Association of Community Cancer Centers

Oncology Reimbursement Meeting

Federal Health Policy: How It May Affect Your Program

June 19, 2018

2018

Agenda

I. Background

II. 340B Drug Discount Program

III. Merit-Based Incentive Payment System (MIPS)

IV. Affordable Care Act (ACA) Rollback

V. Drug Pricing Trends

VI. Oncology Care Model (OCM)

VII. New Reimbursement Models

VIII. Takeaways

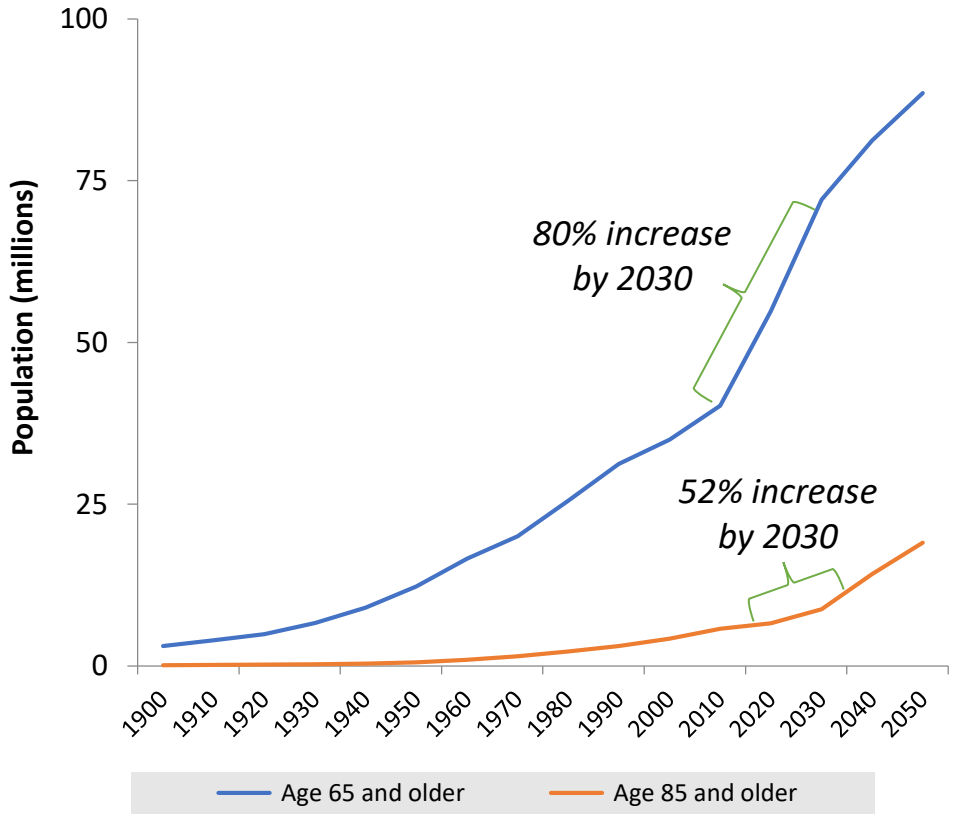
I. Background

I. Background

Medicare and Medicaid Growth

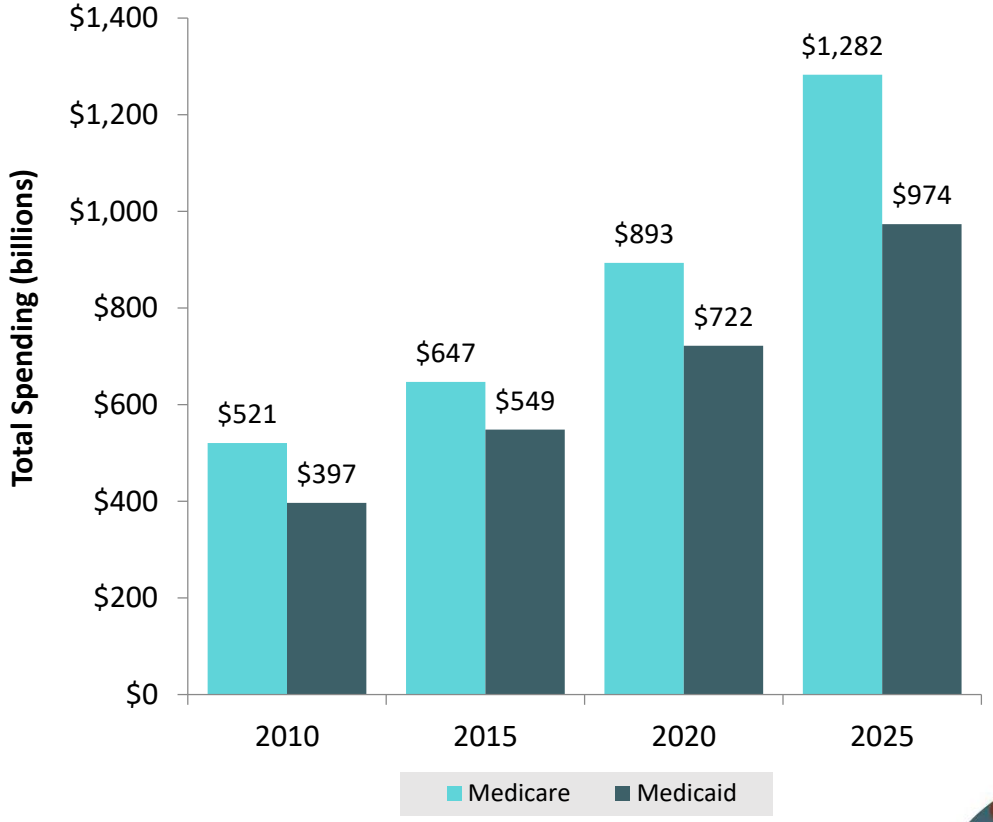
About 3.6 million people age into Medicare every year, creating a greater impetus for the government and providers to rethink how care is delivered and funded.

Population Projections



Source: US Department of Health & Human Services (HHS), Administration on Aging.

Projected Spending

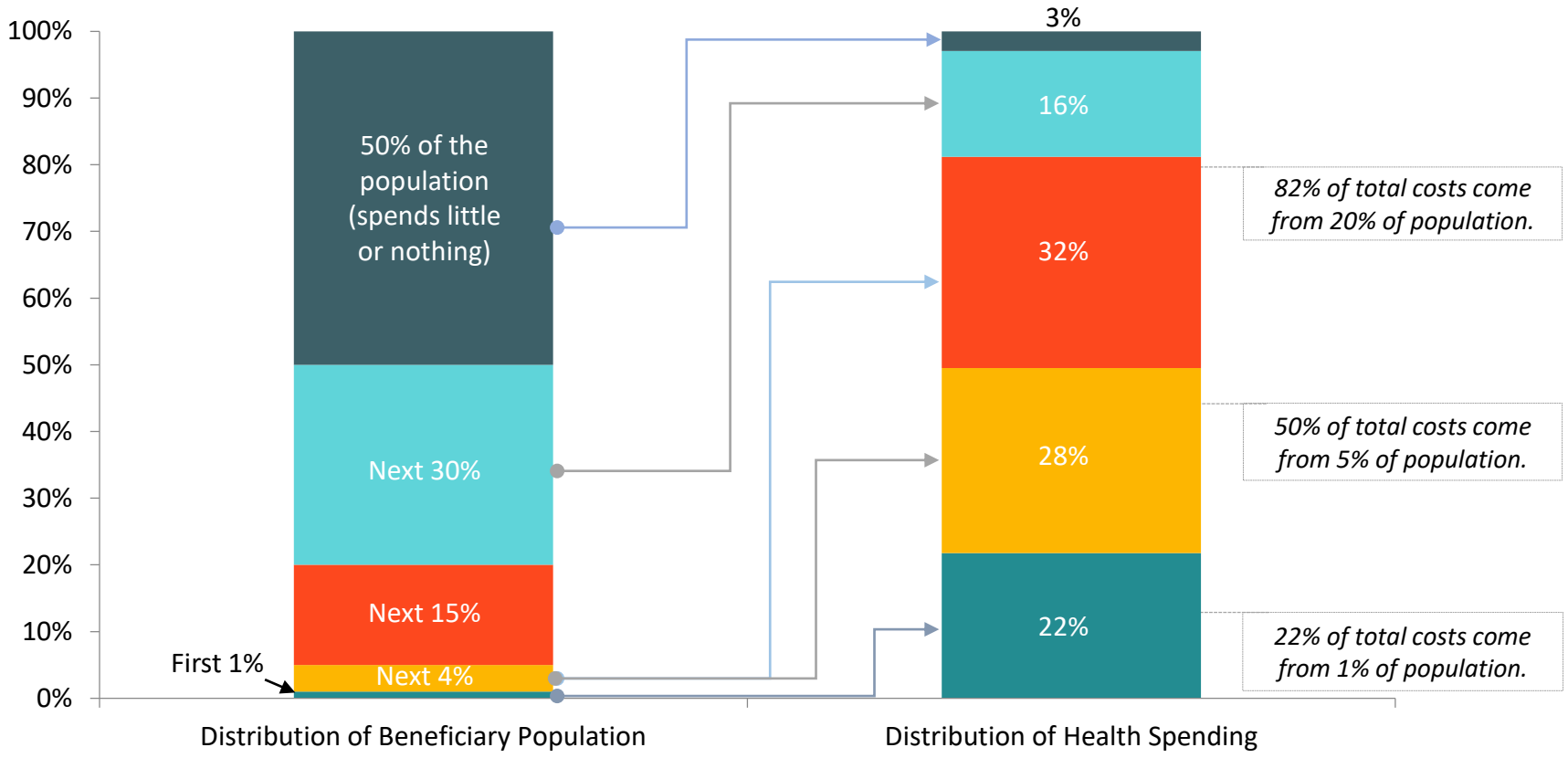


Source: Centers for Medicare & Medicaid Services (CMS), National Health Expenditure Data.

I. Background

5% of Patients Responsible for 50% of Costs

In a fee-for-service (FFS) world, the top 5% of patients (by usage) drive margins; in a value-based world, the top 5% pose a financial challenge that must be well-managed.



Note: Figures may not be exact due to rounding.

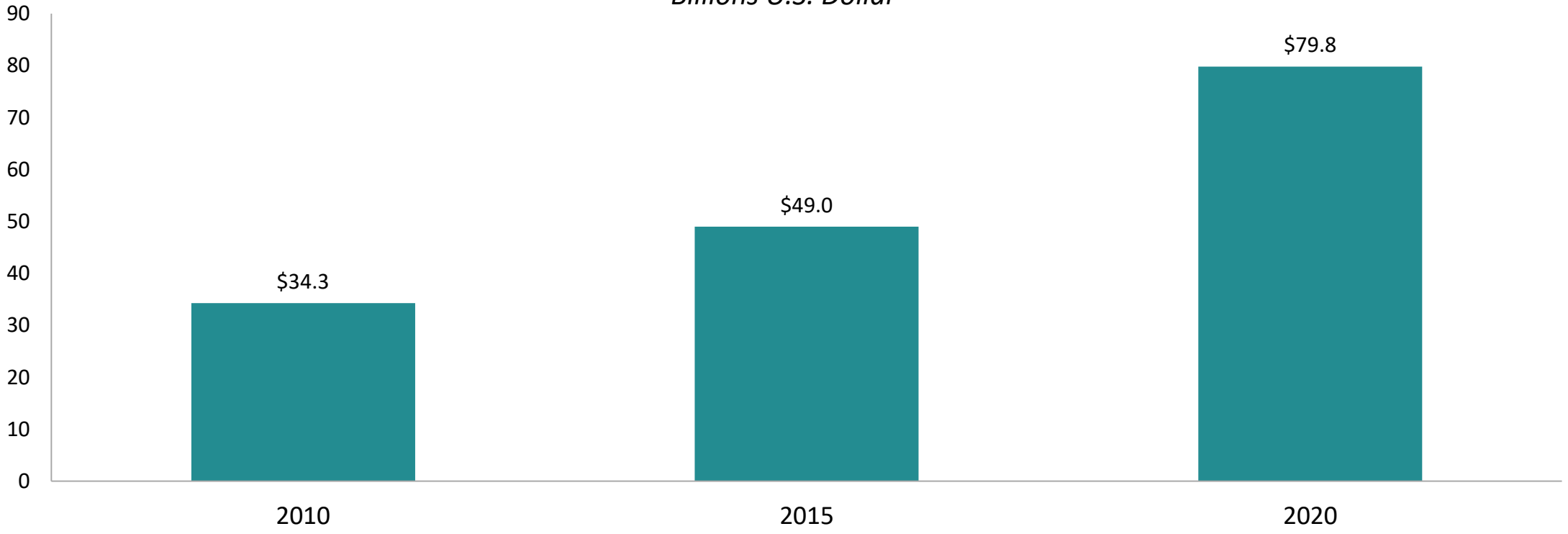
I. Background

U.S. Spending on Oncology

U.S. spending on oncology care is projected to grow rapidly, reaching nearly $80 billion by 2020.

Estimated Annual U.S. Spending on Oncology

Billions U.S. Dollar[1]



[1] Includes diagnosis, surgery, hospitalization, and palliative and end-of-life care. Source: "Global Oncology Trend Report: A Review of 2015 and Outlook to 2020," IMS Institute for Healthcare Informatics, June 2016.

