

Prescription Drug Spending and Payment Reform

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Topics

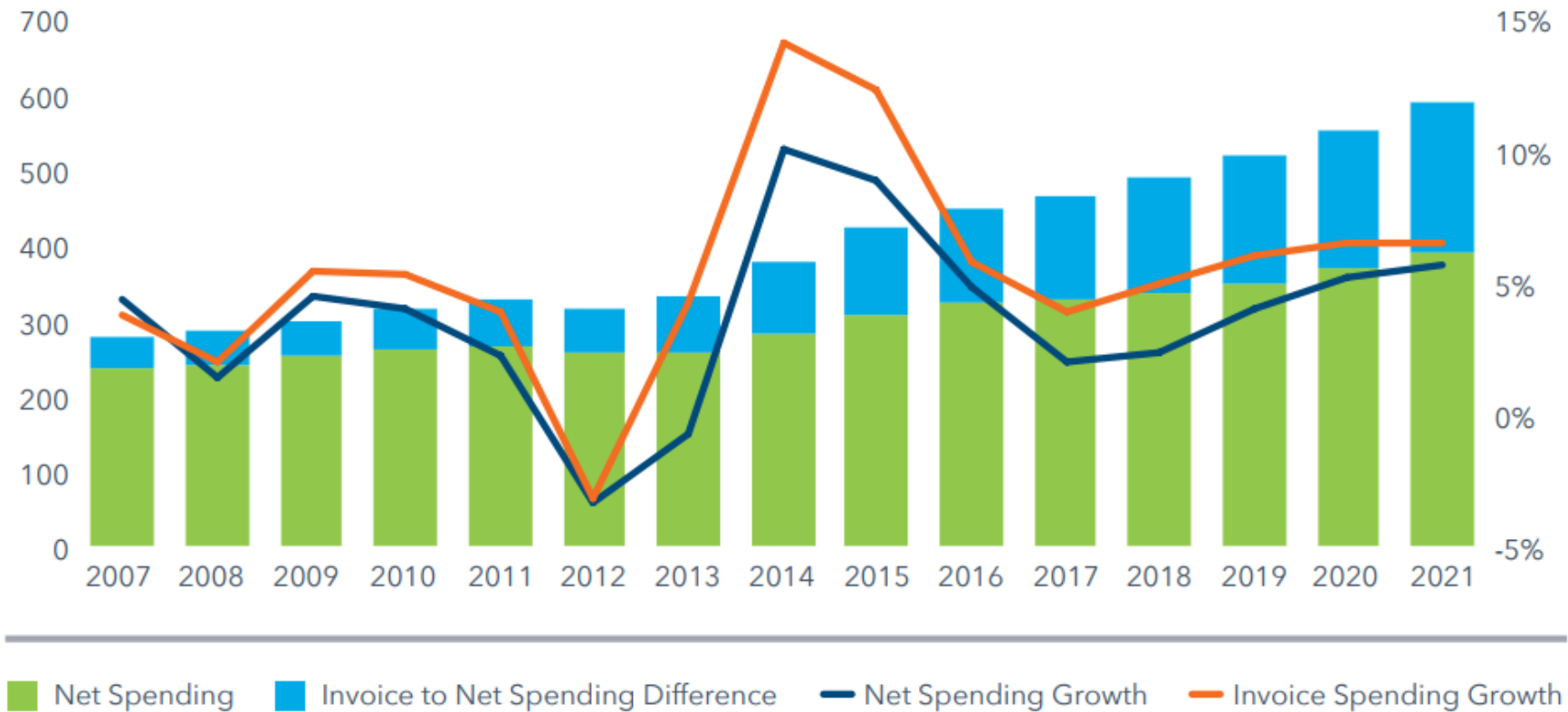
- Drug Pricing and Spending
- Payment Reform

Range of Drug Pricing and Spending Issues

- Oral Drugs/Medicare Part D
- IV/Physician-Administered Drugs/Medicare Part B
- Generic Drugs
- Biosimilars

