



Association of Community Cancer Centers Oncology Reimbursement Meeting

Federal Health Policy: How It May Affect Your Program

December 13, 2018



Agenda

- I. Background
- II. Drug Pricing Trends
- III. 340B Drug Pricing Program
- IV. Oncology Care Model (OCM)
- V. New Reimbursement Models
- VI. Affordable Care Act (ACA) Rollback
- VII. Merit-Based Incentive Payment System (MIPS)
- VIII. Takeaways



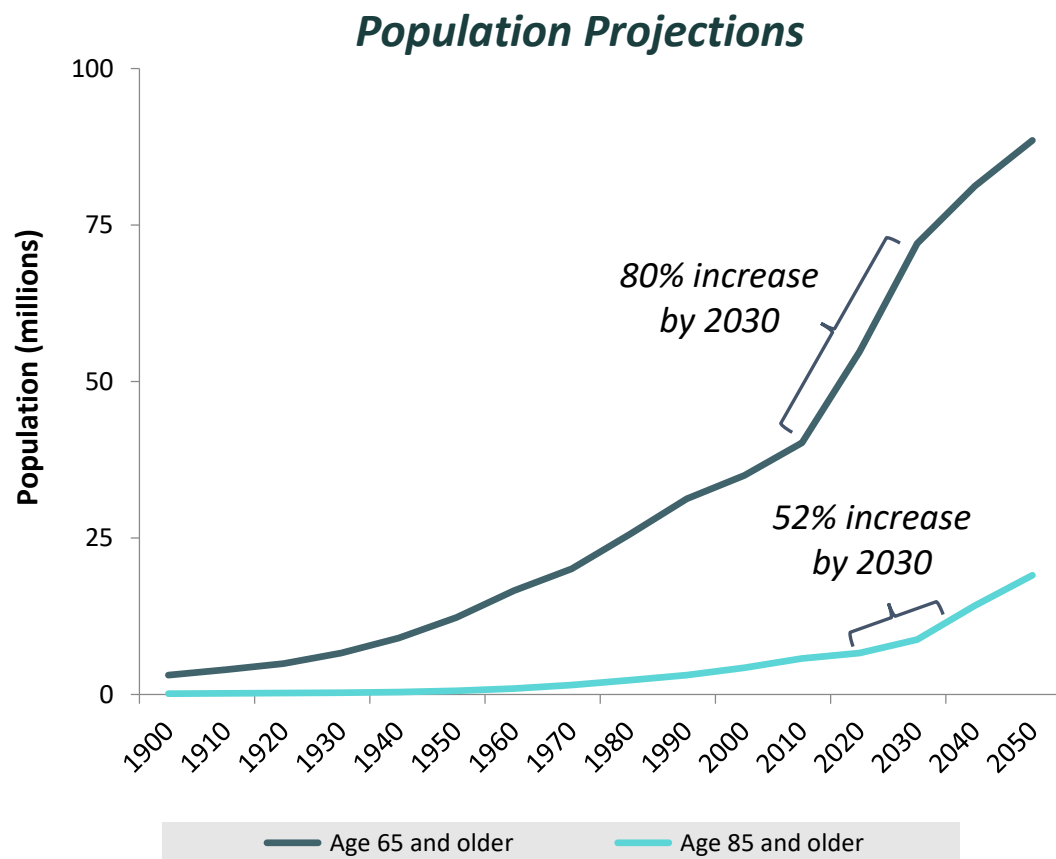
I. Background



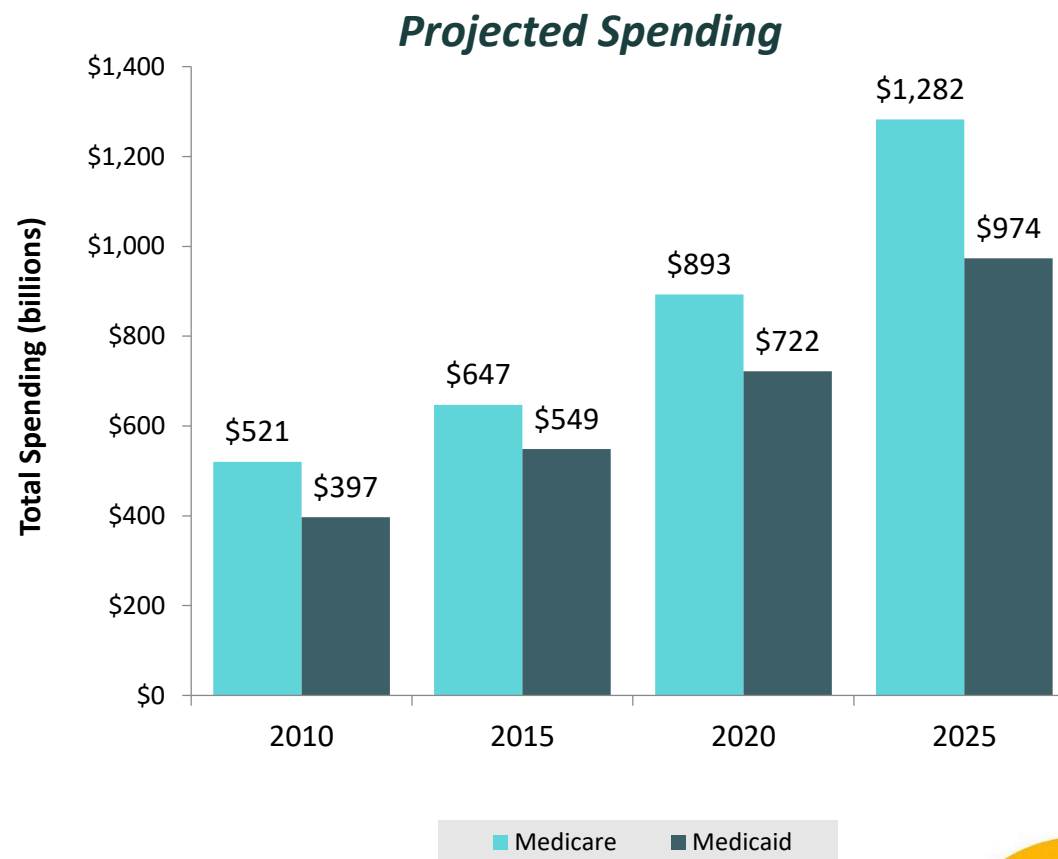
I. Background

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.



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



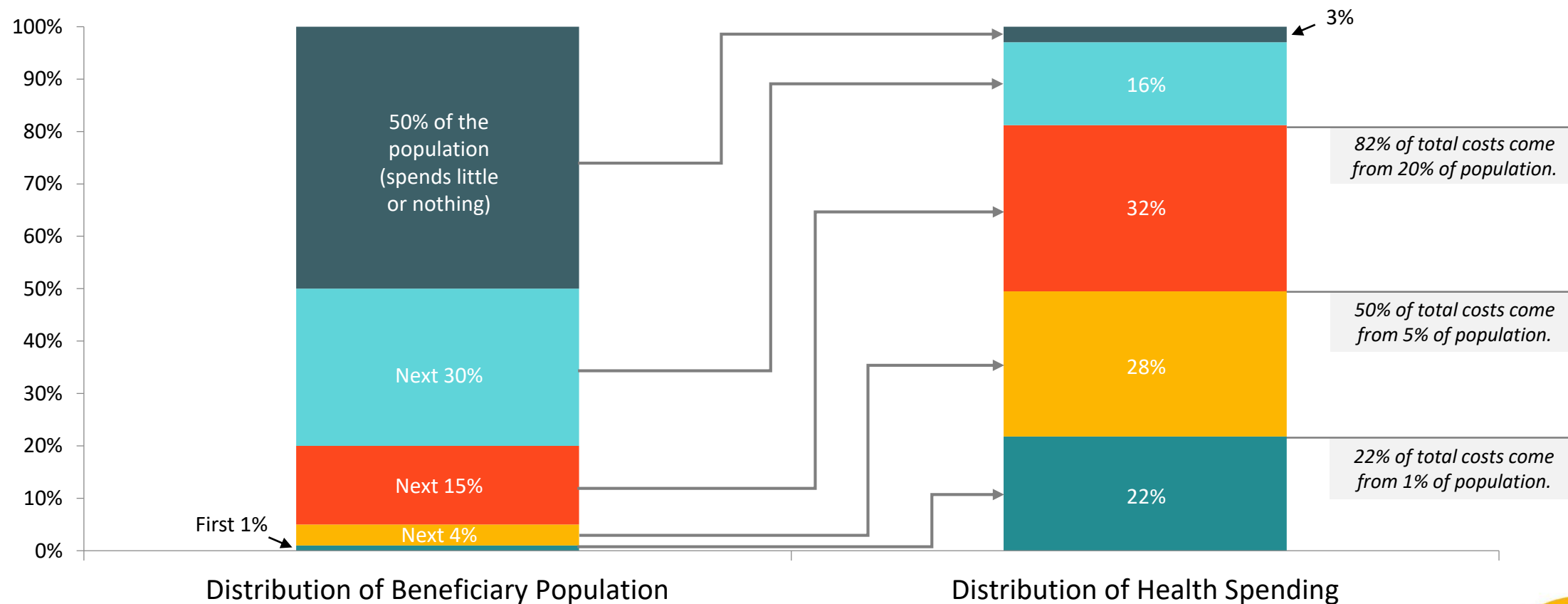
Source: Centers for Medicare & Medicaid Services (CMS), National Health Expenditure Data.