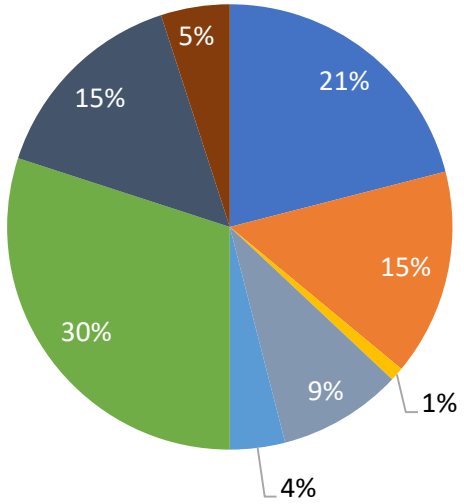
2018

I. Background

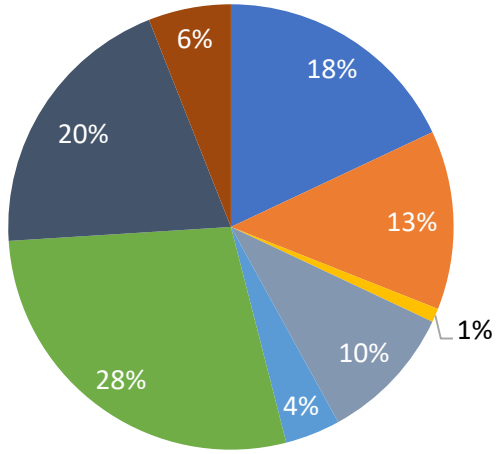
U.S. Spending on Oncology *(continued)*

Average spending per commercial patient increased by 62% from 2004 to 2014. Chemotherapy[1] is a key cost driver and represents a growing share of total expenditures.

Commercial Spending by Service, 2004 ($55,789 per Patient)



Commercial Spending by Service, 2014 ($90,656 per Patient)



Hospital Inpatient Admissions | Cancer Surgeries | ER | Radiology (Other)
Radiation Oncology | Other Outpatient Services | Chemotherapy | Other Services

Source: "The Evolution of Oncology Payment Models: What Can We Learn from Early Experiments?," Deloitte Center for Health Solutions.

[1] Chemotherapy includes cytotoxic chemotherapy, other chemo and cancer drugs, and biologic chemotherapy.

II. 340B Drug Discount Program

II. 340B Drug Discount Program

Overview

Savings from the 340B Drug Discount Program are used by participating hospitals to subsidize charity care or to offer nonreimbursable services such as cancer navigators, nutrition, and social support services to patients.

- Since 1992, the program allows covered entities to purchase separately payable outpatient prescription drugs and biologicals at significantly discounted prices.
- Drug manufacturers that participate in Medicaid are required to participate in the 340B program.
- The mission of the program is to support participating hospitals' abilities to provide services to disadvantaged and underserved patients.
- Proponents claim that without 340B operating margins, they would not be able to invest in capital improvements or offer critical nonreimbursable support services.
- Opponents of 340B claim that the program lacks oversight and that many participating hospitals do not return the funds to the community as they should.

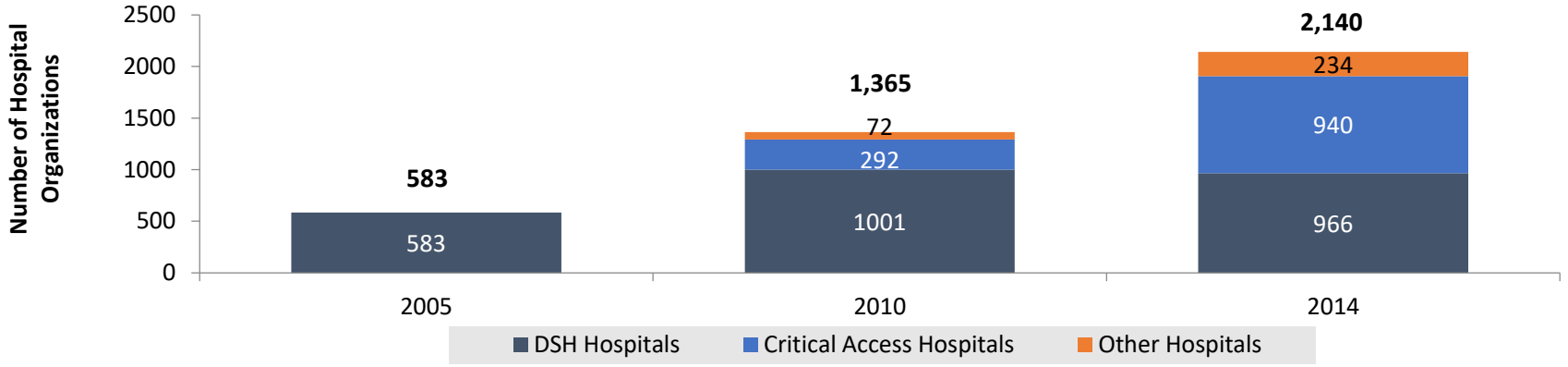
Notes: http://www.medpac.gov/docs/default-source/reports/may-2015-report-to-the-congress-overview-of-the-340b-drug-pricing-program.pdf?sfvrsn=0.
https://s3.amazonaws.com/public-inspection.federalregister.gov/2017-23932.pdf.

2018

II. 340B Drug Discount Program

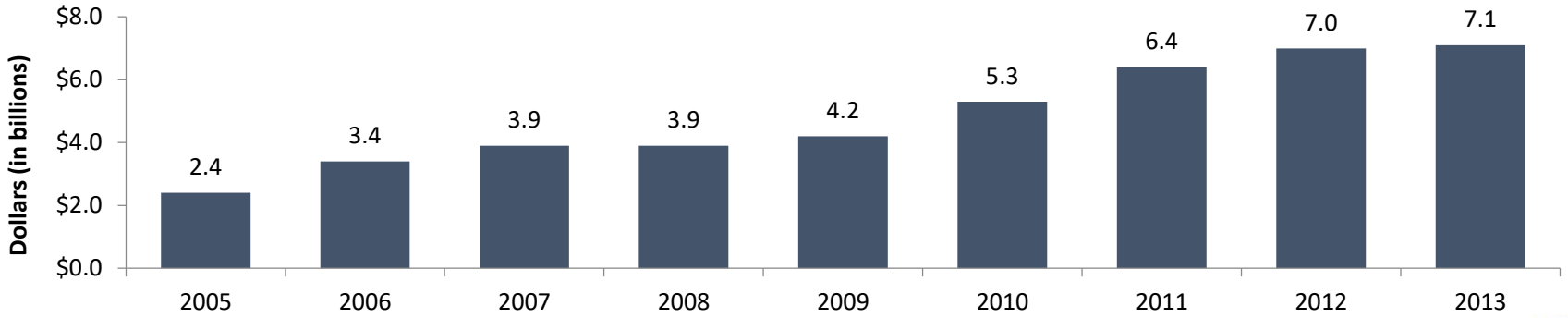
MedPAC Targets 340B Hospitals for Reductions

As the number of organizations participating in 340B and expenditures on the program have grown, MedPAC has focused on reducing spending.



The number of hospital organizations participating in the 340B program more than tripled between 2005 and 2014.

The amount spent by covered entities on 340B drugs tripled from 2005 to 2013.



Source: MedPAC *Report to the Congress: Overview of the 340B Drug Pricing Program*, May 2015.

II. 340B Drug Discount Program

340B Reimbursement Changes

CMS modified 340B funding for 2018. Medicare payments to hospitals for most separately payable drugs acquired through the 340B program will be subject to a payment reduction of approximately 30%.

Overview of the Payment Cut

- Payment reduction is only applicable to payments made under the Medicare hospital OPPS.
- Payment rate is reduced from ASP plus 6% to ASP minus 22.5%.
- "Savings" generated from the payment cuts are redistributed across all hospitals/services paid under OPPS.
  - Therefore, it is possible that some 340B hospitals could see a net gain from the payment cuts.
  - All non-340B hospitals will see a payment increase.

II. 340B Drug Discount Program

Effects on Non-340B Hospitals

All hospitals participating in 340B except Critical Access Hospitals and Maryland waiver hospitals will need to use new claim modifiers to ensure the proper reimbursement. Hospitals are responsible for indicating when they are owed the non-340B reimbursement rate, which is still ASP plus 6%.

Increased Administrative Burden

- Hospitals billing Part B must add a modifier to claims indicating a drug was ***not*** purchased at 340B prices.
- Without the modifier, CMS will assume the drug was purchased at 340B prices and therefore reimburse at the reduced rate of ASP minus 22.5%.

Source: https://www.advisory.com/research/care-transformation-center/care-transformation-center-blog/2017/07/pef-6-things-340b-and-non-340b.

II. 340B Drug Discount Program

Exclusions

Several exclusions were included in the new rule, as listed below.

Exclusions
• Does not apply to most contract pharmacy arrangements • Does not apply to Critical Access Hospitals • Does not apply to Maryland waiver hospitals • Does not apply to hospital departments excluded from OPPS under the 2015 Section 603 Site-Neutral Payments Provision (at least for now…) • Currently excludes rural sole community hospitals (disproportionate share hospitals [DSHs]), IPPS-exempt cancer hospitals, and children's hospitals, but that may change in the future

II. 340B Drug Discount Program

Litigation Activities

> Although the reimbursement changes have gone into effect, legal activities are underway to contract the scope of the regulation.

Litigation

- Litigation to stop payment cuts was filed by hospital associations and 340B hospitals.
  - Case was dismissed on December 29, 2017.
  - Judge ruled that plaintiffs did not have standing to file the suit.
  - Judge did not rule on the merits of the case.
  - Appeal was filed in early January 2018.
- Expect continued litigation following payment of a claim at the reduced rate.
- Underlying legal issues are related to administrative law as well as the intent of the 340B program.

Recent Developments: March 2018

- Plaintiffs filed court papers detailing the significant impact of the 340B cuts.
- HHS filed a brief defending the cuts on March 20.
- The plaintiffs' response is due April 2 and oral arguments in the case are scheduled for May 4.

II. 340B Drug Discount Program

Legislative Activities

> Several legislative activities aimed at eliminating or slowing down Medicare cuts to 340B are also under development.

Legislation

- Multiple legislative efforts are in process, including the following:
  - HR 4392: This would prevent CMS from implementing the payment cuts; it has significant bipartisan support.
  - HR 4710 (340B PAUSE Act): This would impose a two-year moratorium on new 340B DSHs and locations and would also require for DSHs, cancer hospitals, and children's hospitals: (1) additional data reporting, (2) OIG study on charity care, and (3) GAO report on hospital/government contracts and 340B revenue.
  - S 2312 (HELP Act): It would also impose a two-year (possibly longer) moratorium on new 340B DSHs and locations. This law is similar to but more comprehensive than HR 4710.
- Areas of focus for new legislation include:
  - Strong focus on 340B-participating hospitals (not on grantees) and limitations on patient eligibility.
  - Limits on amounts that could be charged for 340B drugs.
  - Limits on contract pharmacies by number and location.
  - Required reporting of amount and use of 340B savings.

The uncertainty and risk currently associated with the 340B program is likely to continue in the foreseeable future.

III. Merit-Based Incentive Payment System

III. Merit-Based Incentive Payment System

Overview of the Final Rule

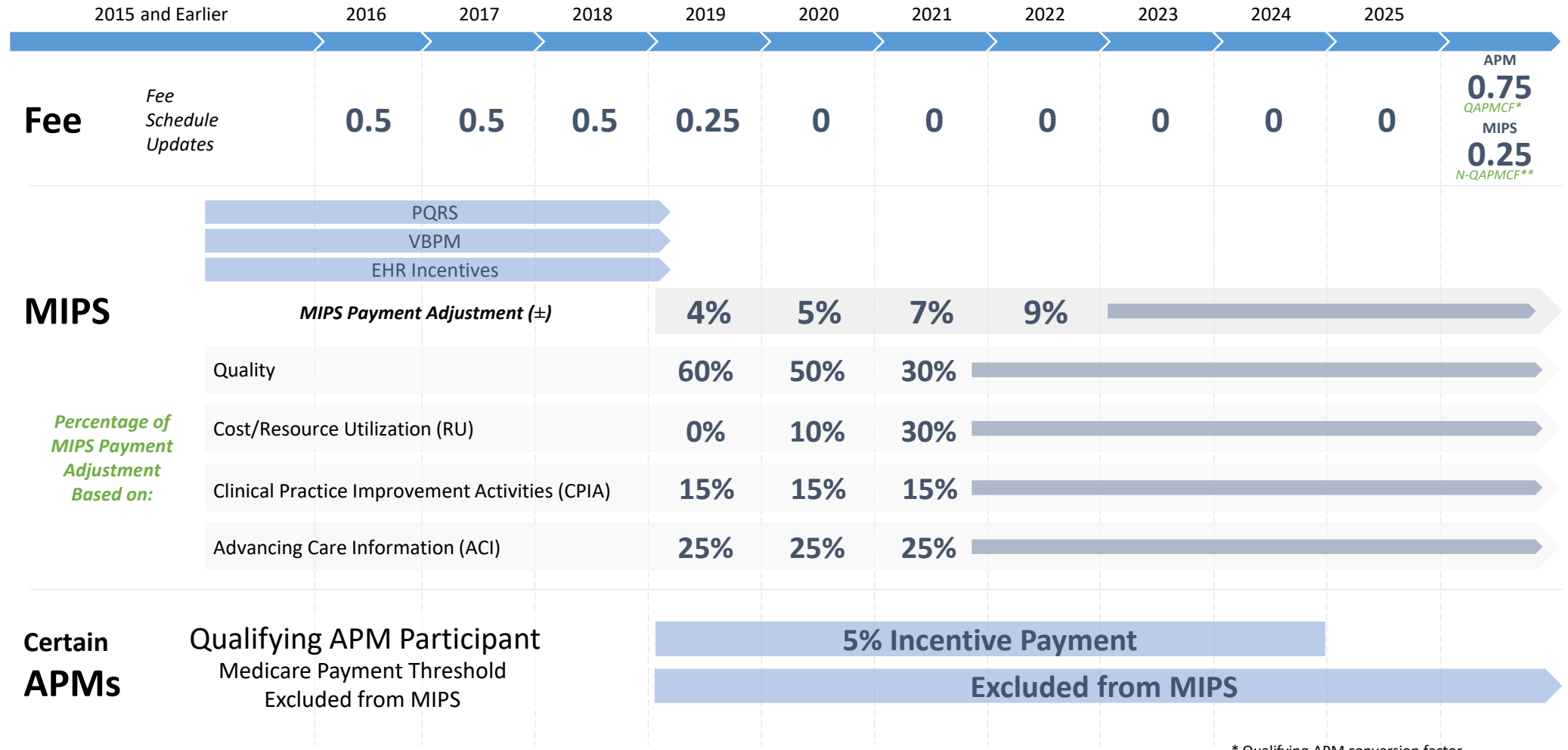
MACRA institutes a new payment structure that will place most providers that accept Medicare beneficiaries at risk for their value-based performance.