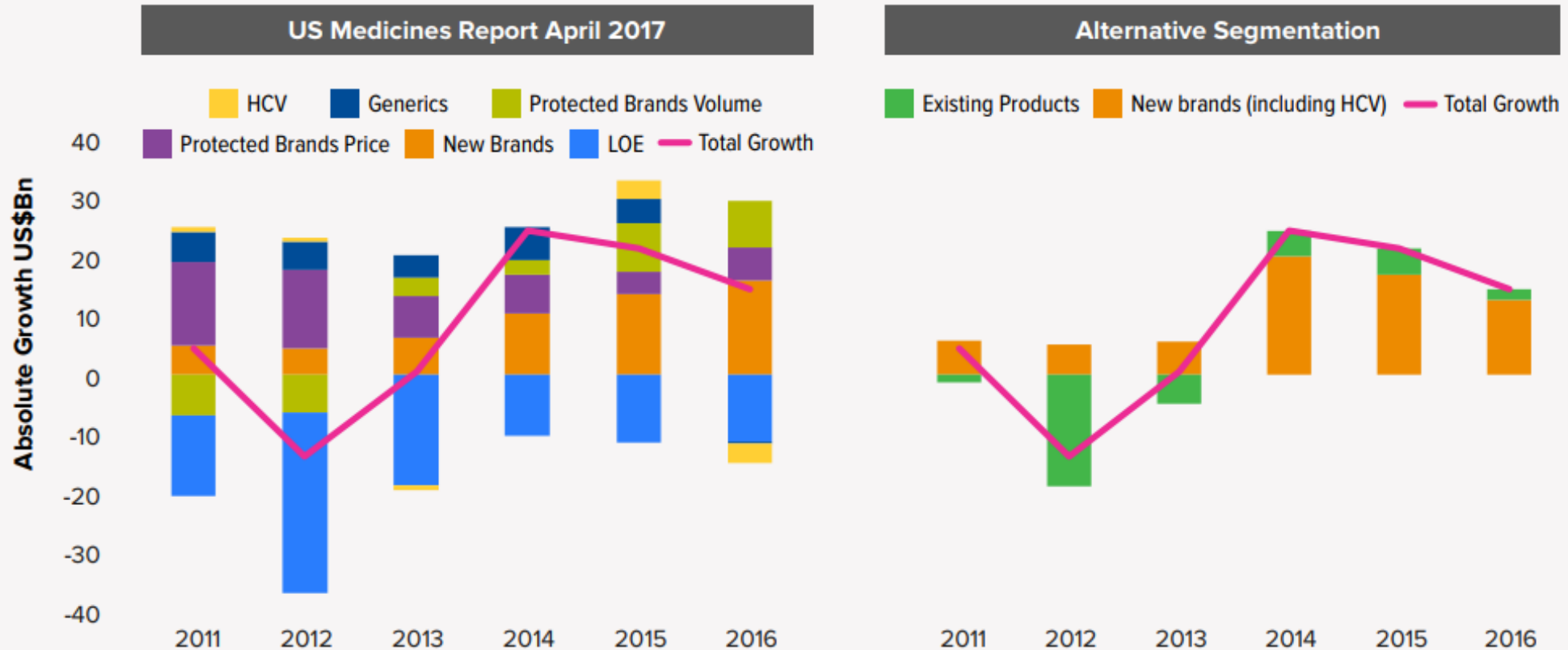
Slowing but significant drug spending growth