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.

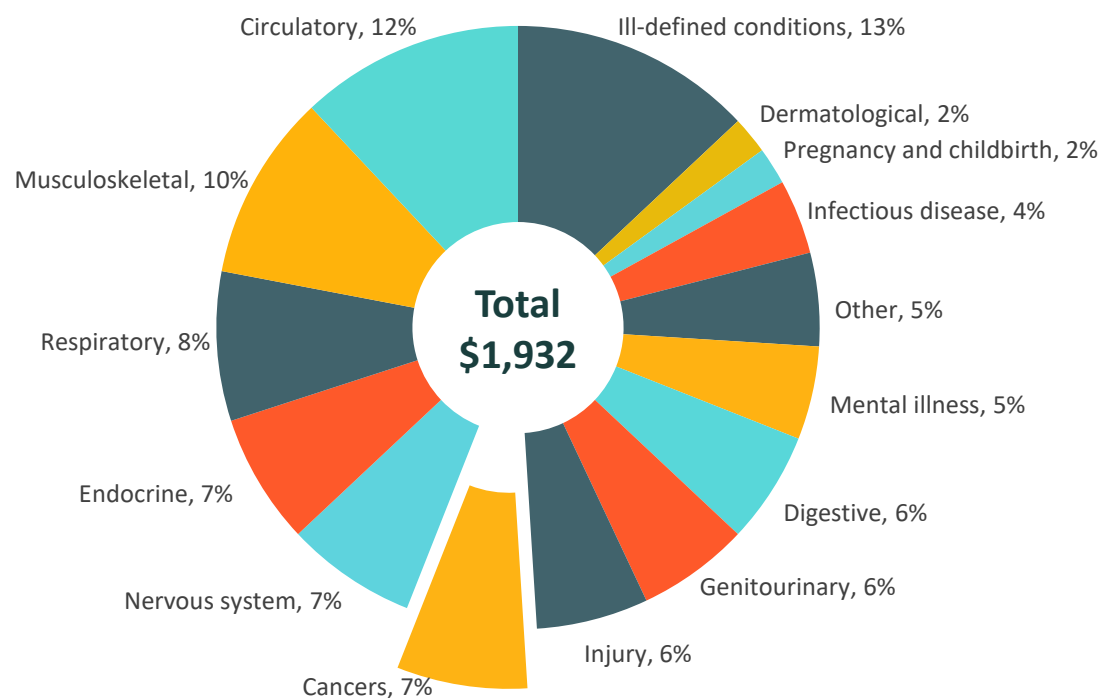


I. Background

US Spending by Disease Category

While cancer care is very expensive, on average only 6% of adults will develop cancer during their lifetime. Thus, spending on cancer care accounts for only 7% of US healthcare spending.

Health System Tracker
Total Expenditures by Disease Category, 2018 (US dollars in billions)



Note: Spending on dental services, nursing homes, and prescriptions that cannot be allocated to a specific disease not included above.
 Source: Henry J. Kaiser Family Foundation analysis of Bureau of Economic Analysis Health Care Satellite Account (Blended Account) and National Health Expenditure data (accessed on March 17, 2017).

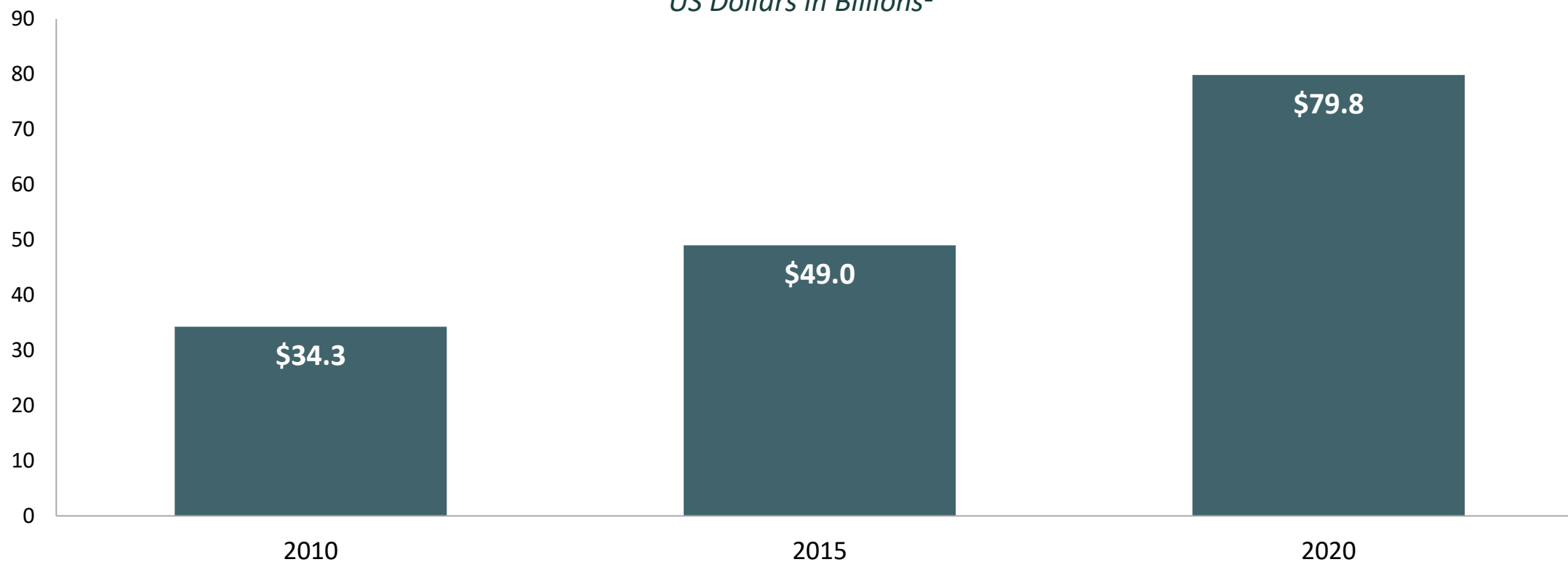


I. Background

US Spending on Oncology

US spending on oncology care is projected to grow rapidly, doubling between 2010 and 2020.

Estimated Annual US Spending on Oncology
US Dollars in Billions¹



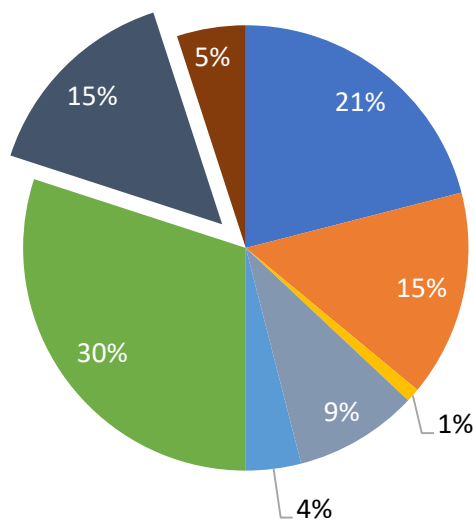
¹ Includes diagnosis, surgery, hospitalization, and palliative and end-of-life care. Source: "Global Oncology Trend Report: A Review of 2015 and Outlook to 2020," IMS Institute for Healthcare Informatics, June 2016.