Key Provisions

Two-Track System	• MIPS • Advanced Alternative Payment Models (APMs)
More Consistent Rate Increases	• Rate increases have been standardized at 0.5% for 2016 through 2018 and 0.25% for 2019. • Rates will remain constant from 2020 through 2025. • Beginning in 2026, rate increases will be dependent on an eligible clinician's designated track (MIPS at 0.25% and APMs at 0.75%).
Integrated Quality Payment Program (QPP)	• The MIPS track combines the historical Physician Quality Reporting System (PQRS), meaningful use (MU), and the VBPM program. • The APM track includes similar performance categories, and metrics already incorporate value-based payment programs.

III. Merit-Based Incentive Payment System

Payment Adjustments Summary



Source: CMS, "The Medicare Access and CHIP Reauthorization Act of 2015: Path to Value."

* Qualifying APM conversion factor.
** Nonqualifying APM conversion factor.

2018

III. Merit-Based Incentive Payment System

Summary of 2018 Changes

The 2018 final rule extends and expands upon many of the transition features from the 2017 final rule. The Bipartisan Budget Act of 2018 also includes a number of revisions to MIPS.

Repeal of MIPS Payment Adjustment to Part B Drugs

The MIPS payment adjustment was limited to professional services only.

Physician Fee Schedule

The 2019 update to the MPFS was reduced from 0.50% to 0.25%.

Provider Minimum Participation

The Medicare low-volume threshold has been raised (<$90,000 in Part B allowed charges or <200 Part B beneficiaries), meaning that more practices (32.5%) will be exempt from MIPS.

Performance Threshold

The performance threshold has been increased from 3 to 15 points.

III. Merit-Based Incentive Payment System

Summary of 2018 Changes *(continued)*

No More "Pick Your Pace"

- In 2017, CMS provided several options to avoid a negative payment adjustment in 2019.
- Physicians must report fully in 2018 to avoid negative adjustments in 2020.

Quality Measures

- There is less credit given for quality measures with incomplete data (1 point vs. 3 points in 2017).
- Data completeness standard was increased to 60%.

Performance Period

- 12-month calendar year for quality and cost measures.
- 90 days for ACI and improvement activities.

Cost Component

- Cost measures will be assessed in 2018, weighted at 10% of the MIPS final score.
- For the second through fifth years of the program (2020 through 2023), the cost performance category "shall not be less than 10% and not more than 30% of the MIPS score."

III. Merit-Based Incentive Payment System

Summary of 2018 Changes *(continued)*

Group Reporting Options

The option to report as a virtual group was added.

Bonus Points

- Bonus points are available in 2018 for demonstrating improvement in quality (10%) and cost (1%) compared to 2017.
- Up to 5 bonus points are available for practices with 15 or fewer clinicians.
- Up to 5 bonus points are available as measured by the Hierarchical Condition Category risk score and percentage of dual-eligible beneficiaries.
- There is an up to 25% bonus for high-priority measures and end-to-end reporting for ACI.

EHR Editions

Credit for 2014 edition certified EHR is allowed.

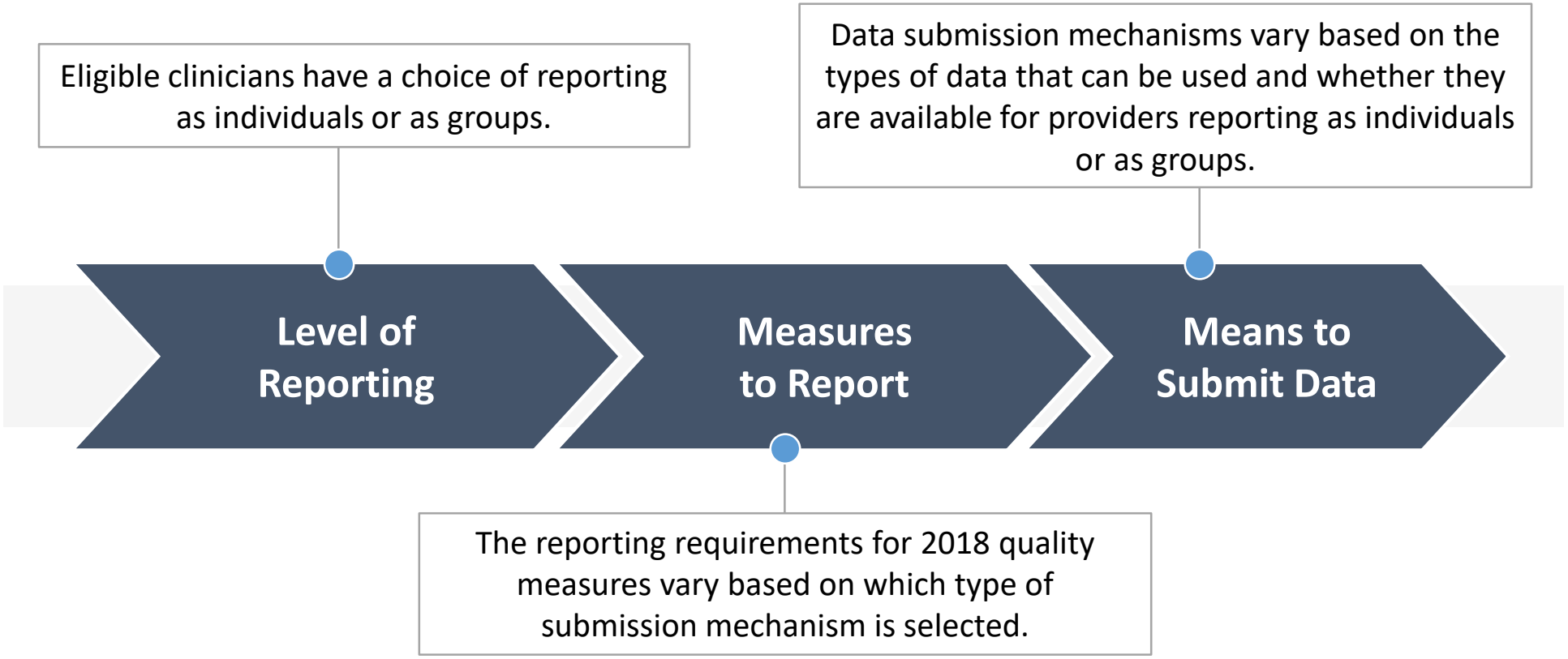
Submission Methods

- A different submission method can be used for each performance category.
- CMS may make the option to use different submission methods within each performance category available in future years.

III. Merit-Based Incentive Payment System

Decision-Making Framework and Key Decision Points

There are three major categories of decisions that must be made: (1) at which level to report, (2) which measures to report, and (3) through which means the data should be submitted.



This is not an entirely linear decision-making process, as the decisions are interrelated.

III. Merit-Based Incentive Payment System

Levels of Reporting

New for 2018

	Individual	Group	Virtual Group
Definition	Single NPI tied to a single TIN	Set of clinicians (identified by NPI) sharing a TIN	Different TINs (with 1 to 10 MIPS-eligible clinicians) coming together with at least one other such TIN to form a virtual group
Reporting	Individual data	Group-level data	Virtual group–level data
Basis of Payment Adjustment	Individual performance	One payment adjustment based on group's performance	One payment adjustment based on group's performance
Common Submission Methods	EHR, qualified registry, QCDR	EHR, qualified registry, QCDR	EHR, qualified registry, QCDR
Unique Submission Methods	Medicare claims	CMS web interface (25 or more)	CMS web interface (25 or more)
CAHPS for MIPS Survey	Not applicable	Can include as one quality measure	Can include as one quality measure
All-Cause Hospital Readmission Measure	Not applicable	Applicable to groups of 16 or more	Applicable to groups of 16 or more

III. Merit-Based Incentive Payment System

Reporting-Level Considerations

	Individual Reporting	*Group Reporting*
Flexibility/ Relevance	You have the ability to select measures relevant to your oncology practice.	You may forfeit the ability to select measures (CMS Web Interface, measures are preselected and primary care–focused).
Performance	If your performance is low, joining a group may help boost your scores.	Poor performers may bring your scores down; strong performers may bring your scores up.
Activity Participation	Each individual must meet all reporting requirements.	Only one clinician needs to participate in an improvement activity.
Minimum Thresholds	Each individual must meet the minimum case thresholds.	The same minimum case thresholds are applied to the whole group.
Additional Requirements	There are no additional reporting requirements.	Groups of 15 or more clinicians must report all-cause hospital readmissions.
Exempt Clinicians	Allows clinicians exempt from MIPS to avoid reporting their performance.	You must report on all clinicians in the group, including those who are exempt.

III. Merit-Based Incentive Payment System

Performance Reporting Options

CMS has outlined several methods for an organization to report data; aligning the reporting method across the incentive categories can present an opportunity to gain efficiencies and earn bonus points.

Reporting Method	Description	Quality	CPIA	ACI
QCDR	Registries that meet CMS qualifications and can report more than just PQRS measures	✓	✓	✓
EHR	EHRs that interface directly with CMS	✓	✓	✓
Qualified Registry	Registries that meet CMS qualifications but report only PQRS measures	✓	✓	✓
CMS Web Interface	Reporting via QPP website (groups of 25 or more only)	✓	✓	✓
Attestation	Attest via the QPP website		✓	✓
CAHPS Vendor	CMS-certified CAHPS vendors (groups only)	✓		
Claims	CMS has claims data; clinicians will need to add certain billing codes to eligible claims (individual reporting only)	✓		

Organizations can earn bonus points for end-to-end electronic reporting in the Quality category (up to 10% of the denominator).

2018

III. Merit-Based Incentive Payment System

Quality Measure Selection Strategies

Strategies to Use

Select Measures Relevant to Practice

- Pick measures relevant to your practice area (specialty-specific measures).
- Choose measures that impact outcomes for the patient and the practice.
- Select measures in areas in which the practice performs well.

Reduce Administrative Burden

- Look for opportunities to utilize measures already being reported under a previous program.
- Review your Quality and Resource Use Report to identify quality measures you have already reported and in which you performed well.

Maximize Performance Opportunities

- Evaluate availability of benchmarks (non-MIPS quality measures will receive a maximum of 3 points due to lack of benchmarks).
- Evaluate differences in benchmarks between submission methods.
- Avoid topped-out measures.
- Ensure you have enough patient volume to meet minimum thresholds.
- Consider whether the performance rate is achievable for the selected measures/submission methods.
- Consider bonus points for chosen measures (outcome, high priority, patient experience).
- Determine whether the manner in which you chose to report will meet end-to-end reporting bonus requirements.

III. Merit-Based Incentive Payment System

Measure Selection Strategies

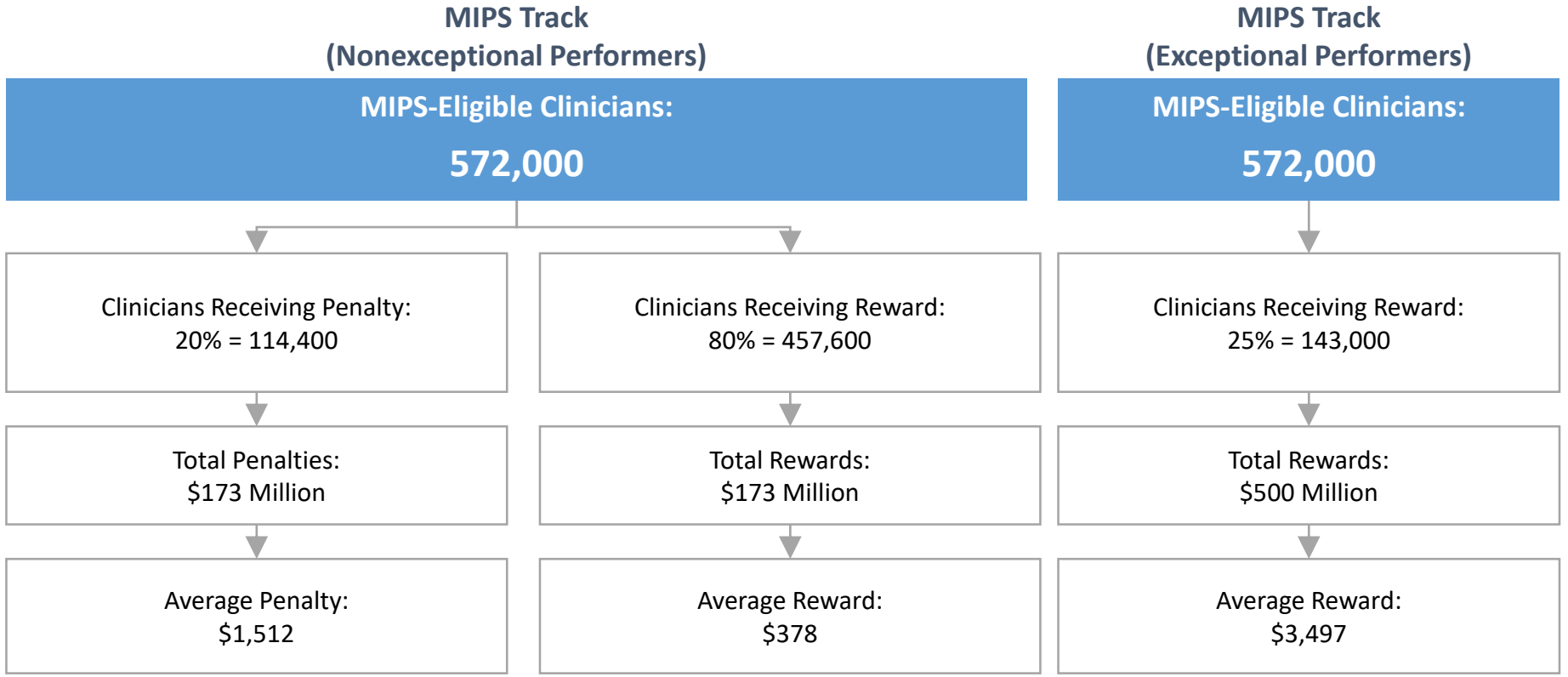
Strategies to Avoid

- Picking a submission method (EHR, QCDR, etc.) solely based on the number of measures available
- Focusing on measures offered by your EHR vendor
- Setting your strategy based on your organization's traditional reporting methods

III. Merit-Based Incentive Payment System

Some Rough Numbers

While it is not possible to estimate MACRA's penalties and rewards with accuracy, we can make reasonable estimates based on information provided by CMS.[1]



[1] Number of participants and aggregate bonuses/penalties provided by CMS in the 2018 proposed rule.