Chart 26: Total Spending on Medicines US\$Bn



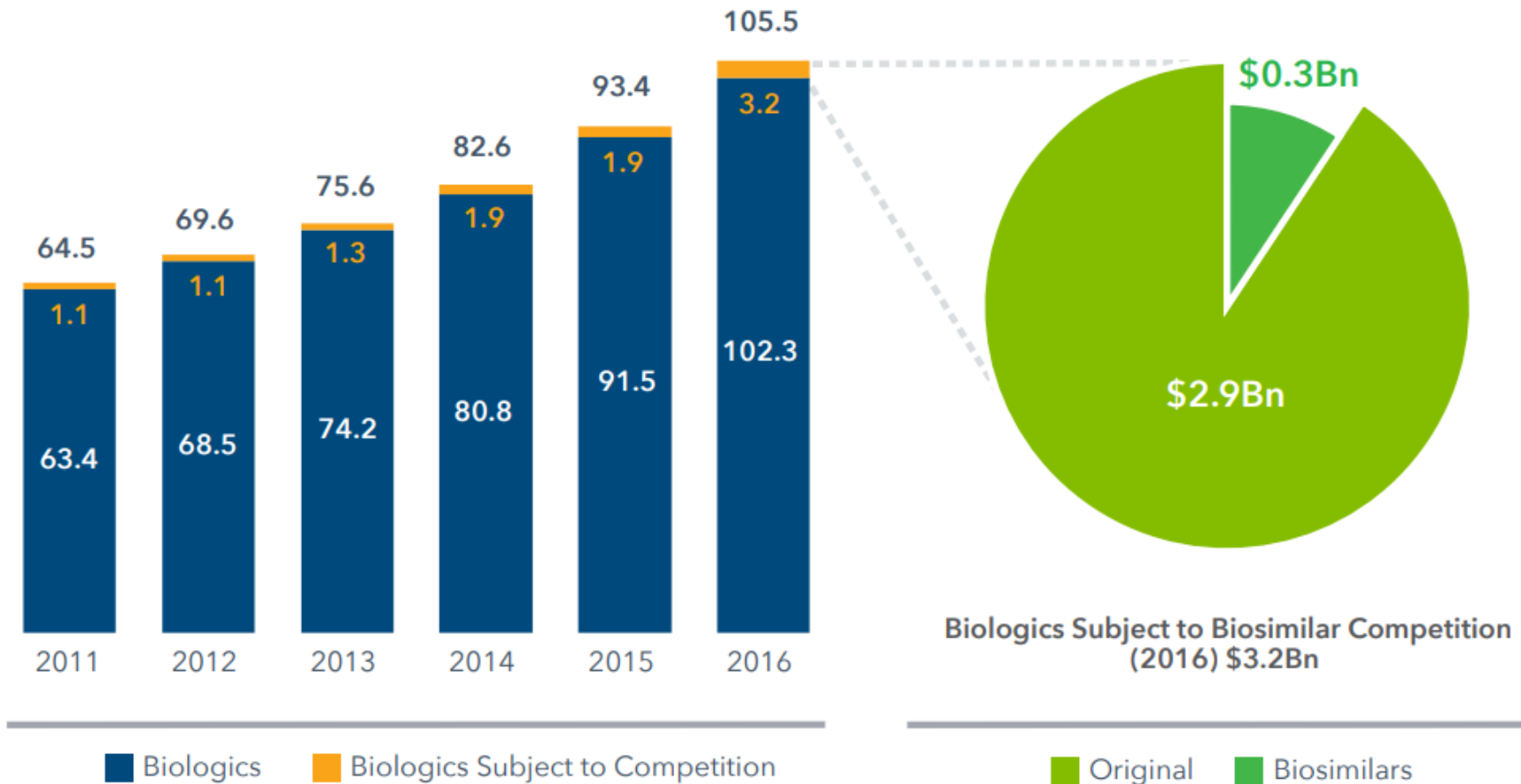
Source: IQVIA Market Prognosis, IQVIA Institute of Human Data Science, Mar 2017

New brand drugs and brand volume increases driving most spending growth



Source: QuintilesIMS, National Sales Perspectives, Dec 2016; QuintilesIMS Institute Aug 2017

Accelerating spending growth on biologics- with limited impact of biosimilars so far



Source: IQVIA, National Sales Perspectives, Dec 2016; IQVIA Institute of Human Data Science

FDA-Related Issues: Generic Drugs

- Guidance/pathways for combination generics
 - Off-patent active ingredient with patented/complex delivery
 - Generic drugs with Risk Evaluation and Mitigation Strategies (REMS)
- More straightforward pathways and lower-burden manufacturing regulation for thin-market generics
 - Small populations
 - Sterile injectable drugs
- Manufacturer access to drug samples

FDA-Related Issues: Brand Drug Competition

- Accelerated approval pathway for limited-competition drugs
- Postmarket evidence on comparative effectiveness

FDA-Related Issues: Biosimilars

- Guidance on regulatory approval pathways
- Standards for similarity/ interchangeability