I. Background

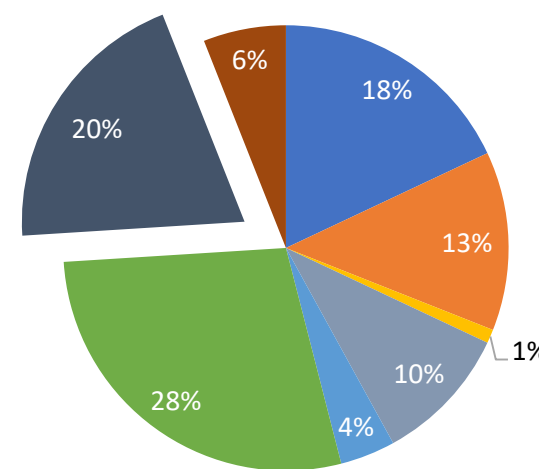
US Spending on Oncology *(continued)*

Average spending per commercial patient increased by 62% from 2004 to 2014. Chemotherapy¹ 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

¹ Chemotherapy includes cytotoxic chemotherapy, other chemo and cancer drugs, and biologic chemotherapy.
Source: "The Evolution of Oncology Payment Models: What Can We Learn from Early Experiments?" Deloitte Center for Health Solutions.



II. Drug Pricing Trends



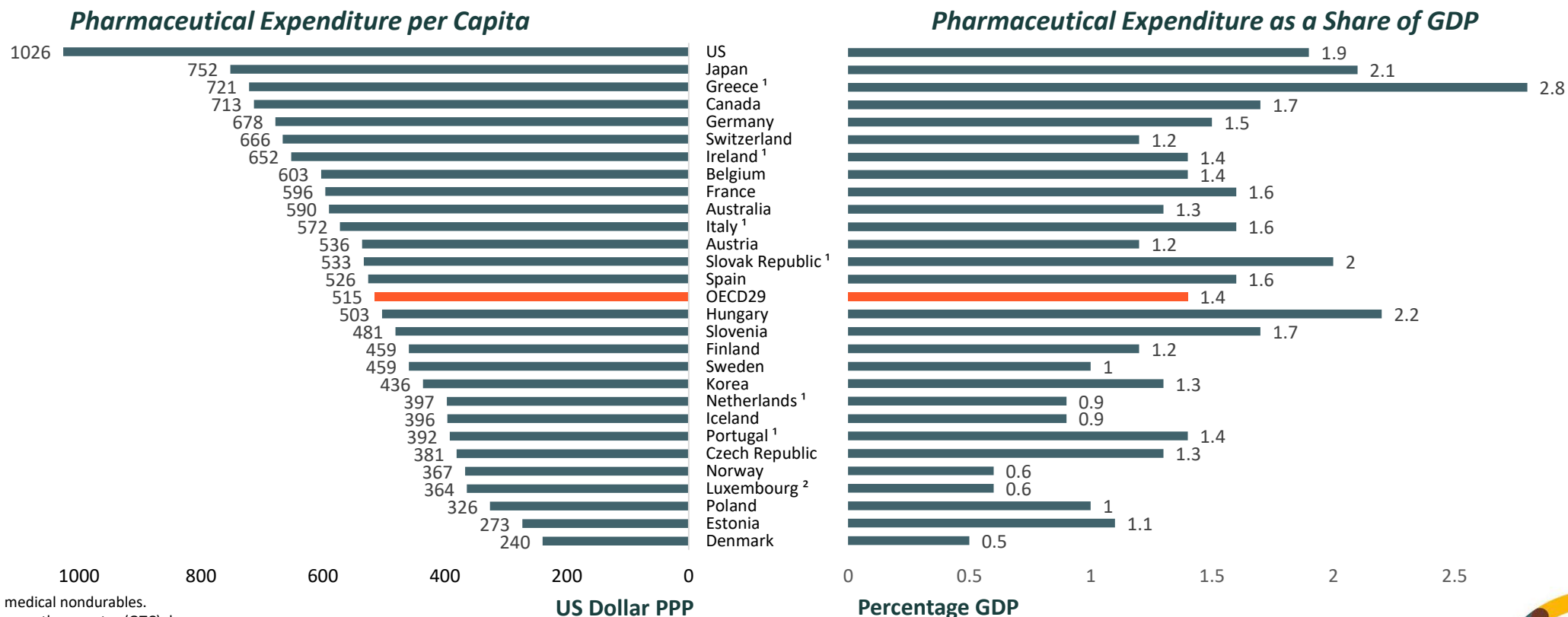
II. Drug Pricing Trends

US Spending in Context

The US spends more per capita than any other nation on pharmaceuticals.

Pharmaceutical Spending Trends and Future Challenges

Expenditure on Retail Pharmaceuticals per Capita and as a Share of GDP, 2013 (or nearest year)



¹ Includes medical nondurables.

² Excludes over-the-counter (OTC) drugs.

Source: Organisation for Economic Co-operation and Development (OECD), "Pharmaceutical Spending Trends and Future Challenges" (*Health at a Glance 2015*, 2015).

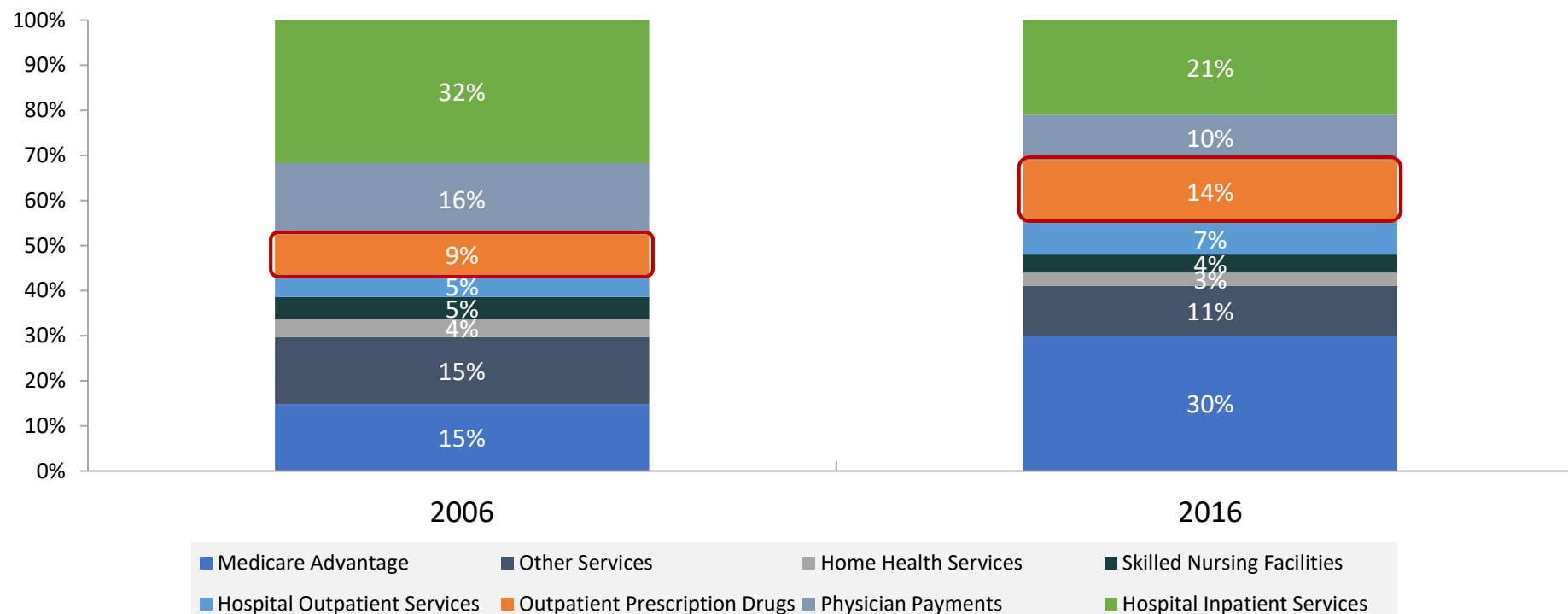


II. Drug Pricing Trends

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



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.

Sources: 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.