The reputational impact associated with public reporting of clinician performance should also be considered.

IV. ACA Rollback

IV. ACA Rollback

Legislative Action

> The Trump administration's efforts over the past year to roll back the ACA have focused on weakening the law's provisions as opposed to fully repealing the law.

December 2017

- Eliminated the individual mandate by reducing the penalty to zero.

February 2018

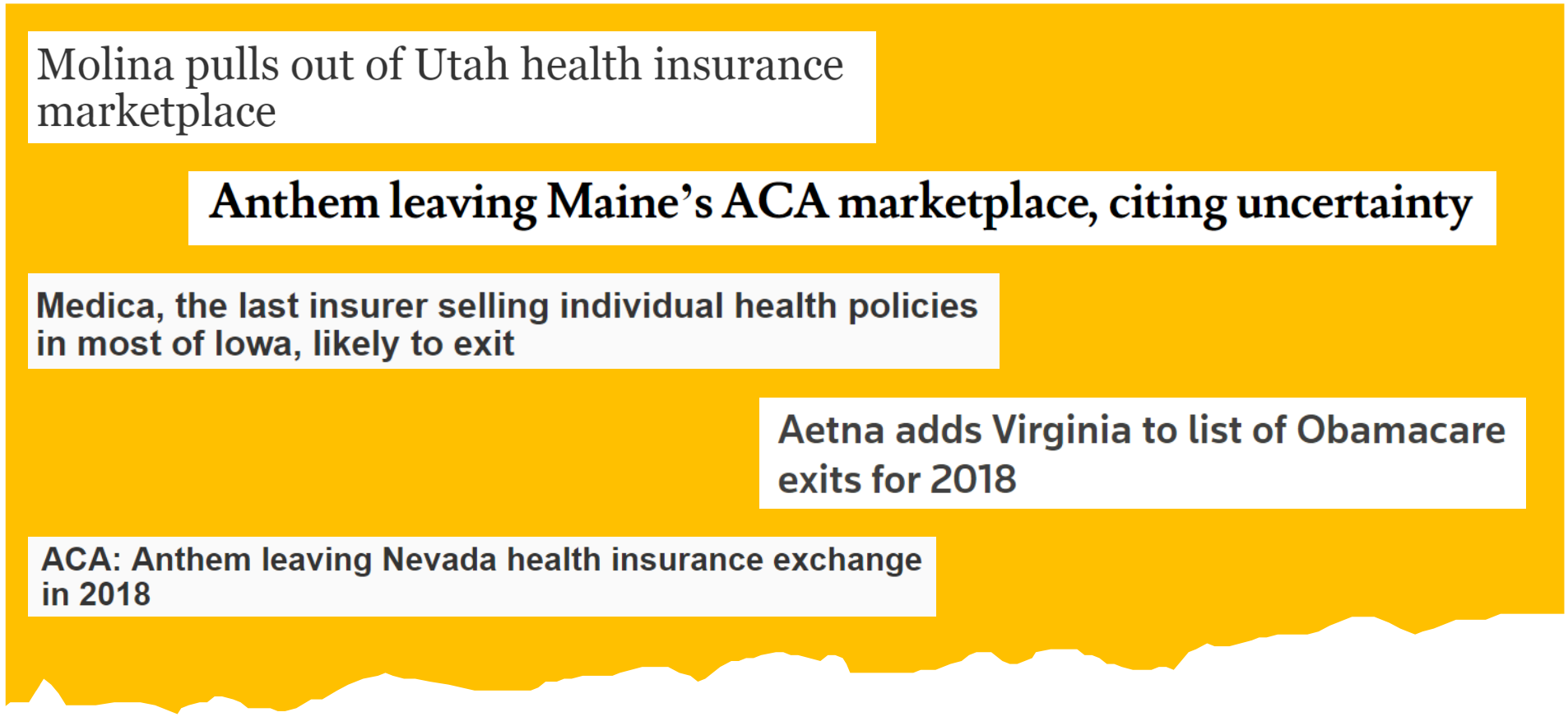
- Proposed regulations making it easier for health insurers to sell short-term coverage policies, which are generally cheaper because they exclude key benefits mandated by the ACA. Under the regulations, short-term plans:
  - Do not have to cover mental health and other "essential benefits."
  - Can have annual or lifetime limits on the bills the insurance company will pay.
  - Are available only to individuals with good health status.

Source: https://www.huffingtonpost.com/entry/trump-obamacare-insurance-rules_us_5a3d3cb5e4b06d1621b42a1b.

IV. ACA Rollback

Insurer Participation in ACA Marketplaces

News of insurers exiting ACA health insurance marketplaces made headlines across the country through the latter half of 2017, and the trend is likely to continue as legislation rolling back Obamacare goes into effect.

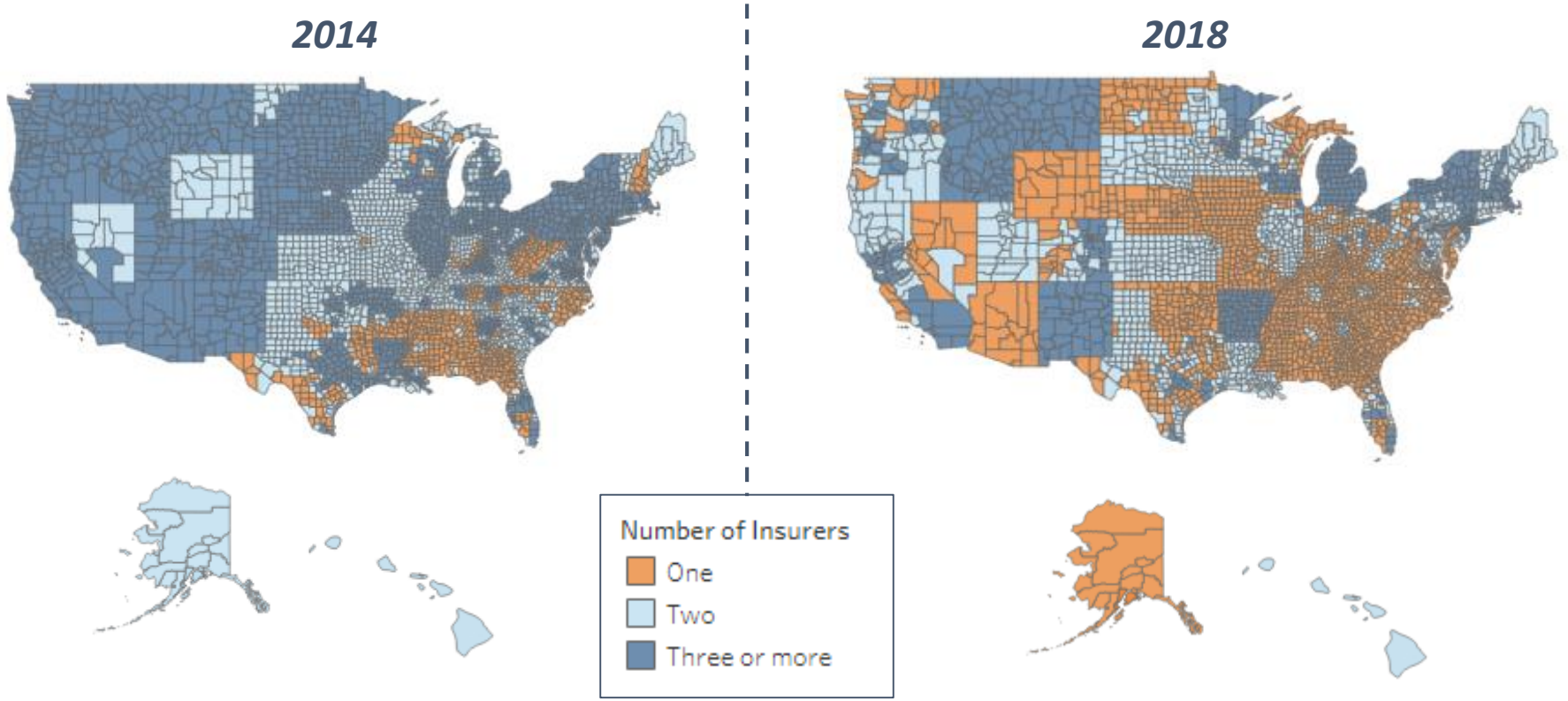


IV. ACA Rollback

Insurer Participation in ACA Marketplaces *(continued)*

In 2018, 48% of enrollees (living in about 18% of counties) have a choice of three or more insurers, down from 58% in 2017 and 85% in 2016.

Insurer Participation on ACA Marketplaces: 2014 versus 2018



Source: https://www.kff.org/health-reform/issue-brief/insurer-participation-on-aca-marketplaces/.

IV. ACA Rollback

Expected Impacts

Eliminating the individual mandate is estimated to leave 4 million people without insurance over the course of one year. Other anticipated impacts are listed below.

The insurance market is expected to continue to erode as enrollment continues to drop and insurers exit ACA marketplaces.

Re-emergence of short-term coverage policies will increase financial risk for consumers over the long term.

The higher risk profile of enrollees who remain on ACA exchange products will drive up insurance premiums.

Hospitals will see increases in bad debt due to growth of the uninsured population.

Note: Estimated increase of 10% according to *Health Affairs*: "Eliminating the Individual Mandate Penalty in California: Harmful but Non-Fatal Changes In Enrollment and Premiums." https://www.healthaffairs.org/do/10.1377/hblog20180223.551552/full/.

V. Drug Pricing Trends

V. Drug Pricing Trends

Rising Costs

Patients, providers, and payors alike are experiencing significant financial pressures due to the cost of cancer care drugs. The sustained increases in costs over recent years have accelerated interest in industry-wide drug pricing reform.

Rising Unaffordability of Care[1]

25% . . . of all cancer patients chose not to fill a prescription due to cost in 2013.

20% . . . of all cancer patients filled only part of a prescription or took less than the prescribed amount.

30% . . . of Medicare patients failed to fill their prescription for Gleevec, a life-saving leukemia drug that costs up to $146,000 per year.

ONE Cancer treatment

As much as **$300,000** Annual cost[2]

Rising Drug Spending[3]

- Drugs currently account for **19%** of total U.S. healthcare spending.
- Spending on drugs is projected to **outpace Medicare Part A and Part B** at a growth rate of 1% per year.

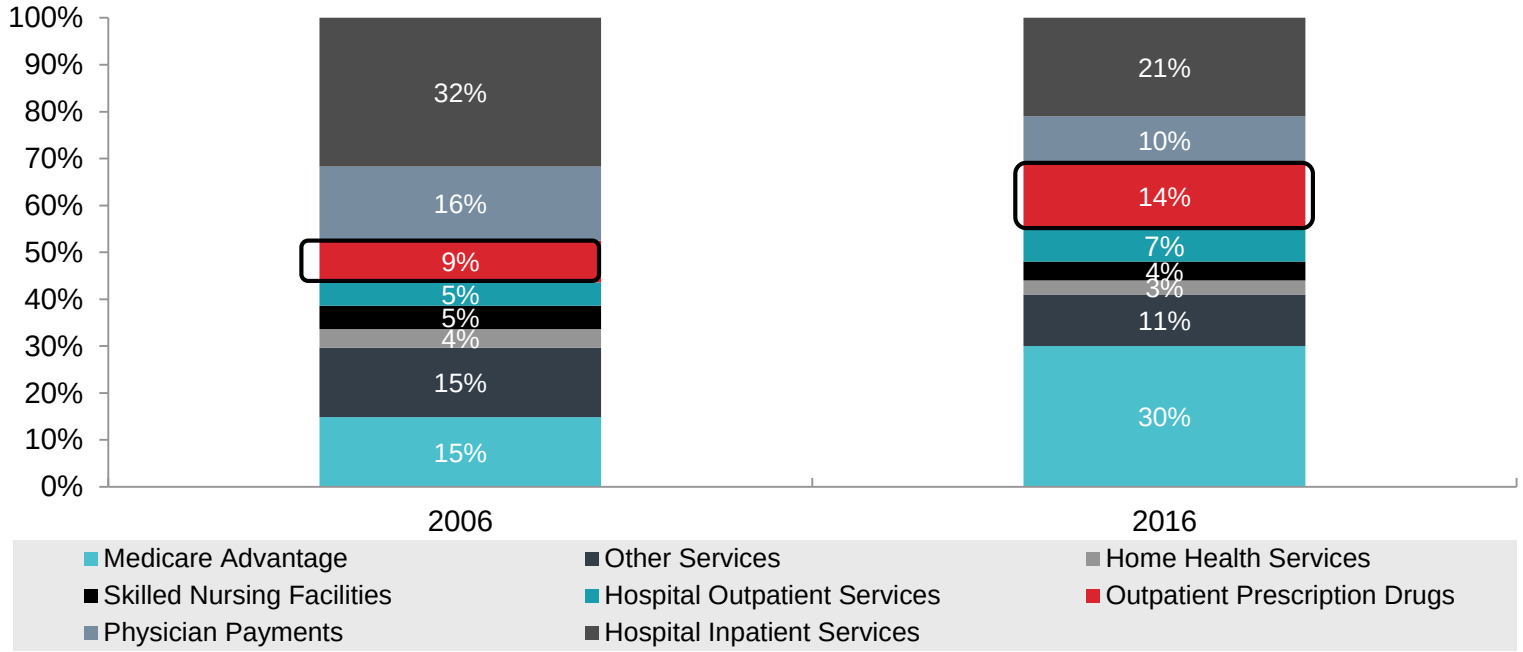
[1] http://www.npr.org/sections/health-shots/2017/03/15/520110742/as-drug-costs-soar-people-delay-or-skip-cancer-treatments.
[2] ASCO *State of Cancer Care in America* reports for 2016 and 2017.
[3] http://www.ascopost.com/issues/march-10-2017/value-based-approaches-to-the-rising-costs-of-cancer-drugs/.