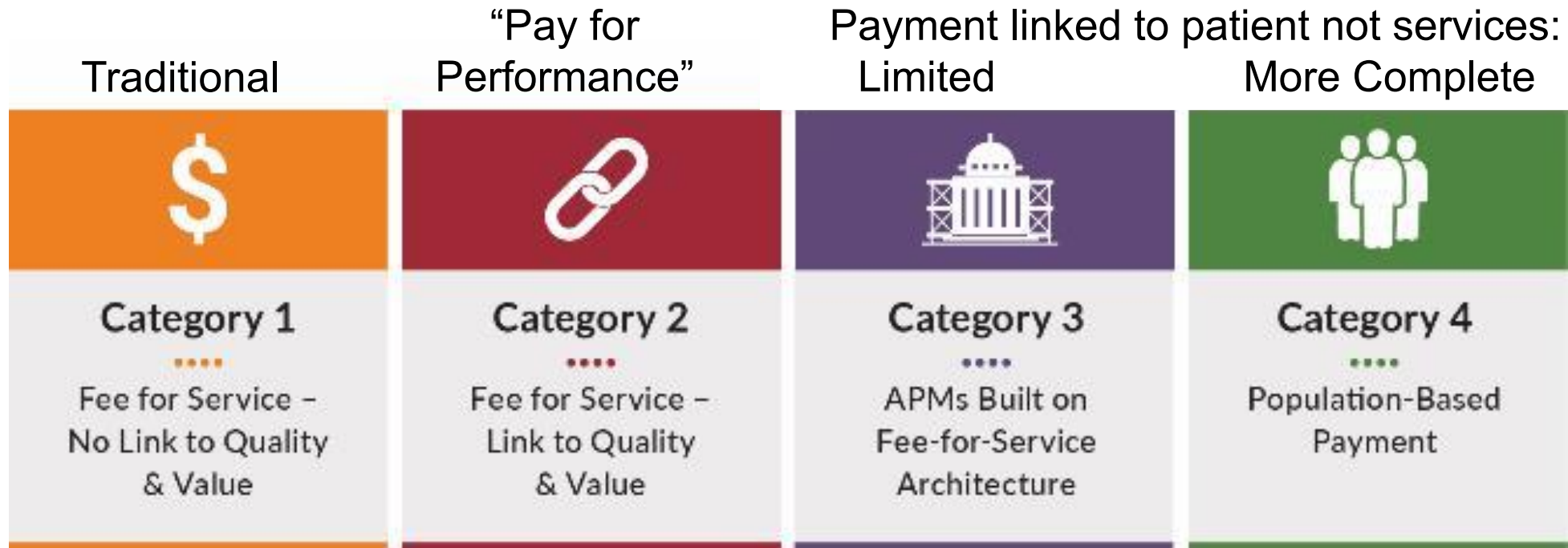
Reforms for Part B/ Physician-Administered Drugs

- Shift to Formulary-Based Approaches
 - MedPAC proposal: CMS selects Part B drug benefit manager(s)
 - Competitive bidding to supply physician offices, with ability to set formularies
 - Competing Part B drug benefit managers
- Pricing Changes
 - Biosimilar ASP reforms
 - Medicaid AMP reforms
 - 340B program reforms