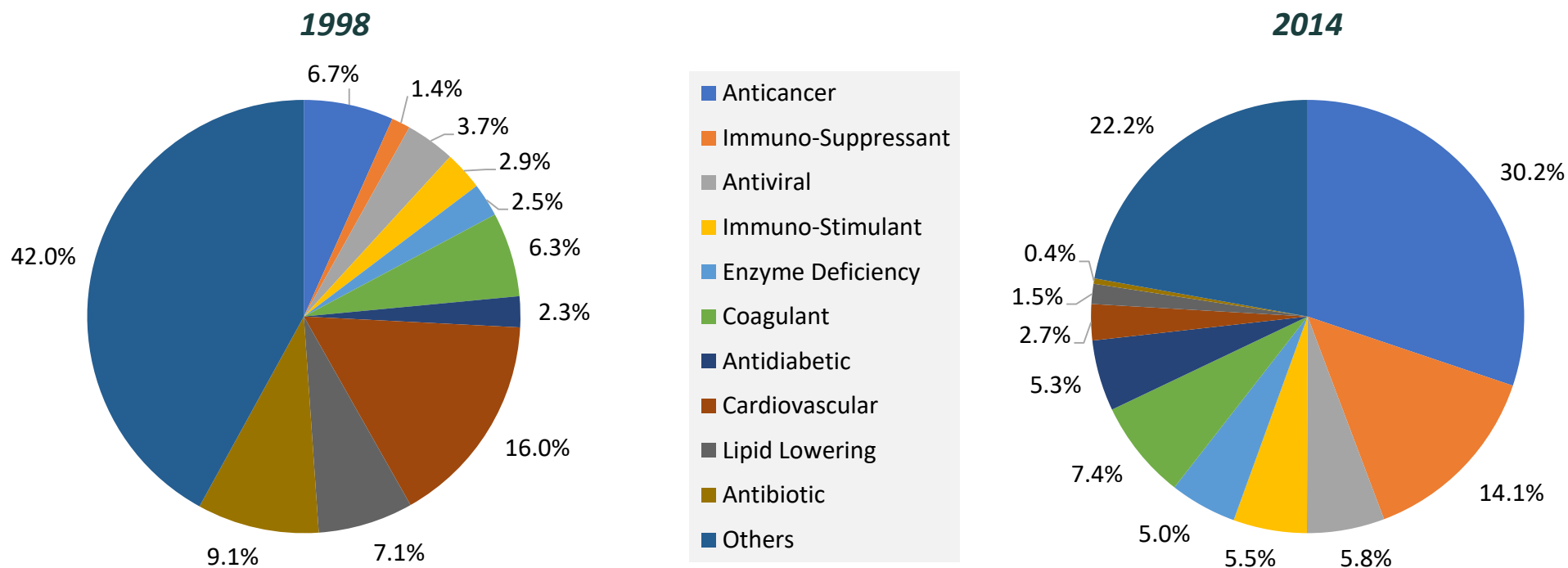
Notes: Consists of Medicare benefits spending on hospice, durable medical equipment, Part B drugs, outpatient dialysis, ambulance, lab services, and other Part B services. Figures may not be exact due to rounding.



II. Drug Pricing Trends

Trends in Cancer Spending

While spending for cancer care represents only 7% of US healthcare expenses, cancer drugs represent over 30% of pharmaceutical expenses.



Distribution of drug expenditure for 10 major drug classes per HMO member in 1998 and 2014. The overall distribution differed significantly between 1998 and 2014 (P <0.001).

Source: Yossef Lomnický et al., "Trends in Annual Drug Expenditure: A 16-Year Perspective of a Public Healthcare Maintenance Organization" (*Israel Journal of Health Policy Research*, Vol. 5, No. 37, 2016). Web, September 5, 2018.



II. Drug Pricing Trends

Drug Development Pipeline

In recent years, there has been more activity in the development of new cancer agents than in many other disease areas combined. While this is exciting news for patients and clinicians, it does not bode well for the cost of drugs.

Medicines in Development for Noncommunicable Diseases

	Phase One	Phase Two	Phase Three	Regulatory Review	Total
Cancer	1,265	1,507	288	13	3,073
Cardiovascular	128	230	85	7	450
Diabetes	103	132	43	3	281
Respiratory	123	198	47	2	370

Source: Analysis Group, "Innovation in the Biopharmaceutical Pipeline: A Multidimensional View" (2013), http://www.analysisgroup.com/uploadedFiles/Publishing/Articles/2012_Innovation_in_the_Biopharmaceutical_Pipeline.pdf.

II. Drug Pricing Trends

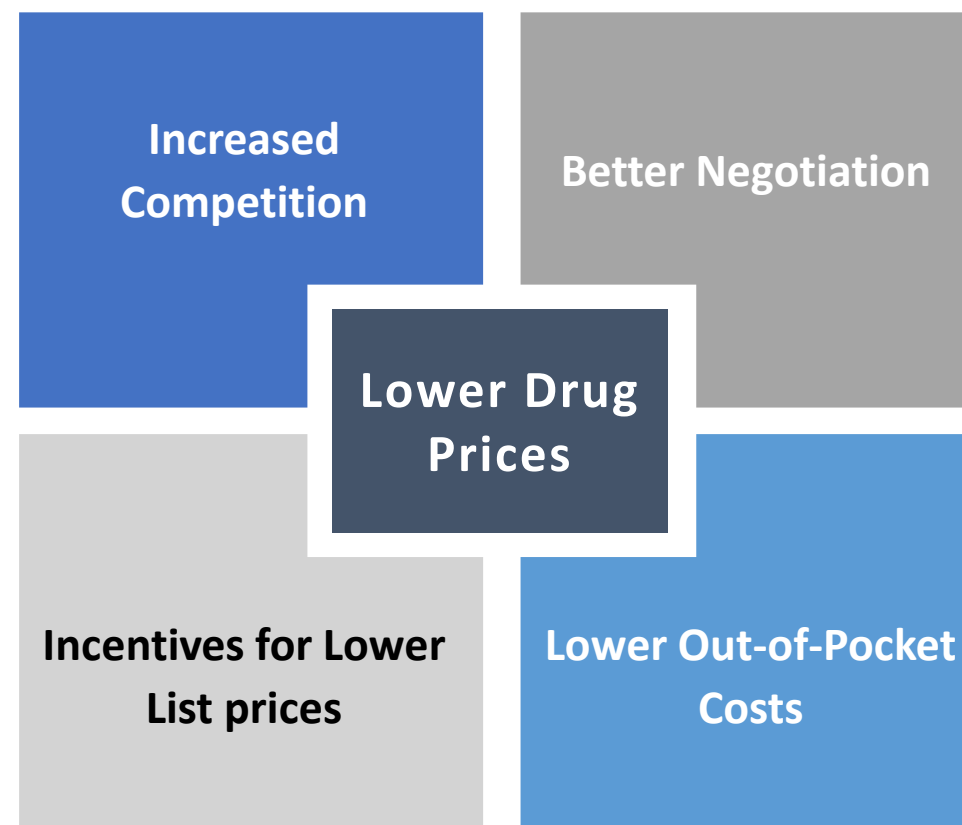
Trump Administration Blueprint

In June 2018, the Trump administration announced a “blueprint” to lower drug prices, citing several system elements that drive up prices.

Issues Driving High Prices

- Overall lack of transparency in drug pricing
- Gaming of the regulatory system by drug companies to keep lower-cost generic drugs out of the market
- The US government’s inability to negotiate drug prices
- Concerns over how facilities with access to 340B drug pricing use the savings to facilitate charity care to low-income patients
- Foreign markets’ negotiation of low prices from US drug makers, which shifts the burden of financing drug development onto American patients and taxpayers

The Blueprint’s Four Pillars



II. Drug Pricing Trends

Trump Administration Blueprint: Key Tactics

While the overall plan lacks detail, the administration has started to outline specific tactics it will pursue.

Tactic	Description
Increase Number of Generic Drugs on the Market	Overhaul the regulatory and patent processes that are commonly used by brand-name drug companies to slow the process for generic drug development and approval.
Improve OTC Drug Approval Processes	Streamline and accelerate the approval process for OTC drugs.
Foster Pricing Transparency	Evaluate opportunities to increase transparency of drug prices in pharmaceutical advertisements.
Shift to Value-Based Care	Expand outcome-based payments for drugs within Medicare and Medicaid.
Improve Negotiation Power	Give Medicare Part D plan sponsors more negotiation power with drug makers.
Eliminate Rules Restricting In-formation Sharing with Patients	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.



II. Drug Pricing Trends

Trump Administration Blueprint: Missing Elements

The blueprint, however, lacks additional 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 in annual spending.¹
- ▶ **Purchasing Drugs from Foreign Countries:** Some have advocated that the US should purchase drugs from other countries (e.g., Canada) to generate savings. Instead, the president 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 US Prices Will Need More Action Steps” (May 17, 2018).

II. Drug Pricing Trends

Trump Administration Blueprint: Key Tactics *(continued)*

Much of the proposed blueprint will require additional regulation 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									
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 Beneficiary 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

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

Year	Spending per Dosage Unit
2012	\$16.38
2013	\$15.96
2014	\$13.55
2015	\$14.60
2016	\$16.68

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



II. Drug Pricing Trends

Trump Administration Blueprint: 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 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



II. Drug Pricing Trends

Other Recent Developments: Proposed 2019 Medicare PFS Changes

CMS has proposed reducing the wholesale acquisition cost (WAC) add-on for in-office drugs from 6% to 3% beginning January 1, 2019. Comments on the proposed changes were accepted through September 10, 2018.