V. Drug Pricing Trends

Pressure to Reduce Costs

CMS is exploring a number of strategies to reduce overall costs. Drug reimbursement methodology is under particular scrutiny because drugs represent such a significant portion of Medicare's annual benefit payments.

Medicare Benefit Payments by Type of Service, 2006 and 2016



Sources: Juliette Cubanski and Tricia Neuman, Henry J. Kaiser Family Foundation, "The Facts On Medicare Spending and Financing," 2016, https://www.kff.org/medicare/issue-brief/the-facts-on-medicare-spending-and-financing); in 2016, Medicare represented 15% and Medicaid 10% of the total federal budget. Congressional Budget Office, June 2017, Medicare Baseline.

Notes: Consists of Medicare benefits spending on hospice, durable medical equipment, Part B drugs, outpatient dialysis, ambulance, lab services, and other Part B services. Figures may not be exact due to rounding.

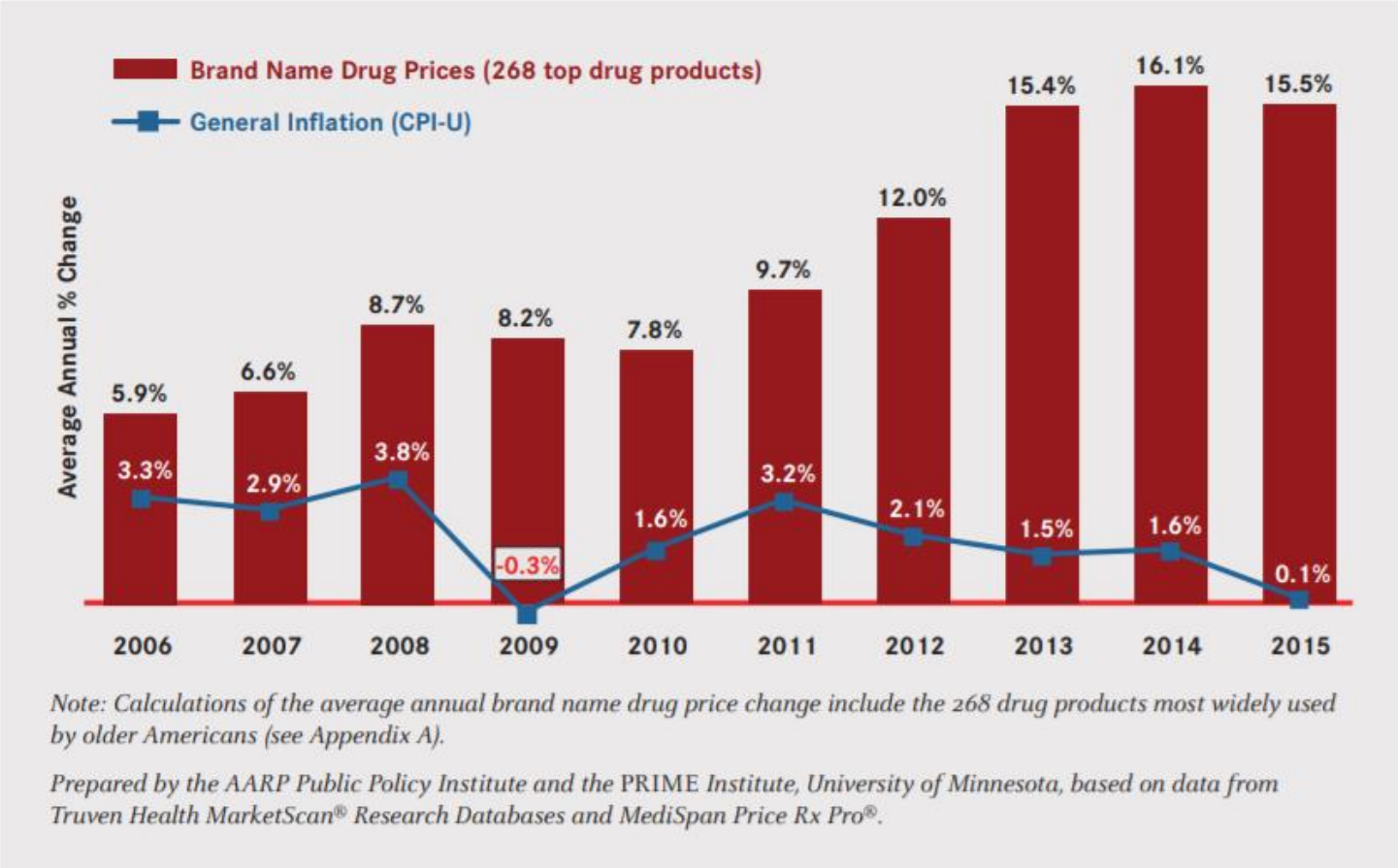
With pressures such as the projected depletion of the Medicare Part A trust fund by 2027, CMS has renewed its focus on reducing costs across the system.

2018

V. Drug Pricing Trends

Drug Price Growth

Drug prices have soared in recent years, particularly for older Americans.



Note: Calculations of the average annual brand name drug price change include the 268 drug products most widely used by older Americans (see Appendix A).

Prepared by the AARP Public Policy Institute and the PRIME Institute, University of Minnesota, based on data from Truven Health MarketScan® Research Databases and MediSpan Price Rx Pro®.

Source: AARP Public Policy Institute, "Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans, 2006 to 2015."

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V. Drug Pricing Trends

What's the Problem?

> There are lots of issues; particularly if you follow the money. The business model revolves around opaque rules, a ton of regulation, implications from a global market, and the limited ability for the largest purchaser to negotiate price.

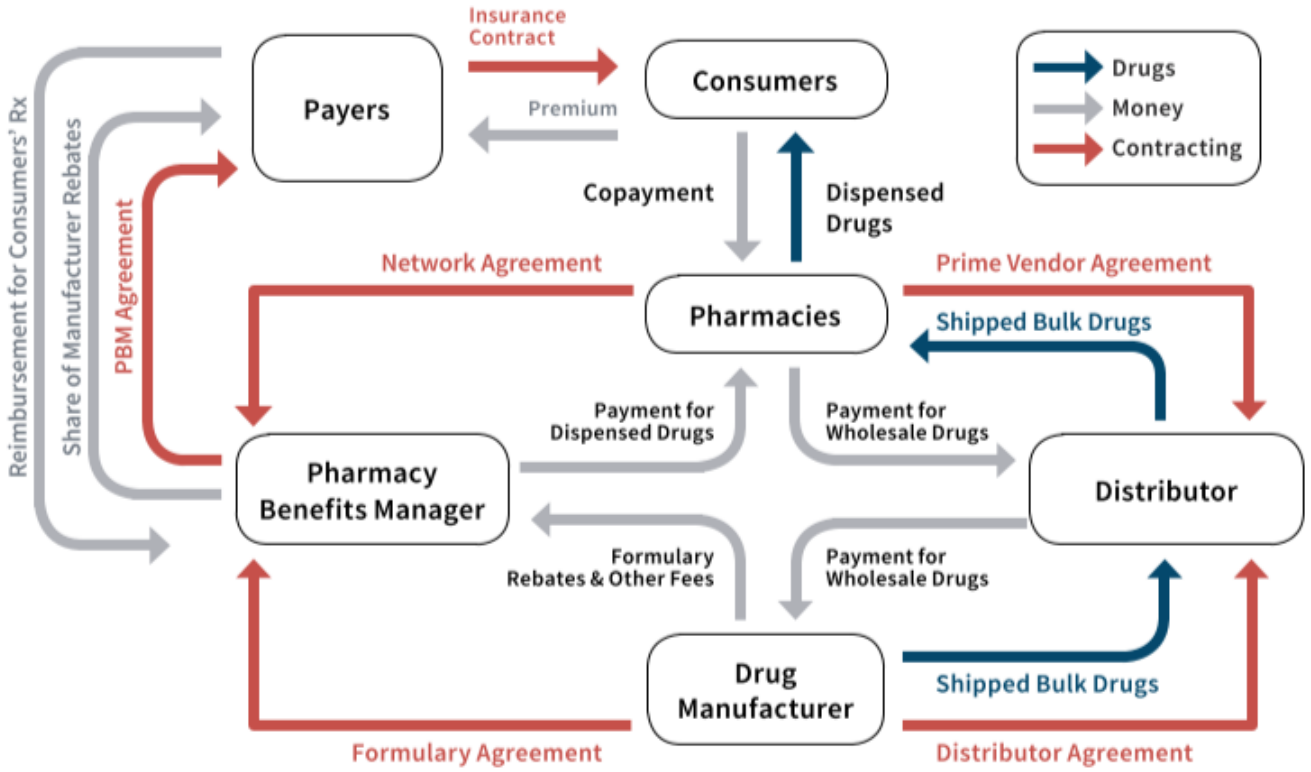

FIGURE 1

ADAPTED FROM: Fein, Adam. J., The 2016 Economic Report on Retail, Mail and Specialty Pharmacies, Drug Channels Institute, January 2016.

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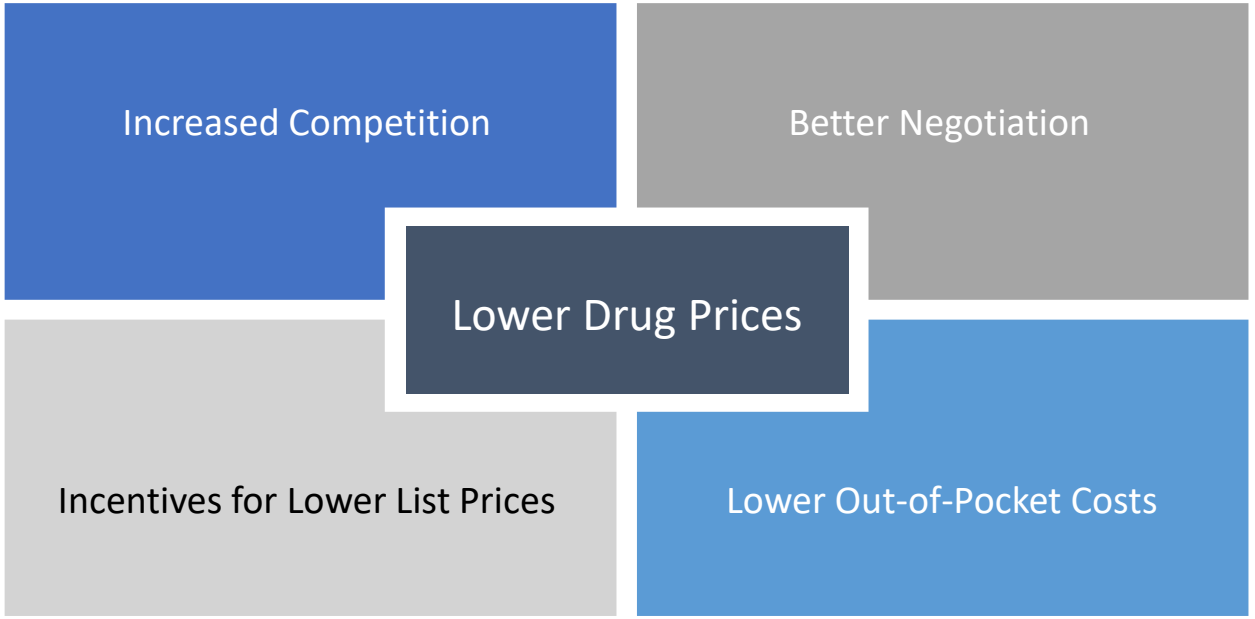
V. Drug Pricing Trends

Trump Administration Blueprint

In response, the Trump administration issued a four-platform “blueprint” to lower prices.



V. Drug Pricing Trends

Key Tactics

While much of the blueprint still lacks detail, the administration has started to outline specific tactics it plans to deploy.