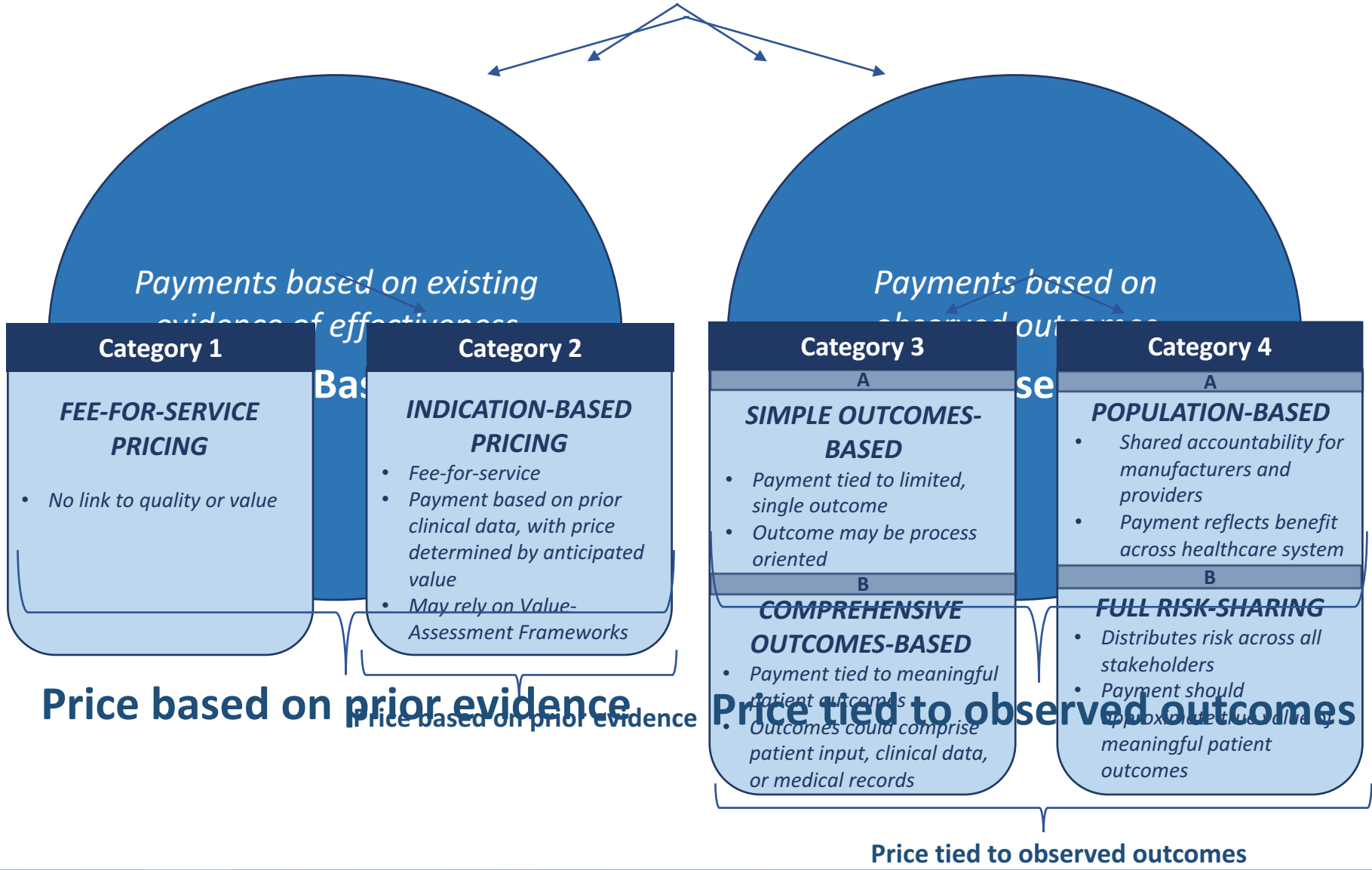
Part D Reforms

- List vs Net Price Adjustments
- Reduced reinsurance for very high drug spending in Medicare through lower Medicare payment share
 - Could be paired with more risk adjustment
- Restructure Medicare copays in Low-Income Subsidy Program, to increase copay differentials for non-preferred brand drugs and generics
- Reassess "protected drug" classes and formulary requirements

Alternative Payment Models (APMs)



VBP Pathway: Moving from Fee-For-Service to Value for Results



Factors influencing outcome-based drug payment reform success and impact

- **Drug factors**

- Indication-specific pricing: clear evidence of variation in effectiveness and safety across different types of patients and uses
- Outcomes-based contracts: uncertainty or disagreement about key aspects of value, such as outcome consequences or benefits relative to existing treatments; potential for manufacturers to improve targeting and quality of use in practice
- “Transformative” treatments where payments based on outcomes over time can also reduce short-term budget impacts

- **Operational factors**

- High-cost, potentially high-value: impact of payment model on reducing payer costs or uncertainty is worth the implementation cost
- Data for key performance measure(s) can be reliably obtained at reasonable cost
- Reasonable consensus on meaningful performance measures related to drug use (outcome, quality, utilization/cost) – preferably including meaningful outcomes or biomarkers that do not require very long-term monitoring
- Opportunity to realize value in short- to medium-term time horizon
- Opportunity for alignment with provider payment reforms

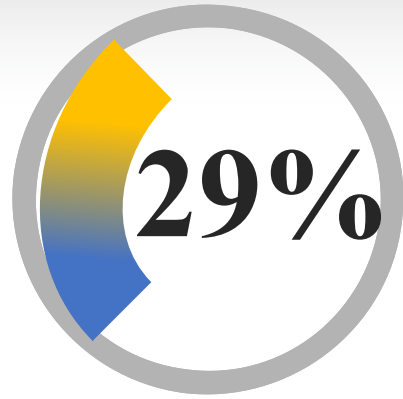
- **Regulatory factors**

- MBP and other pricing rules: confidence that “unit prices” in contract will not adversely affect Medicaid and other best price contracts (smaller outcome-based rebates on larger populations perceived as less risky)
- Limited willingness to explore manufacturer-payer-provider collaborations to provide data/analytics, care management services, etc given potential anti-kickback implications
- Ability to share economic and outcome information to support contract negotiations and