- CMS has proposed to reduce the WAC add-on from 6% to 3%. Reimbursement is currently calculated by adding 6% to the WAC for drugs and biologics.
- While this will decrease the amount of money Medicare and beneficiaries pay for in-office drugs, it results in a significant reduction in the amount Medicare pays physicians for new prescription drugs.
 - This proposed rule would not affect Part B drugs where average sales price (ASP) data has already been made available. There is concern from industry groups regarding the impact this proposal will have on access to new therapies for cancer patients.
- Opponents of this change, such as the AHA, have expressed their belief that CMS should target the list prices set by pharmaceutical companies rather than reducing payment for providers.



II. Drug Pricing Trends

Other Recent Developments: Proposed International Pricing Index Model

CMS is soliciting comments on a proposed model that is designed to test whether changing Part B drug reimbursement leads to higher-quality care for Medicare beneficiaries and reducing spending for the program.

The International Pricing Index (IPI) Model includes a three-pronged approach:

- Phasing down the Medicare reimbursement amount for selected Part B drugs to align with prices paid by foreign countries
- Allowing private-sector vendors to negotiate prices for drugs and compete for physician and hospital business
- Changing the 4.3% (post-sequester) drug add-on payment to a flat payment amount

Who Will Participate?

Physician practices and hospital outpatient departments in select geographic areas (to be determined by CMS) will participate in the IPI Model.

What Drugs Are Included?

The IPI Model will initially focus on single-source drugs and biologicals.

What Is the New Payment Model?

For any drug where ASP is higher than international prices, CMS will pay for drugs based on a target price derived from the IPI. The target price will be phased in over five years.

Who Supplies the Drugs?

Private-sector vendors will take on the financial risk of acquiring and billing for drugs. Physicians and hospitals would be able to contract with multiple vendors for different drugs and to change vendors.

The proposed model would run from spring 2020 through 2025. CMS is soliciting comments from the public through December 31, 2018.



II. Drug Pricing Trends

Other Recent Developments: Medicare Advantage and Part D Proposed Rule

CMS is soliciting comments through January 25, 2019, on a proposed model that is intended to improve access to lower-cost options to seniors and provide program sponsors with tools to lower the cost of prescription drugs.

- **Reform to Medicare Part D's Protected Class Drugs**
 - Part D plans will no longer be required to cover all drugs within the six “protected” categories. At a minimum, plans will have to carry at least two drugs per category.
 - Drugs can be excluded in situations where:
 - A drug's price increases too quickly over a certain period of time.
 - There is no material difference between a new drug and its prior version(s).
 - Plans will use prior authorization and step therapy to manage usage of protected-class drugs.
- **Real-Time Benefit Tools (RTBTs):** Part D plans will adopt EHR-integrated RTBTs to inform prescribers about lower-cost alternatives for prescription drugs.
- **Medicare Advantage and Step Therapy for Part B Drugs:** Prior authorizations and step therapy will also be used to manage utilization of Part B drugs.
- **Prohibition against Gag Clauses:** Pharmacy gag clauses disallowing pharmacies from disclosing lower cash prices to enrollees will be prohibited.

Protected Drug Categories

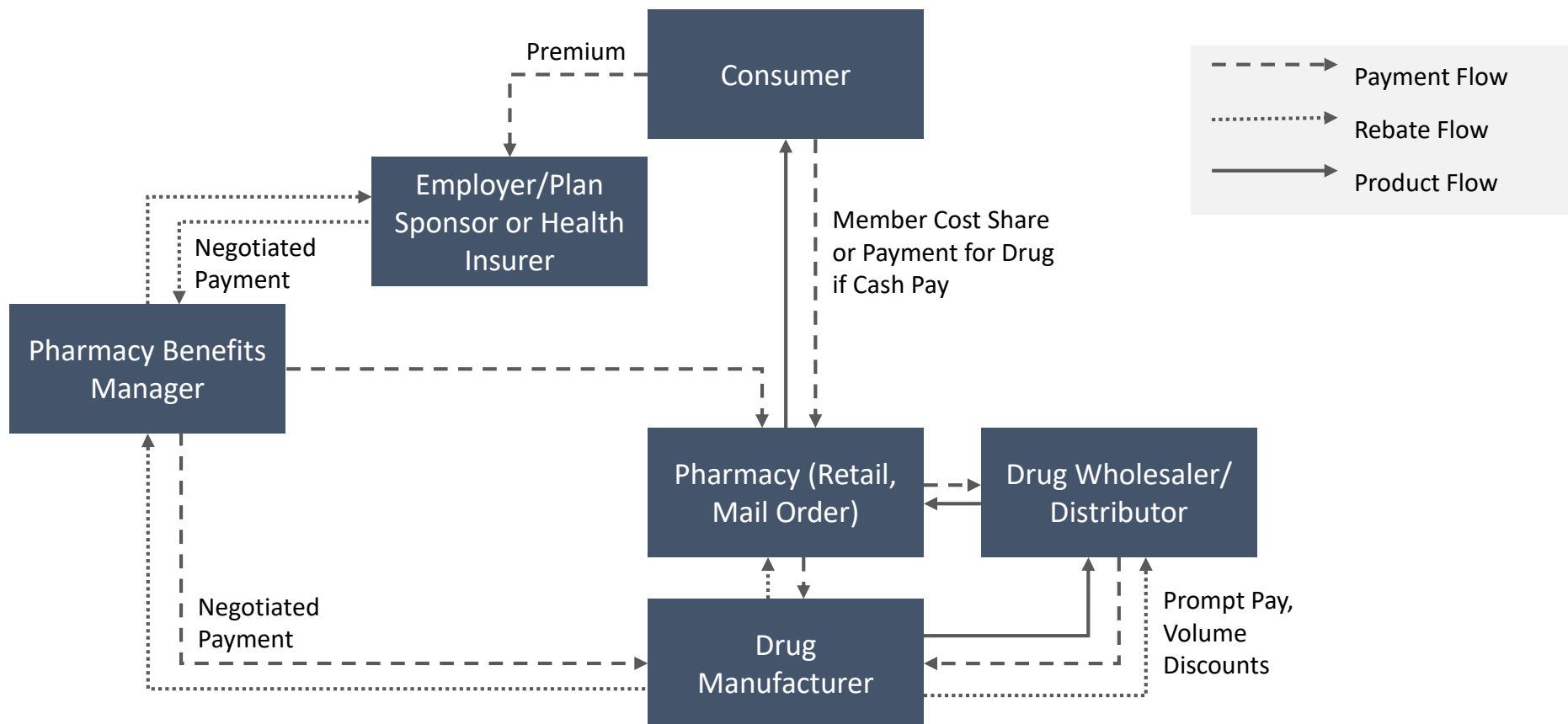
- Antidepressants
- Antipsychotics
- Anticonvulsants
- Immunosuppressants
- Antiretrovirals
- Antineoplastics



II. Drug Pricing Trends

Other Recent Developments: Rebates for Consumers

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



II. Drug Pricing Trends

Impact on Providers

Absent broader payment reform, any efforts to reduce drug acquisition costs will have a direct and negative impact on the bottom line for oncology providers.

- ▶ Most of the proposals discussed in this section target the supply cost of drugs.
- ▶ In the current environment, providers are paid a “commission” for administering drugs to patients.
- ▶ If the underlying cost basis decreases, all other factors being the same, the provider’s margin will also decrease.
- ▶ Given the current environment, a shift to new payment models in the oncology space is plausible (e.g., enhanced administration fees, payment management fees) or even likely.

III. 340B Drug Pricing Program

III. 340B Drug Pricing Program

Overview

Savings from the 340B Drug Pricing 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.