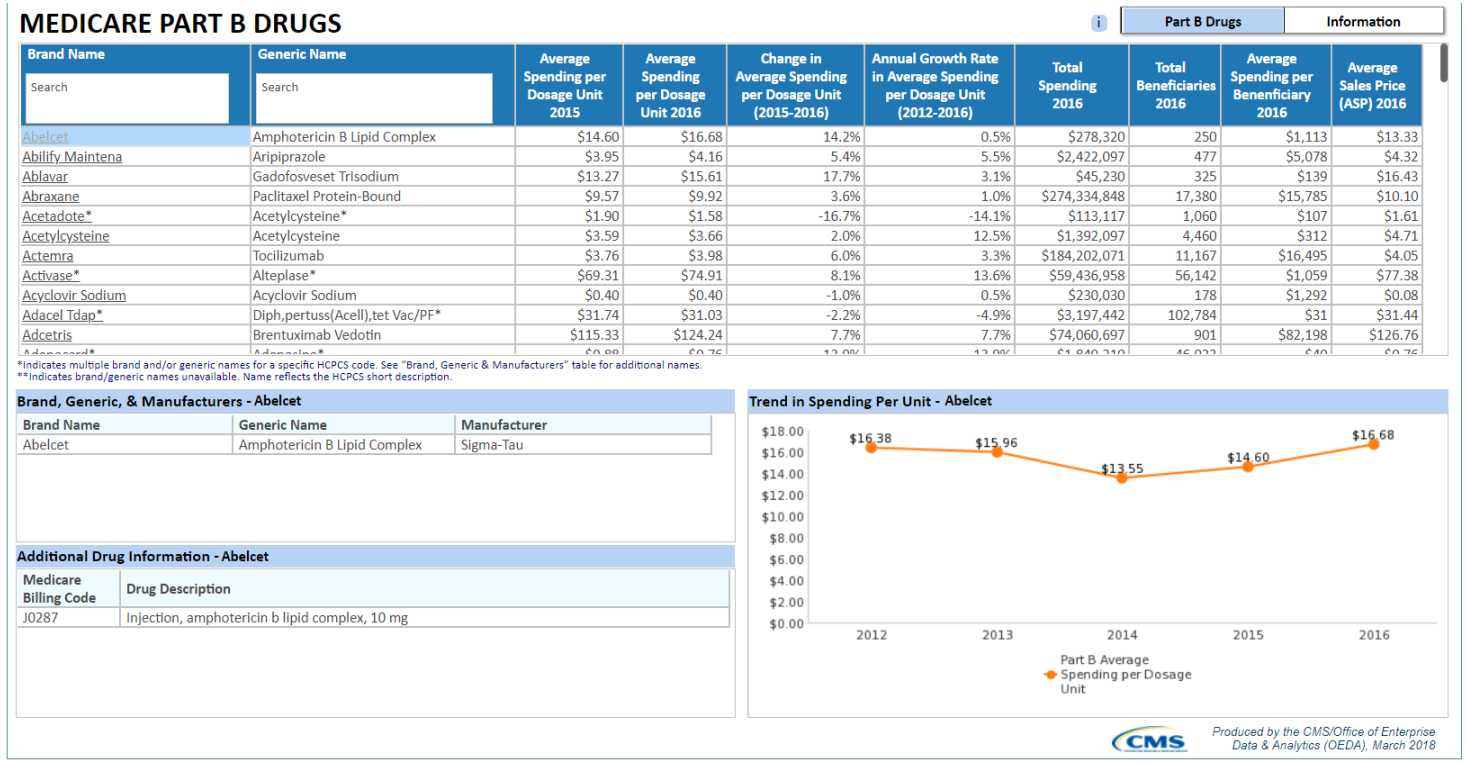
Tactic	Description
Increase Competition	Overhaul the regulatory and patent processes, support innovation, and promote the use of biosimilars. Streamline and accelerate the approval process for OTC drugs.
Incentivize Lower Prices	The FDA is evaluating a requirement to list drug prices in pharmaceutical advertisements. Update the Medicare drug pricing dashboard. Evaluate the rebate system and PBMs. Reform the 340B Drug Discount Program.
Shift to Value-Based Care	Expand outcome-based payments for drugs within Medicare and Medicaid.
Improve Negotiation Power	Reform Medicare Part D to give more negotiation power with drug makers. Evaluate price negotiation for Part B drugs through Part D plans. Utilize CAP for Part B. Evaluate site neutrality in payment.
Lower Out-of-Pocket Costs	Eliminate Part D contracts that include “gag rules” preventing pharmacists from informing patients when they could pay less out of pocket by not using insurance.

V. Drug Pricing Trends

Key Tactics *(continued)*

> Much of the proposed blueprint will require additional regulations and/or congressional input, but the administration is moving ahead quickly where it can, such as sharing more information with the public.

Medicare Part B Drug Spending Dashboard



MEDICARE PART B DRUGS

Part B Drugs | Information

Brand Name	Generic Name	Average Spending per Dosage Unit 2015	Average Spending per Dosage Unit 2016	Change in Average Spending per Dosage Unit (2015-2016)	Annual Growth Rate in Average Spending per Dosage Unit (2012-2016)	Total Spending 2016	Total Beneficiaries 2016	Average Spending per Benenficiary 2016	Average Sales Price (ASP) 2016
Abelcet	Amphotericin B Lipid Complex	$14.60	$16.68	14.2%	0.5%	$278,320	250	$1,113	$13.33
Abilify Maintena	Aripiprazole	$3.95	$4.16	5.4%	5.5%	$2,422,097	477	$5,078	$4.32
Ablavar	Gadofosveset Trisodium	$13.27	$15.61	17.7%	3.1%	$45,230	325	$139	$16.43
Abraxane	Paclitaxel Protein-Bound	$9.57	$9.92	3.6%	1.0%	$274,334,848	17,380	$15,785	$10.10
Acetadote*	Acetylcysteine*	$1.90	$1.58	-16.7%	-14.1%	$113,117	1,060	$107	$1.61
Acetylcysteine	Acetylcysteine	$3.59	$3.66	2.0%	12.5%	$1,392,097	4,460	$312	$4.71
Actemra	Tocilizumab	$3.76	$3.98	6.0%	3.3%	$184,202,071	11,167	$16,495	$4.05
Activase*	Alteplase*	$69.31	$74.91	8.1%	13.6%	$59,436,958	56,142	$1,059	$77.38
Acyclovir Sodium	Acyclovir Sodium	$0.40	$0.40	-1.0%	0.5%	$230,030	178	$1,292	$0.08
Adacel Tdap*	Diph,pertuss(Acell),tet Vac/PF*	$31.74	$31.03	-2.2%	-4.9%	$3,197,442	102,784	$31	$31.44
Adcetris	Brentuximab Vedotin	$115.33	$124.24	7.7%	7.7%	$74,060,697	901	$82,198	$126.76

*Indicates multiple brand and/or generic names for a specific HCPCS code. See "Brand, Generic & Manufacturers" table for additional names.
**Indicates brand/generic names unavailable. Name reflects the HCPCS short description.

Brand, Generic, & Manufacturers - Abelcet

Brand Name	Generic Name	Manufacturer
Abelcet	Amphotericin B Lipid Complex	Sigma-Tau

Additional Drug Information - Abelcet

Medicare Billing Code	Drug Description
J0287	Injection, amphotericin b lipid complex, 10 mg

Trend in Spending Per Unit - Abelcet

CMS

Produced by the CMS/Office of Enterprise Data & Analytics (OEDA), March 2018

Source: CMS.

2018

V. Drug Pricing Trends

Key Tactics *(continued)*

In another example of information sharing, the FDA launched a website in May 2018 that publishes information on drug makers who hinder the generic drug development process by restricting access to branded drugs for research purposes.

Reference Listed Drug (RLD) Access Inquiries

Product	RLD Sponsor[3]	Number of Inquiries Received by FDA	Does the product have a REMS with ETASU Impacting Distribution?	For Products with REMS with ETASU Impacting Distribution: Date(s) of Safety Determination Letter(s) Issued (if applicable)
Absorica (isotretinoin)	RANBAXY INC/SUN PHARMACEUTICAL INDUSTRIES INC	5	Yes	12/9/2015
Abstral (fentanyl citrate)	GALENA BIOPHARMA	1	Yes	
Accutane (isotretinoin)	ROCHE PALO ALTO LLC	2	Yes	6/23/2009
Adempas (riociguat)	BAYER HEALTHCARE PHARMACEUTICALS INC	2	Yes	9/27/2016; 5/2/2017
Afinitor (everolimus)	NOVARTIS PHARMACEUTICALS CORP	1	No	N/A
Amnesteem (isotretinoin)	MYLAN PHARMACEUTICALS INC	3	Yes	
Ampyra (dalfampridine)	ACORDA THERAPEUTICS INC	4	No	N/A

Source: FDA

V. Drug Pricing Trends

Missing Elements

The blueprint lacked elements that advocates hoped for and that President Trump had previously promised.

- **Negotiating Drug Prices through a Central Agency:** Despite his campaign promises, President Trump dropped this tactic, which, by some estimates, could save $154 billion[1] in annual spending.
- **Purchasing Drugs from Foreign Countries:** Some have advocated that the U.S. should purchase drugs from other countries (e.g., Canada) to generate savings. Instead, President Trump suggested that other countries should pay more for drugs.
- **Providing Value Assessments:** Countries such as Germany require pharmaceutical companies to include "value assessments," measures of clinical efficacy, in addition to price.[2] No such provisions are included in the Trump plan.

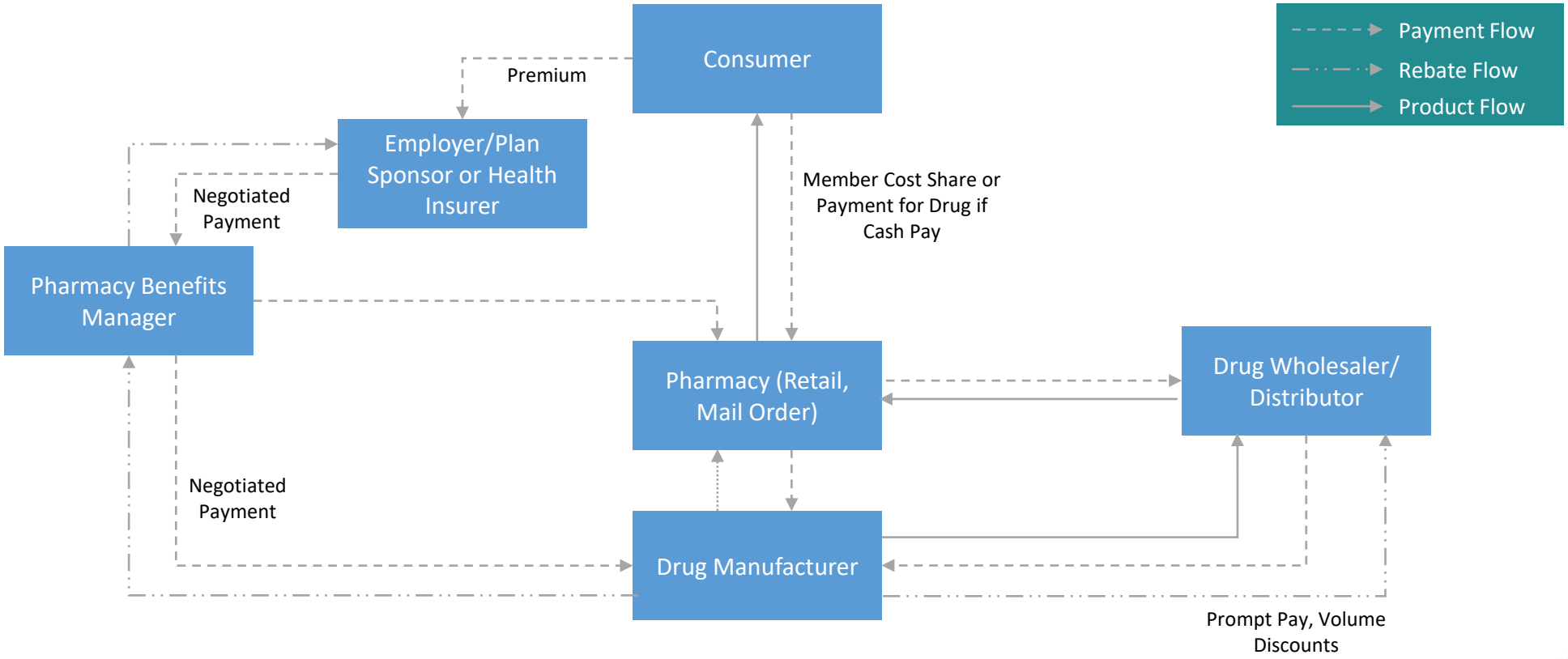
[1] Adam Gaffney, "Trump's plan won't lower prescription drug prices. Ours would." *Washington Post*, May 23, 2018.
[2] The Commonwealth Fund, "Trump Administration's Prescription Drug 'Blueprint' to Tackle High U.S. Prices Will Need More Action Steps," May 17, 2018.

Notably, pharmaceutical and pharmacy benefit manager companies' stock prices increased after the plan was announced.

V. Drug Pricing Trends

Rebates

Earlier this year, several health insurers (including UnitedHealthcare) announced plans to pass on drug rebates to consumers for retail prescriptions. Of interest to cancer programs: Does this signal a trend that may expand to include injectable pharmaceuticals?



Source: Health Strategies Consultancy, *Follow the Pill: Understanding the U.S. Commercial Pharmaceutical Supply Chain*.

V. Drug Pricing Trends

Impact on Providers

> How these changes will impact providers has not yet been addressed by the administration. In the current cost-plus environment in which oncologists operate, a reduction in drug prices will translate to less revenue for practices.

- For practices operating under a cost-plus model, reductions in drug costs promised by the proposed initiatives will lead to less revenue and lower margins for oncology providers.
- Based on communications to date, it does not appear that the administration is contemplating any measures to abate this impact.
- Should these proposed changes come to fruition, it is plausible that there will be a shift toward different payment models in the oncology space (e.g., enhanced administration fees, payment management fees).

Providers should remain vigilant, as details of the administration's plan will likely come into focus over the next few months.

VI. Oncology Care Model

VI. Oncology Care Model

Overview

> This five-year CMS Medicare demonstration project is designed to improve care coordination, access, and appropriateness while lowering the total cost for Medicare beneficiaries receiving cancer treatment.

Program Aim

Promote whole practice transformation through the use of aligned financial incentives, including performance-based payments, to improve care coordination, appropriateness of care, and access for FFS Medicare beneficiaries undergoing chemotherapy.

Program Participation

187 practices and 14 payors are currently participating in OCM.

Source: CMS.

Current OCM Participating Practices

VI. Oncology Care Model

Episode Definition

> Care episodes are six months in length and include all Medicare Part A and B services received by beneficiaries.

