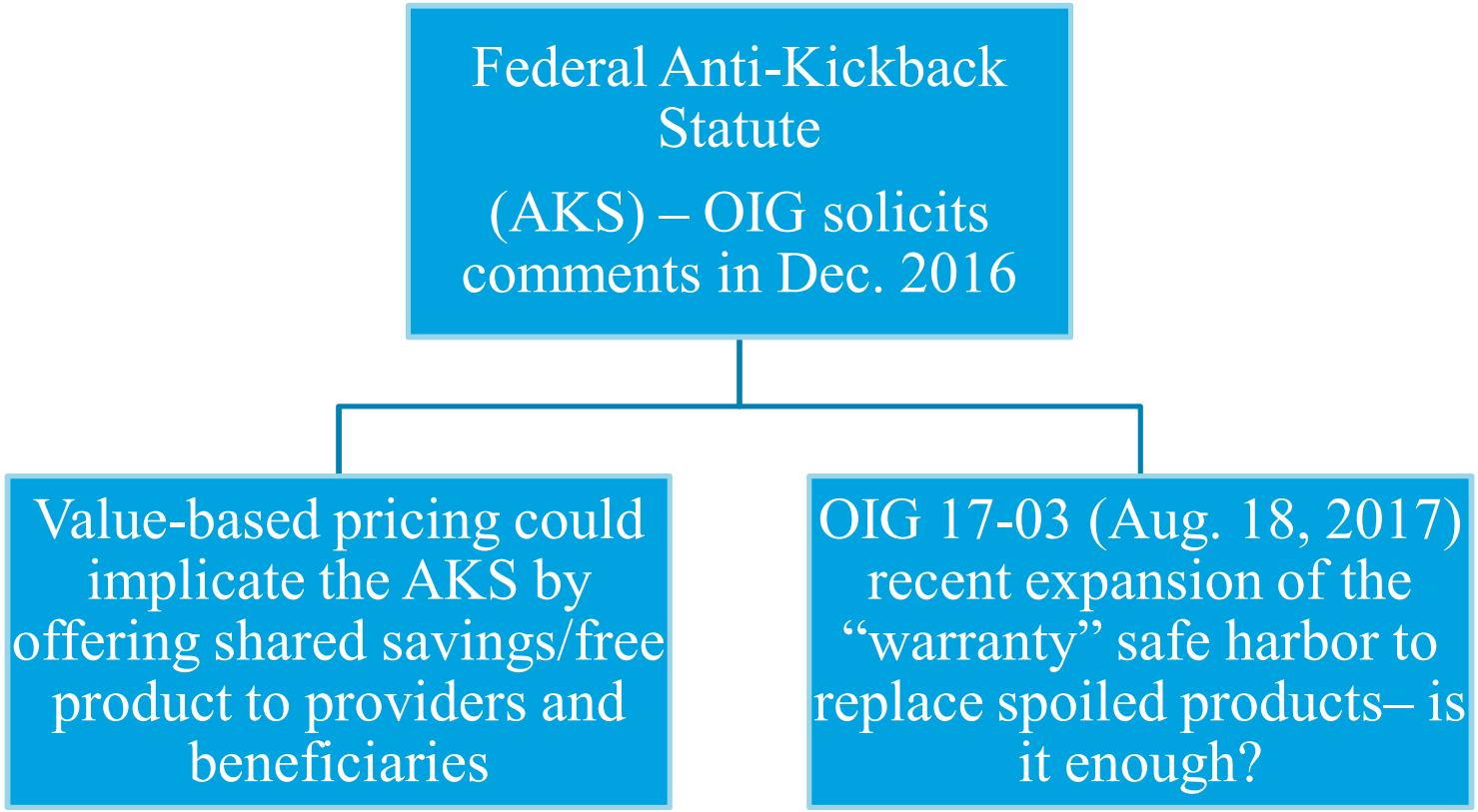
There is no "rebate" or other mechanism to return funds to the Medicare program itself in the event "value" is not delivered

- And manufacturers do not want a Medicare Part B rebate structure!

More Flexibility in Medicare Part D



Other Compliance Issues -- AKS



Other Issues -- HIPAA

- Personal Health Information (PHI) is health-related information that can be used to identify a specific individual.
- PHI is highly sensitive, and the privacy of patients' PHI is protected by federal and state laws, including the Health Insurance Portability and Accountability Act (HIPAA).
- Physicians, payors and other customers are "covered entities" under HIPAA.
- While normally the rule is "do not request or collect patients' personal health information (PHI) for any reason," you will need to do so in a value based payment world to understand how you "hit" or "miss" the goal.
- The HIPAA paradigm is a whole new world for manufacturers, who historically try avoid situations likely to lead to disclosure of PHI (such as private conversations between HCPs and patients).

Other Issues – FDA and Promotions

- Promotional communications must be balanced and must avoid misleading representations or omissions, including subjective statements or opinions and misrepresentations of competitor products.
- Promotion includes any express or implied claim about a product's efficacy or safety—which is inherent in any value-based discussions.
- All claims must be consistent with labeling and provide fair balance
  - but value is normally never in a label
  - will FDA give us the tools to navigate this concern?

What's Next?

Monitor CCIIO, and watch expansion to see how the legal framework develops

To encourage value-based pricing, a new statutory paradigm is needed to:

- Exempt value-based pricing from Best Price
- Expand opportunities to create value-based pricing in federal programs themselves

Conclusions

Value-based pricing is receiving more attention

Payers are trending toward greater value-based payment systems

We expect value-based pricing for drugs will expand in the coming years

Compliance will need to be careful, and thoughtful, about how such models affect overall federal program reimbursement

Questions