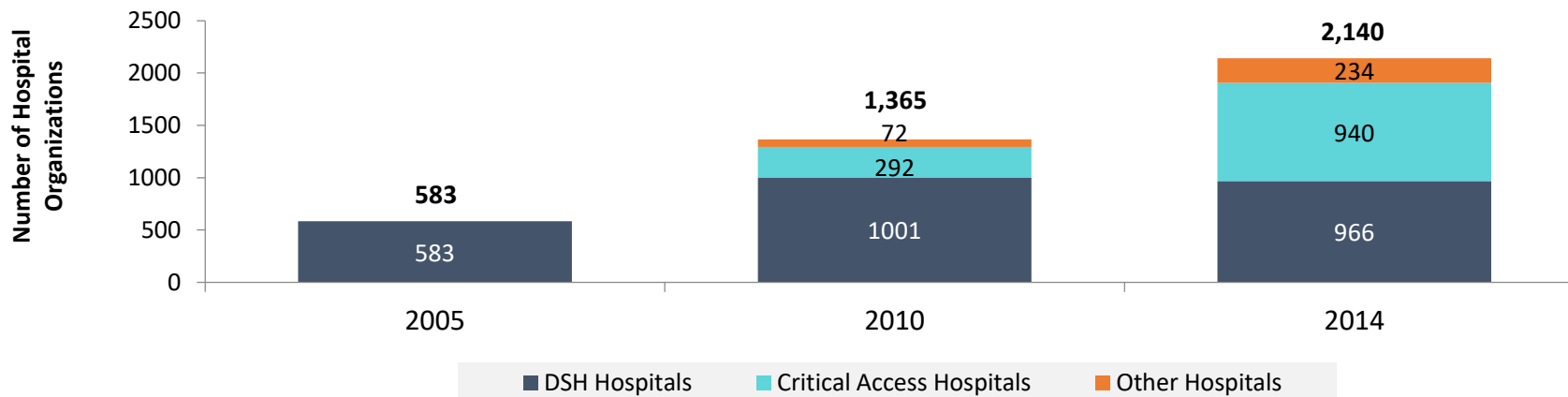
Opponents of 340B claim that the program lacks oversight and that many participating hospitals do not return the funds to the community as they should.

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>.

III. 340B Drug Pricing Program

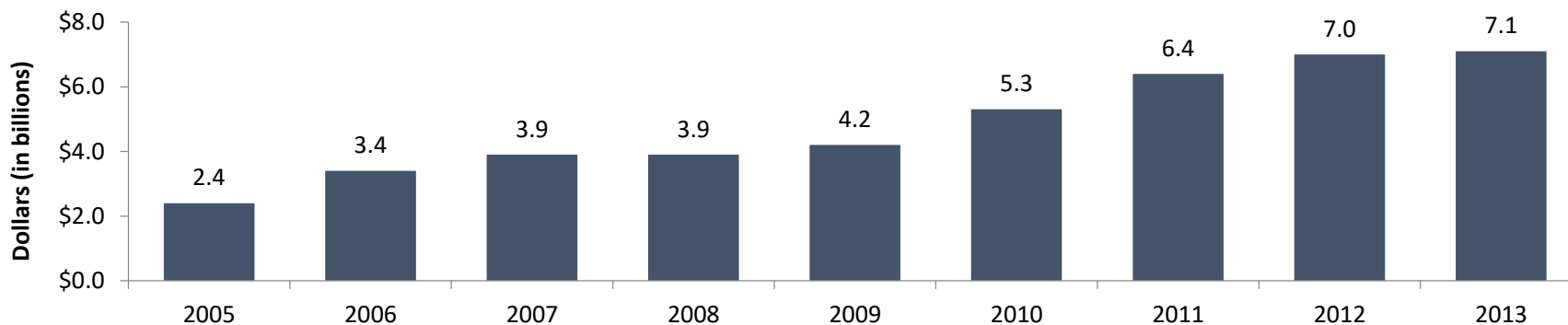
MedPAC Targets 340B Hospitals for Reductions

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.



III. 340B Drug Pricing Program

340B Reimbursement Changes

CMS modified 340B funding in 2018 and is proposing to implement further changes for 2019. As of January 2018, Medicare payments to hospitals for most separately payable drugs acquired through the 340B program are subject to a payment reduction of approximately 30%.

Overview of the 2018 Payment Cut

- Payment reduction is applicable only to payments made under the Medicare hospital OPPS.
- The 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.

Proposed 2019 OPSS Rule

- Payment reduction will now also apply to nonexempted off-campus provider-based departments, in addition to participating entities paid under the Medicare hospital OPSS.
- Critical Access Hospitals, rural sole community hospitals, PPS-exempt cancer hospitals, and children’s hospitals remain excluded from the payment changes implemented in 2018.
- **Comments on the proposed changes will be accepted through September 24, 2018.**



III. 340B Drug Pricing 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%.



III. 340B Drug Pricing Program

Exclusions

Several exclusions were included in the 2018 rule and are expected to remain constant into 2019.

Exclusions

- Does not apply to most contract pharmacy arrangements
- Does not apply to Critical Access Hospitals
- Does not apply to Maryland waiver hospitals
- 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

III. 340B Drug Pricing Program

Litigation Activities

The lawsuit filed against HHS by the American Hospital Association (AHA), Association of American Medical Colleges (AAMC), and America's Essential Hospitals (AEH) was denied by a federal appeals court in July 2018.

Litigation Overview

- In November 2017, a lawsuit was filed by various hospital associations and 340B hospitals to stop the payment cuts.
- It was dismissed in December 2017 based on the judge's ruling that the plaintiffs did not have standing to file the suit.
- After a series of appeals beginning in January 2018, the DC Circuit Court affirmed the lower court's decision and dismissed the case on July 17, 2018, based on the claim that the group had:
 - Filed the lawsuit prematurely.
 - Failed to fulfill the legal prerequisites for judicial review since the OPPI final rule had not become effective yet when the lawsuit was filed.

Latest News

- Following the dismissal, the AHA, AAMC, and AEH stated their intent to refile the lawsuit in district court in an effort to continue the fight to reverse the reimbursement cuts.

AHA 340B lawsuit denied by federal appeals court

Appeals court dismisses 340B payment lawsuit for lack of presentment

Hospital Groups to Continue Fight to Reverse Cuts for 340B Hospitals

AHA Will Refile 340B Lawsuit



III. 340B Drug Pricing Program

Legislative Activities

Several legislative activities aimed at reversing Medicare cuts to 340B have been proposed but are not expected to see passage in the near future. As such, the uncertainty and risk currently associated with the 340B program are likely to continue into the foreseeable future.

Areas of Focus for New Legislation Include:

- Strong focus on 340B-participating hospitals (not on grantees) and limitations on patient eligibility.
- Moratoriums on the registration of certain new 340B hospitals and child sites.
- Increased HRSA oversight authority of 340B program participants.
- Required reporting of amount and use of 340B savings.
- Limits on amounts that could be charged for 340B drugs and on contract pharmacies by number and location.

Current Legislative Proposals

Approximately 15 separate house bills related to the 340B program have been introduced since the reimbursement changes were introduced in late 2017. A selection of these bills is included below.

- **HR 4392:** Prevent CMS from implementing the payment cuts.
- **HR 4710:** Impose a two-year moratorium on new 340B DSHs and locations and require public data reporting.
- **HR 5598:** Establish reporting requirements related to low-income utilization of outpatient hospital services.
- **HR 6071:** Repeal the reimbursement cut, clearly establish the Congressional intent of the 340B program, and impose additional program integrity provisions on drug manufacturers.
- **HR 6240:** Impose a user fee of 0.1% of 340B purchases on hospital-covered entities, which would be used to enhance program integrity and oversight activities and promote access to pharmacy services at hospital-covered entities.

An initial House Energy and Commerce Committee hearing was held in July 2018, with a focus on pulling back the 340B program's ability to expand and limiting patient eligibility. A second hearing is scheduled for September 2018, but it is unclear whether legislation will be produced as a result.



III. 340B Drug Pricing Program

The Outlook

In light of the administration's broader efforts to reduce pharmaceutical costs for consumers, the future of the 340B program is more uncertain than ever.



IV. Oncology Care Model



IV. 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.

Current OCM Participating Practices



IV. Oncology Care Model

Episode Definition

Care episodes are six months in length and include all Medicare Parts 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.



IV. 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

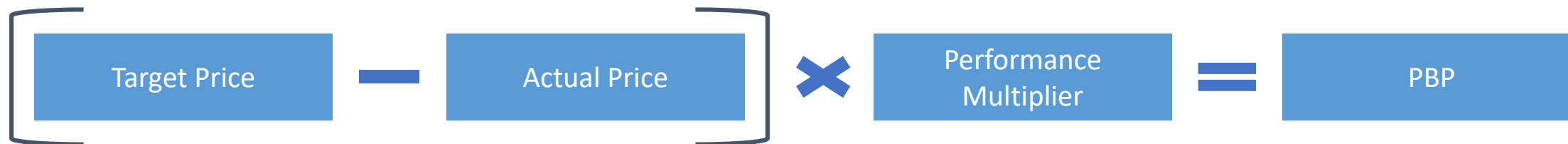
- The MEOS payment provides OCM practices with financial resources to aid in effectively managing and coordinating care for Medicare FFS beneficiaries.
- The \$160 per member per month (PMPM) payment can be billed for OCM FFS beneficiaries for each month of their six-month episodes.