Episode Definition

- An episode is initiated when a beneficiary receives a qualifying chemotherapy drug (first Part B/D chemotherapy claim).
- Each episode lasts for six months.
- If a patient requires chemotherapy beyond those six months, they begin a new episode.
- Beneficiaries may initiate multiple episodes during the five-year model.

Included Services

- All Medicare Part A and B services received by Medicare FFS beneficiaries during the episode.
- Certain Part D expenditures: the Low-Income Cost-Sharing Subsidy (LICS) amount and 80% of the Gross Drug Cost above the Catastrophic (GDCA) threshold.

Source: CMS.

Although the OCM does not change *how* drugs are reimbursed, it incentivizes practices to select high-value options.

VI. Oncology Care Model

Payment Methodology

During OCM episodes, providers continue to bill for standard Medicare FFS payments. OCM incorporates two additional payment mechanisms: a Monthly Enhanced Oncology Services (MEOS) payment and retrospective Performance-Based Payment (PBP).

MEOS

- The MEOS payment provides OCM practices with financial resources to aid in effectively managing and coordinating care for Medicare FFS beneficiaries.
- The $160 per member per month (PMPM) payment can be billed for OCM FFS beneficiaries for each month of their six-month episodes.

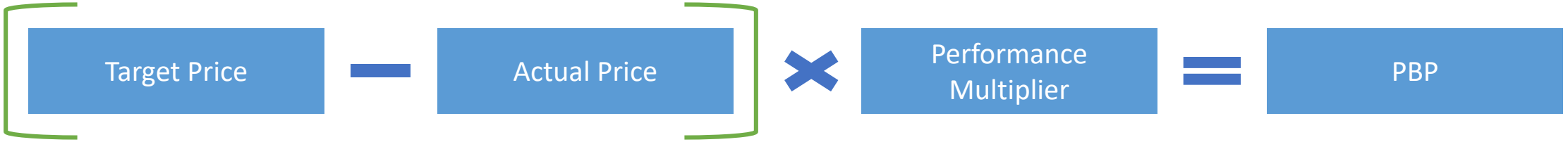
PBP

- PBP encourages OCM practices to improve care for beneficiaries and lower the total cost of care during the six-month episodes.
- PBP is calculated retrospectively on a semiannual basis based on the practice's achievement on quality measures and reductions in Medicare expenditures below a target price.

Source: CMS.

VI. Oncology Care Model

Performance-Based Payment Methodology



1 Calculate Benchmark

CMS calculates benchmark episode expenditures for OCM practices.

- Based on historical data
- Risk-adjusted (including for geographic variation)
- Trended to applicable performance period
- Includes a novel therapies adjustment

2 Determine Target Price

Discount is applied to the benchmark to determine a target price for OCM-FFS episodes.

Example:

- Benchmark = $30,000
- Discount = 4%
- Target Price = $28,800

3 Compare Actual to Target

If actual OCM-FFS episode expenditures are below target, the practice could receive a PBP.

Example:

- Target Price = $28,800
- Actual = $25,000
- PBP = up to $3,800

Note: Actual expenditures include both FFS and MEOS payments.

4 Adjust Based on Performance

The PBP amount is adjusted based on the participant's achievement across five quality domains.

- Communications and care coordination
- Person- and caregiver-centered outcomes
- Clinical quality of care
- Patient safety
- Clinical data

Source: CMS.

Payments are calculated for the total cost for the episode of care (includes Part A, B, and D payments).

VI. Oncology Care Model

Lessons for Every Practice

> While the OCM pilot includes only a small subset of U.S. oncology practices, the pilot is generating important information regarding opportunities to reduce the cost of cancer care.

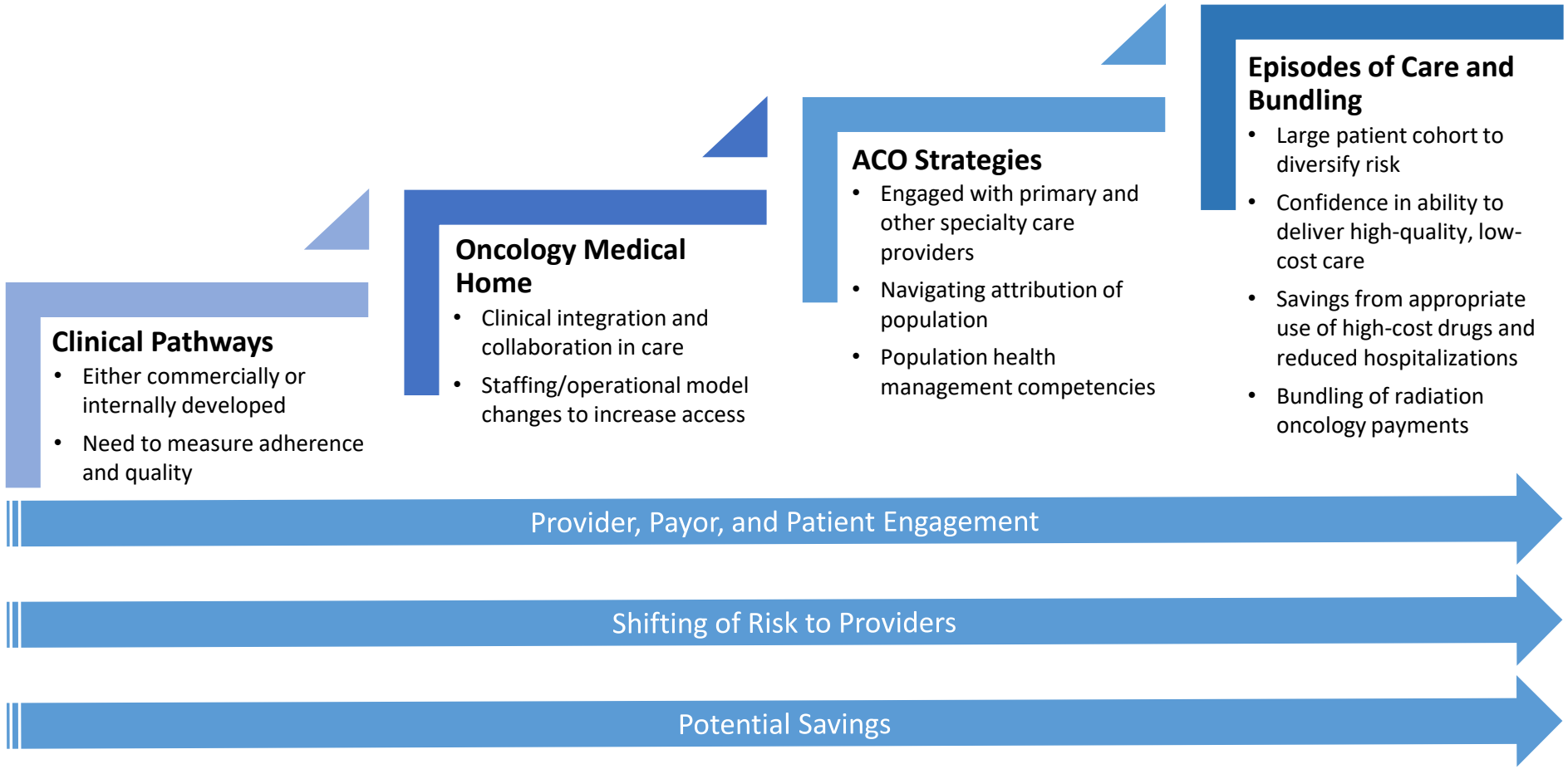
- Active case management is needed.
- Utilization of standardized pathways is critical.
- Without data and analytics, it is impossible to manage or improve performance.
- Narrow networks are essential to ensure pathway compliance and cost management.
- Look for areas of innovation to drive cost reduction all over the practice.
- Provider engagement is critical; without it, change will be nearly impossible.
- Coding and documentation (HCCs) are critical to getting credit for the complexity of your patient population.
- Infrastructure, infrastructure, infrastructure: people, processes, technology, and so forth are vital to generating and managing the information needed to manage change.
- Patient retention is important in a risk-based environment.

VII. New Reimbursement Models

VII. New Reimbursement Models

Increasingly Coordinated Care Models and Incentive Structures

To provide optimal patient care and to align with changing reimbursement mechanisms, providers must assume an increasingly large role in managing overall cancer care, which is becoming more complicated and requires greater integration.



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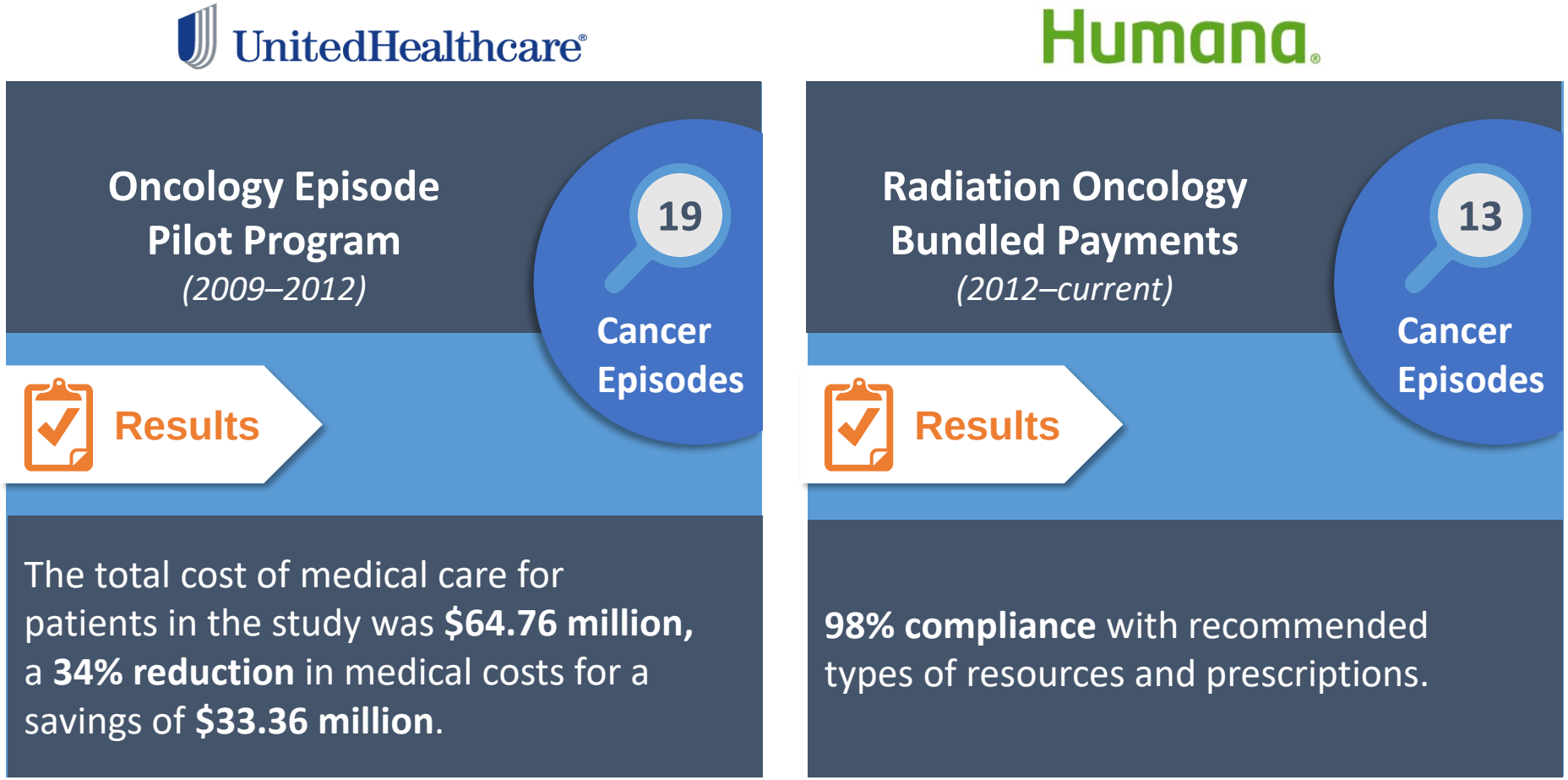
VII. New Reimbursement Models

Commercial Bundled Payments

Commercial payors such as UnitedHealthcare and Humana are beginning to successfully experiment with new reimbursement models for oncology care.



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VII. New Reimbursement Models

Case Study: MD Anderson and UnitedHealthcare Bundled Payment

MD Anderson and UnitedHealthcare entered into a pilot program to test an oncology-focused bundled payment.

THE UNIVERSITY OF TEXAS MD Anderson Cancer Center
Making Cancer History®

UnitedHealthcare®

Motivation

Voluntary experimentation with APMs.

Program

Three-year pilot (2013–2016) of a **one-year prospective bundled payment** for head and neck cancer.

Methodology

Four prospective, risk-adjusted, treatment-based bundles that **begin with treatment,** and payments are made at treatment start.

Results

One-year prospective bundled payment could be implemented, but **existing claims systems lacked flexibility** to automate bundled billings and payment.

Source: Spinks, et al., "Development and Feasibility of Bundled Payments for the Multidisciplinary Treatment of Head and Neck Cancer: A Pilot Program," *JOncPract,* December 2017.

VII. New Reimbursement Models

Case Study: MD Anderson and UnitedHealthcare Bundled Payment *(continued)*

Feasibility

MD Anderson sees 2% of all US head and neck cancers, giving it a **well-understood** patient population with **predictable treatment pathways**.

MD Anderson Resources

Dedicated project teams:

- Bundle design
- Contract negotiation
- Pilot implementation

Representing:

- Clinical operations
- Finance
- Legal
- Clinical support
- Compliance
- Institute of Cancer Care Innovation

UnitedHealthcare Resources

Dedicated project teams:

- Contracting
- Customer service
- Claims processing
- Claim configuration
- Oncology line of service representatives

Source: Spinks, et al., "Development and Feasibility of Bundled Payments for the Multidisciplinary Treatment of Head and Neck Cancer: A Pilot Program," *JOncPract,* December 2017.