Duke-Margolis Value-Based Payment Consortium Regulatory Reform Recommendations

- **Medicaid Best Price**
 - Reinterpret the bundled sales provision
 - Clarify that rebates based on value negotiated by Medicaid managed care organizations do not trigger MBP
 - Modify basis of measurement for MBP in the context of VBP arrangements through regulatory and/or legislative actions
 - Establish Section 402 demonstrations for VBP arrangements
 - Establish safe harbors for MBP
 - Modify Center for Medicare and Medicaid Innovation (CMMI) statutory authority
- **Anti-Kickback Statute**
 - Reinterpret “volume or value of any referrals” in the context of VBP arrangements
 - Reinterpret “Fair Market Value” in the context of VBP arrangements
 - Revise existing safe harbors to facilitate VBP arrangements
 - Establish a VBP arrangement safe harbor
 - Establish clear policy direction with respect to VBP arrangements
- **FDA Regulation of Manufacturer Communications**
 - Expand the scope and finalize the healthcare economic information (“HCEI”) draft guidance
 - Implement a safe harbor for VBP arrangements
 - Permit dissemination of HCEI related to investigational intended use
 - Leverage 21st Century Cures authorities to facilitate development of VBP arrangements with RWE
 - Promulgate regulations on off-label promotion
 - Establish a safe harbor for pre-approval communication of HCEI
 - Create regulatory certainty for off-label information to support value-based care models

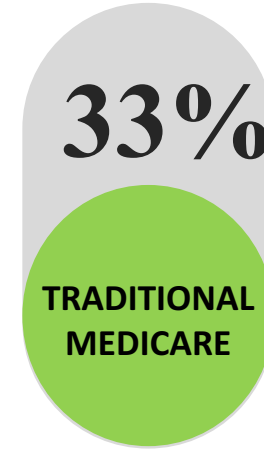
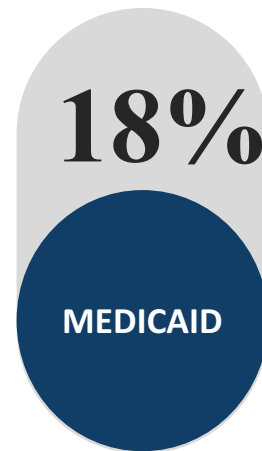
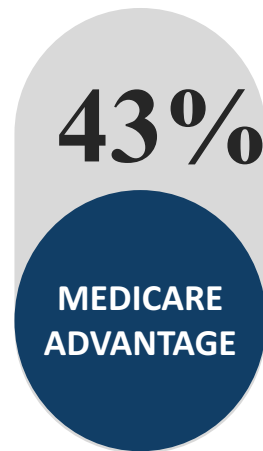
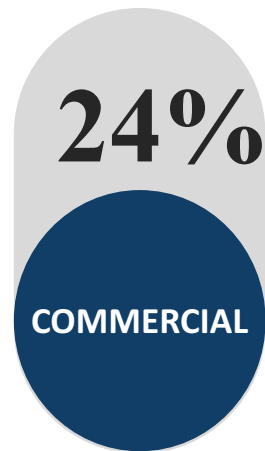
LAN Survey of Health Care Payments



...Of total payments as of late 2016
in LAN categories 3 & 4



% of Healthcare Dollars



New CMS/CMMI Directions for APMs: Work in Progress

- Drugs
- Voluntary
 - Clearer pathway to expansion needed
- Less burdensome for providers
 - Simpler meaningful measures
- Patient/consumer-focused
 - Transparency and public reporting
 - Shared savings with consumers
- More advanced APM options
 - Advanced bundled payment
- Address consolidation
 - ACO/Medicare Shared Savings Program reforms, Direct Primary Care coming
- Specialized care models for physicians
 - OCM, CEC reforms
- Reforms through and in collaboration with private plans and states