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.

IV. 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 Parts A, B, and D payments).



IV. Oncology Care Model

Lessons for Every Practice

While the OCM pilot includes only a small subset of US 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.

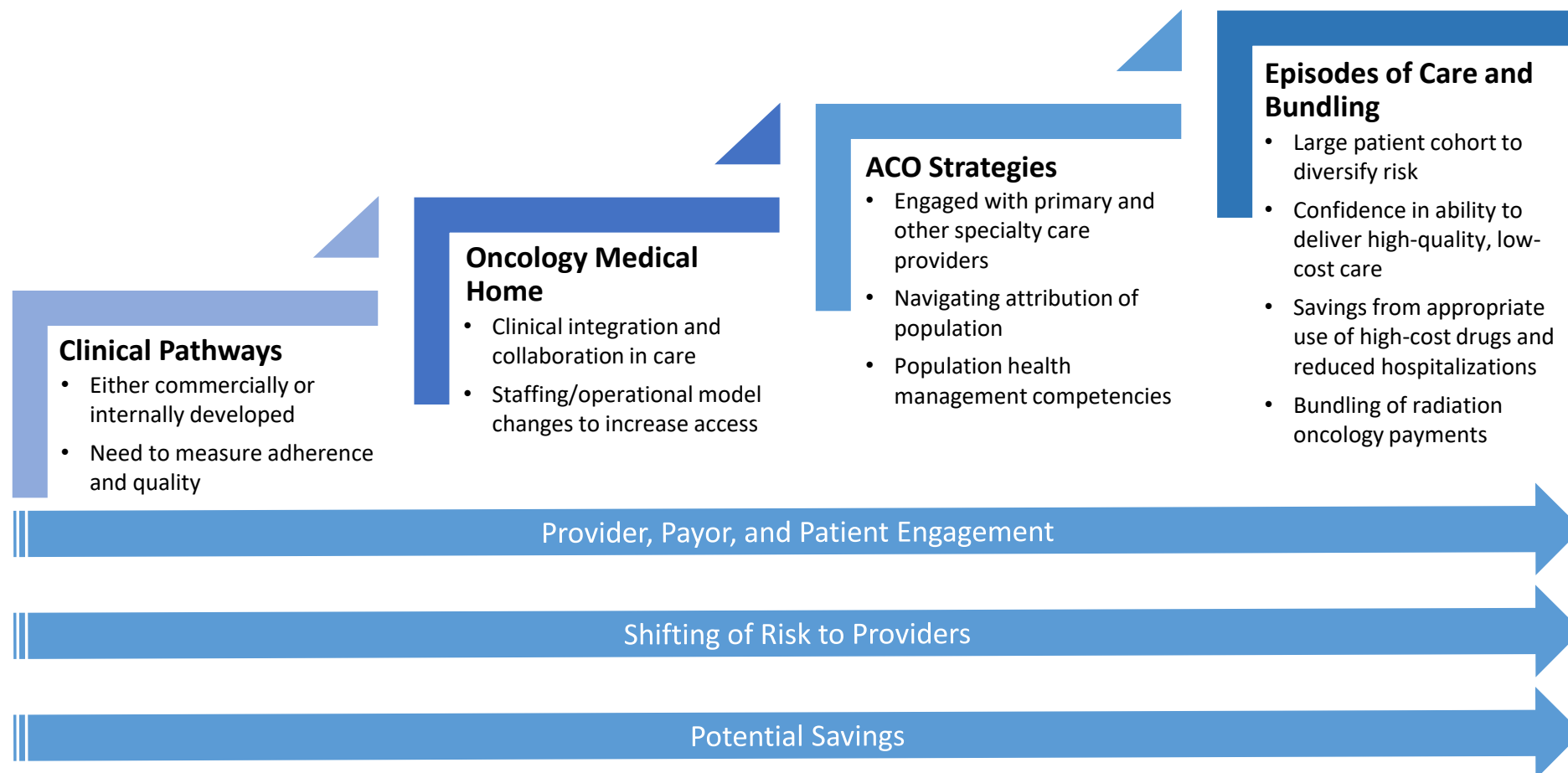


V. New Reimbursement Models

V. 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.



V. 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.



Oncology Episode Pilot Program
(2009–2012)

19
Cancer Episodes

Results

The total cost of medical care for patients in the study was **\$64.76 million**, a **34% reduction** in medical costs for a savings of **\$33.36 million**.



Radiation Oncology Bundled Payments
(2012–current)

13
Cancer Episodes

Results

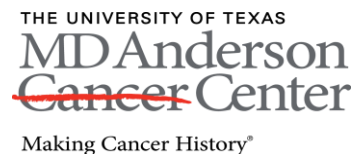
98% compliance with recommended types of resources and prescriptions.



V. 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.



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.

V. 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.



V. New Reimbursement Models

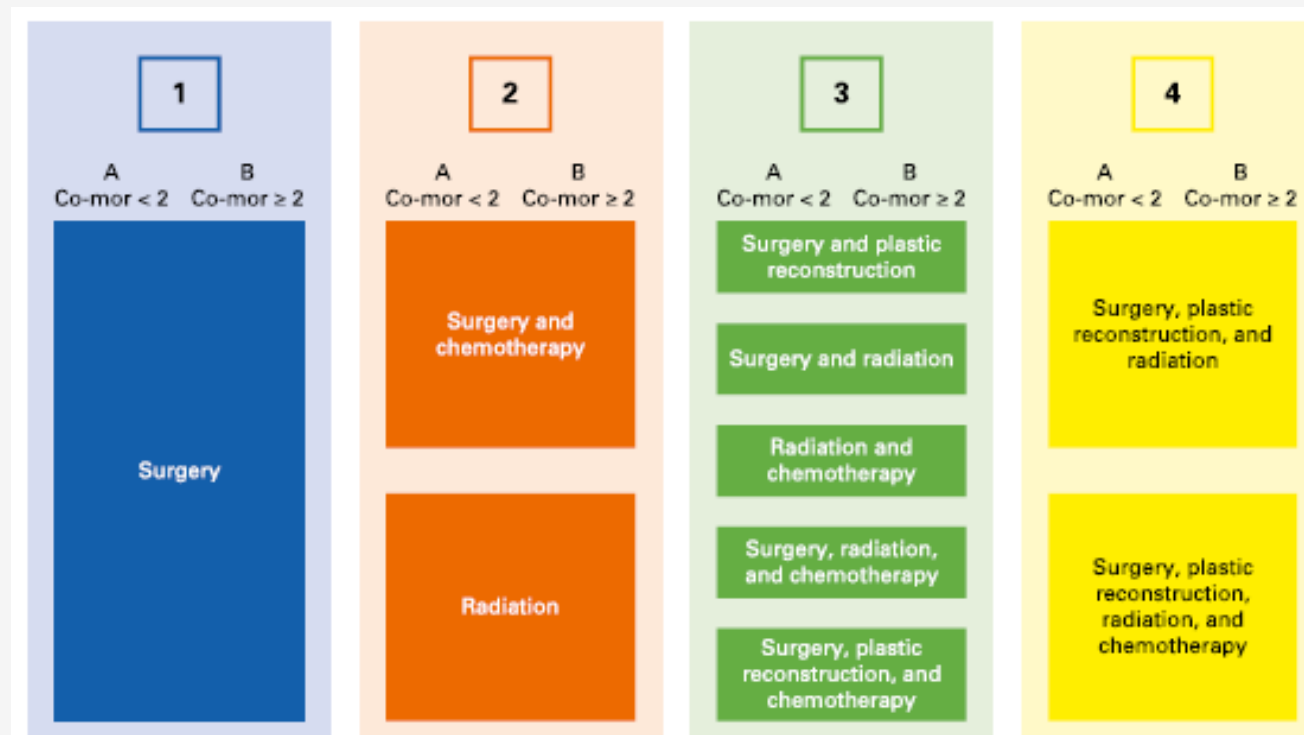
Case Study: MD Anderson and UnitedHealthcare Bundled Payment (*continued*)



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).

V. 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.

V. New Reimbursement Models

Lessons from Other Specialties

In early September CMS released a report on the first year's performance of the Comprehensive Care for Joint Replacement (CJR) Model. Results indicated a savings of nearly \$1,000 per episode. The success of the CJR may fuel interest to expand the concept to other clinical services.