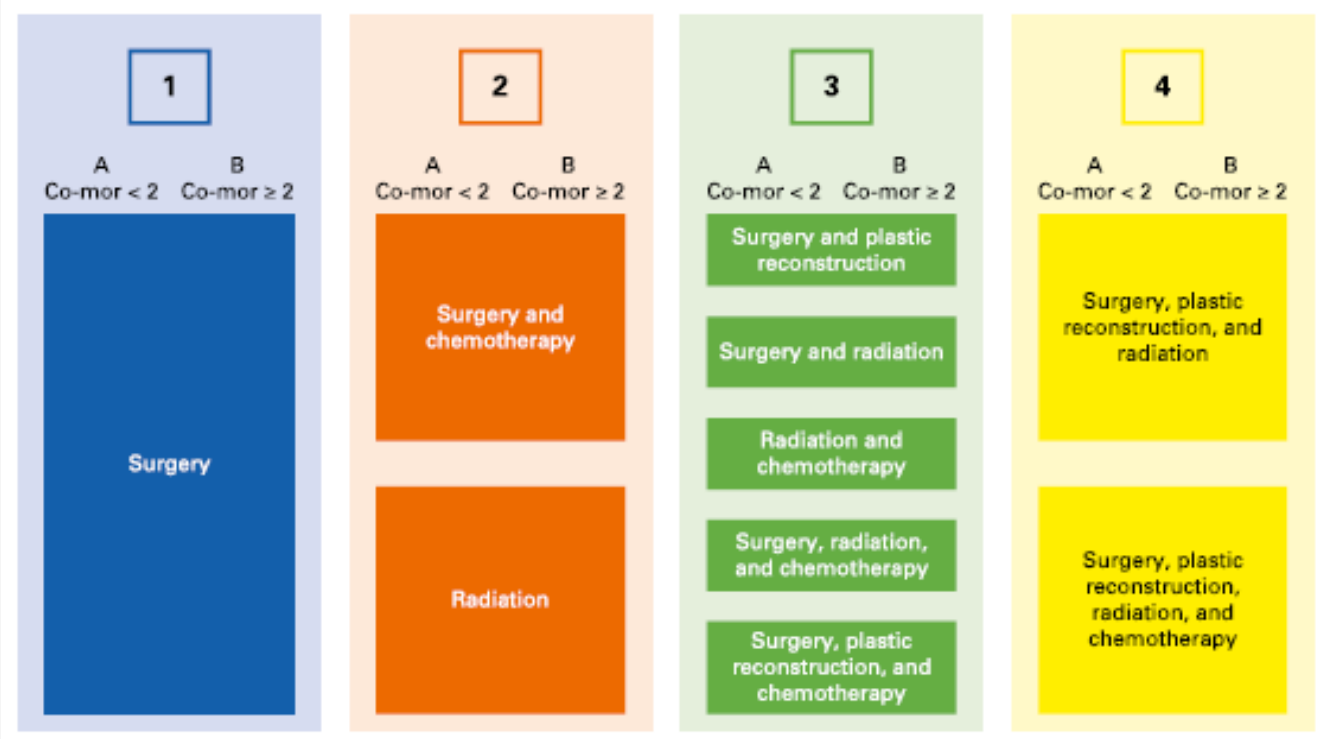
VII. New Reimbursement Models

Case Study: MD Anderson and UnitedHealthcare Bundled Payment *(continued)*

Bundle Design

Primary cancer treatment (surgery, radiation therapy, chemotherapy) and **one year of care,** including:

- Inpatient care
- Surgical reconstruction
- Emergency visits
- Diagnostic imaging
- Internal medicine
- Preventive care



Note: Head and neck bundled payment pilot: four risk-adjusted bundles. The risk-adjusted payment bundles for head and neck cancer are shown with treatment plans included in each bundle. "Co-mor" stands for comorbidity (per the Charlson comorbidity index).

Source: Spinks, et al., "Development and Feasibility of Bundled Payments for the Multidisciplinary Treatment of Head and Neck Cancer: A Pilot Program," *JOncPract,* December 2017.

VII. New Reimbursement Models

Case Study: MD Anderson and UnitedHealthcare Bundled Payment *(continued)*

MD Anderson and UnitedHealthcare's bundle was deemed feasible, but presented operational challenges. Cost and quality outcomes are not yet clear.

Outcome

- After a three-year pilot, it was determined that a single bundled payment for head and neck cancer patients was feasible.
- UnitedHealthcare has not yet expressed interest in expanding the program.[1]

Challenges

- Claims submissions were difficult to do and required manual workarounds. Many billing systems are not well-equipped for bundled payments.
- Payments for newer technology (e.g., proton therapy) were not included in the bundle.

Next Steps

- The bundle's performance on quality and cost is still under evaluation.
- UnitedHealthcare is testing other bundles, such as a program with community medical oncologists.[2]

1 "In the End, It Will Be Episode Payment." *Managed Care,* May 1, 2017.
2 "Study: New Cancer Care Payment Model Reduced Health Care Costs, Maintained Outcomes." UnitedHealth Group, July 8, 2014.

VIII. Takeaways

VIII. Takeaways

Strategic Opportunities: Overview

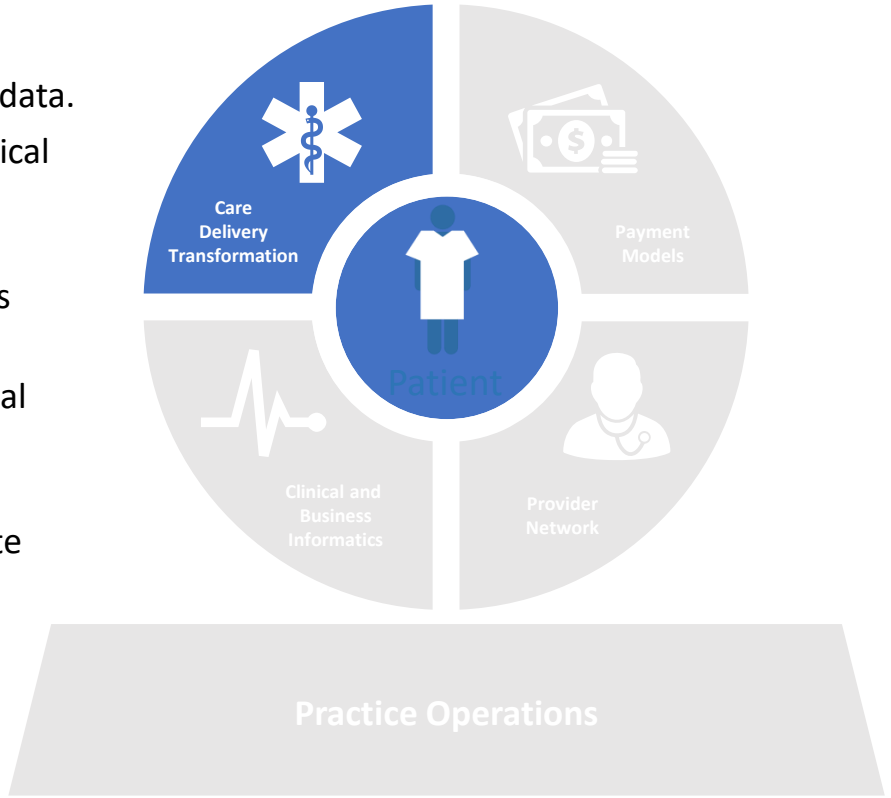
To succeed in the changing healthcare environment, providers need to simultaneously evolve care delivery, align with new payment models, integrate across the care continuum, and improve technological capabilities while maintaining highly efficient operations.

VIII. Takeaways

Strategic Opportunities: Care Delivery Transformation

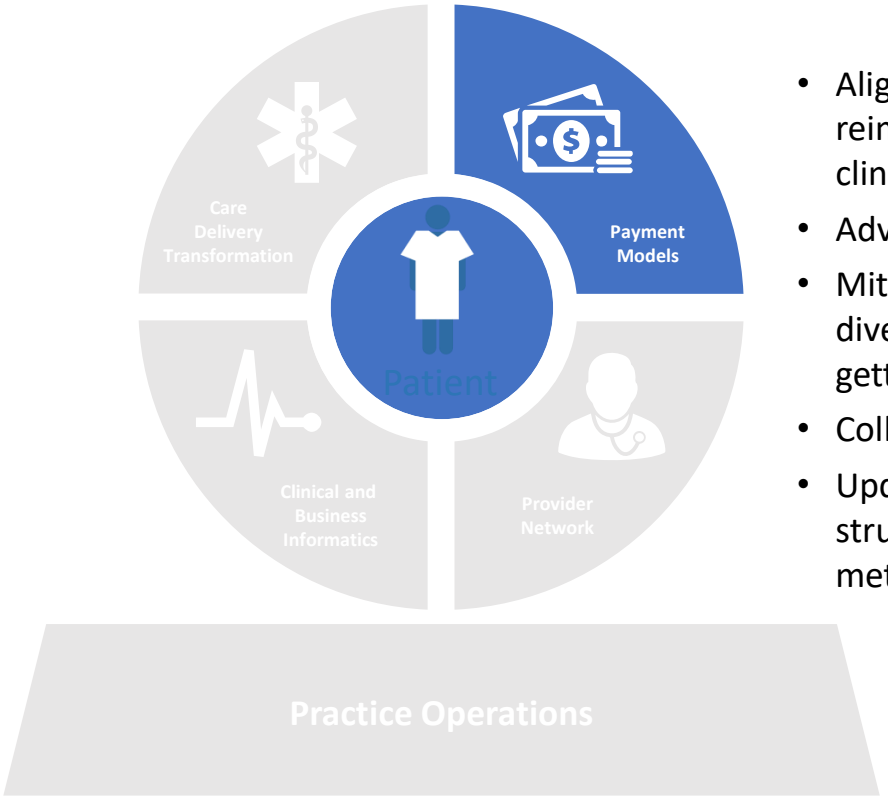
Care Delivery Transformation

- Analyze clinical and claims data.
- Develop and adhere to clinical pathways.
- Develop a formulary and actively manage/enforce its use.
- Outline and prioritize clinical care improvements.
- Oversee clinical teams to address variation and create tools for improvement.
- Evolve the framework for physician leadership, management, and accountability for protocol implementation.



VIII. Takeaways

Strategic Opportunities: Payment Models

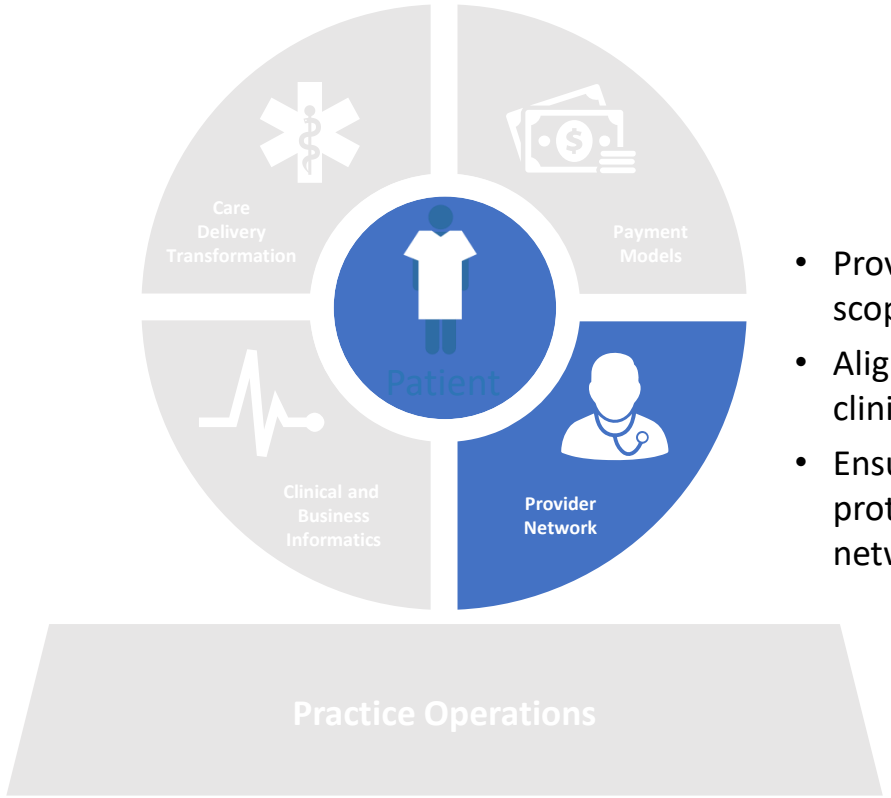


Payment Models

- Align the value-based reimbursement philosophy with clinical goals.
- Advance value payment models.
- Mitigate reliance on FFS by diversifying the portfolio and getting closer to the premium.
- Collaborate with payors.
- Update physician compensation structures to align with new methods of reimbursement.

VIII. Takeaways

Strategic Opportunities: Provider Network



Provider Network

- Provide and coordinate the clinical scope across the care continuum.
- Align the network financially and clinically.
- Ensure that the network follows protocols and facilitates in-network referrals.

VIII. Takeaways

Strategic Opportunities: Clinical and Business Informatics

Clinical and Business Informatics

- Develop reports of clinical and financial performance that reflect the priorities of value-based care.
- Incorporate tools that provide clinical decision support.
- Accomplish data exchanges across the care continuum.

VIII. Takeaways

Strategic Opportunities: Practice Operations

Practice Operations

- Reduce waste associated with high-expense drugs.
- Ensure that overall ordering and inventorying of drug doses match the clinical requirements of the services offered.
- Ensure coding accuracy and compliance.
- Develop and optimize clinical care teams, ensuring all staff practice at the top of the their licensees.
- Standardize processes, roles, and expectations across work areas.
- Eliminate non-value-added operations.

Questions & Answers

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