- First year of the pilot projected included:
 - 731 hospitals
 - 67 Metropolitan Statistical Areas
 - 43,801 care episodes
- Cost savings per episode broke out as follows:
 - \$910 total payments (per episode)
 - \$455 skilled nursing facility payments
 - \$350 inpatient rehabilitation facility payments
 - \$83 Part B payments
 - \$109 readmissions payments
- CMS's final statement in the summary was "The CJR model inspired hospital actions and outcomes that are consistent with what has been achieved in other bundled payment initiatives."

VI. ACA Rollback

VI. ACA Rollback

Legislative Action

The Trump administration 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

- The individual mandate was eliminated by reducing the penalty to zero.

August 2018

- New regulations were introduced 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.”
 - Do not have to cover prescription drugs.
 - Can have annual or lifetime limits on the bills the insurance company will pay.
 - Are available only to individuals with good health status.
- Originally limited to three months, these policies can now last up to a year and be renewed to last as long as three years.

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



VI. 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.

Molina pulls out of Utah health insurance marketplace

Anthem leaving Maine's ACA marketplace, citing uncertainty

Medica, the last insurer selling individual health policies in most of Iowa, likely to exit

Aetna adds Virginia to list of Obamacare exits for 2018

ACA: Anthem leaving Nevada health insurance exchange in 2018

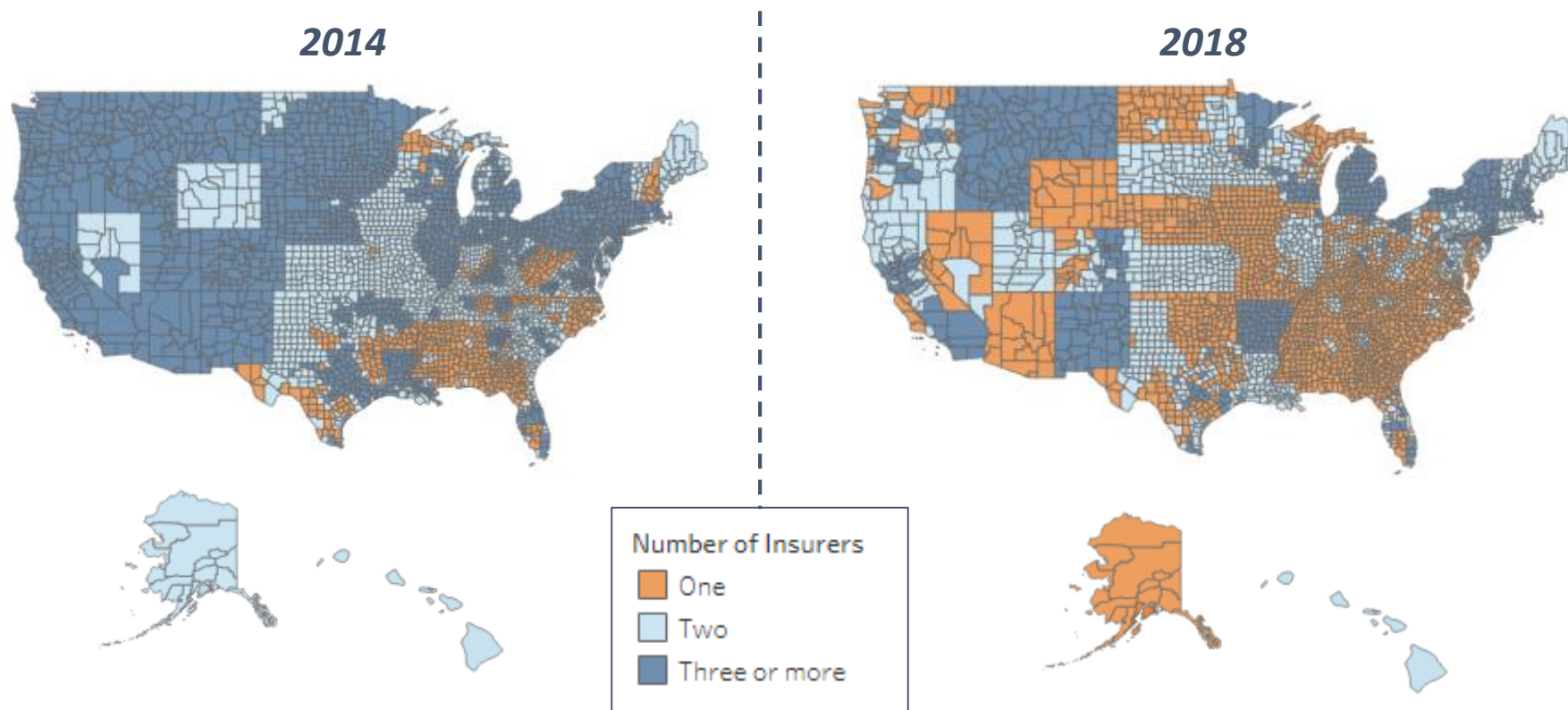


VI. ACA Rollback

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>.



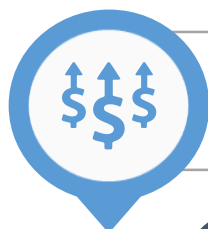
VI. ACA Rollback

Expected Impacts

Eliminating the individual mandate is estimated to leave 4 million fewer 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.



Reemergence 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/doi/10.1377/hblog20180223.551552/full>.

VII. Merit-Based Incentive Payment System

VII. 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)

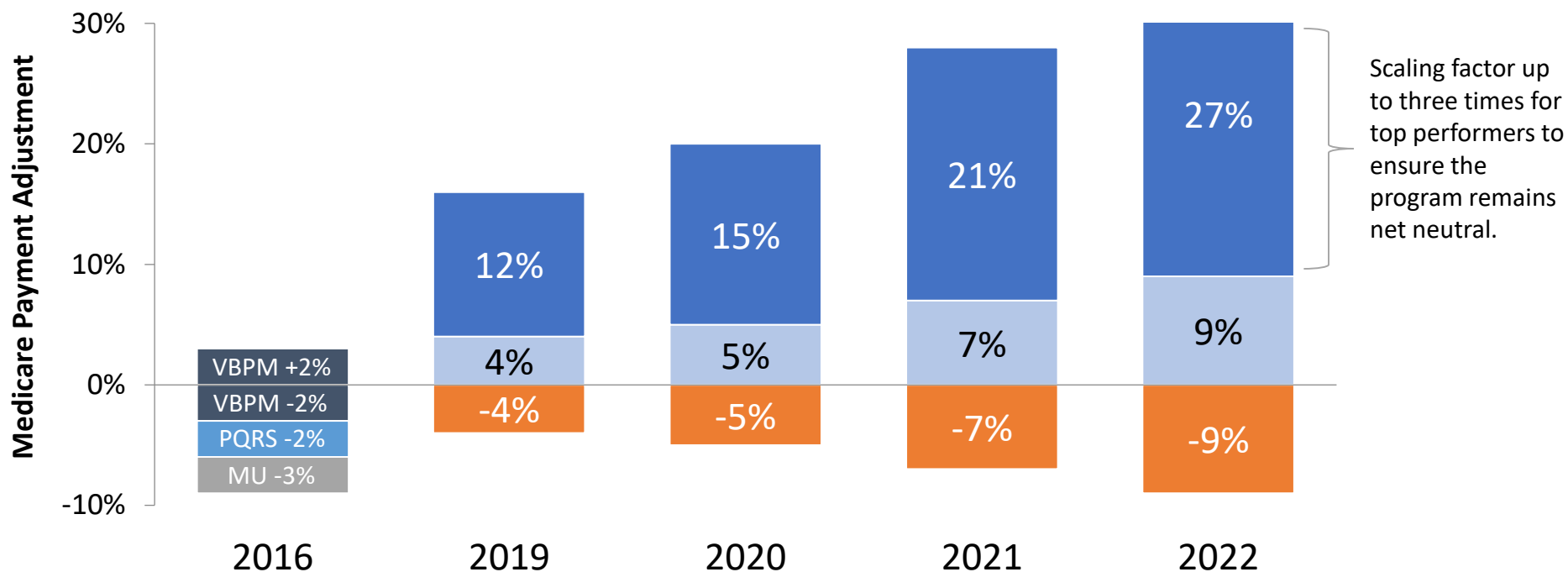
- The MIPS track combines the historical Physician Quality Reporting System (PQRS), meaningful use (MU), and the VBPM program.
- The APM track includes similar performance categories, and metrics already incorporate value-based payment programs.



VII. Merit-Based Incentive Payment System

Comparison to Existing Incentives

Under MIPS, the range of upside/downside potential is substantially greater than it is for the existing programs MIPS replaces.



1 Providers will be assigned a score of 0 to 100 based on their performance across the four categories.

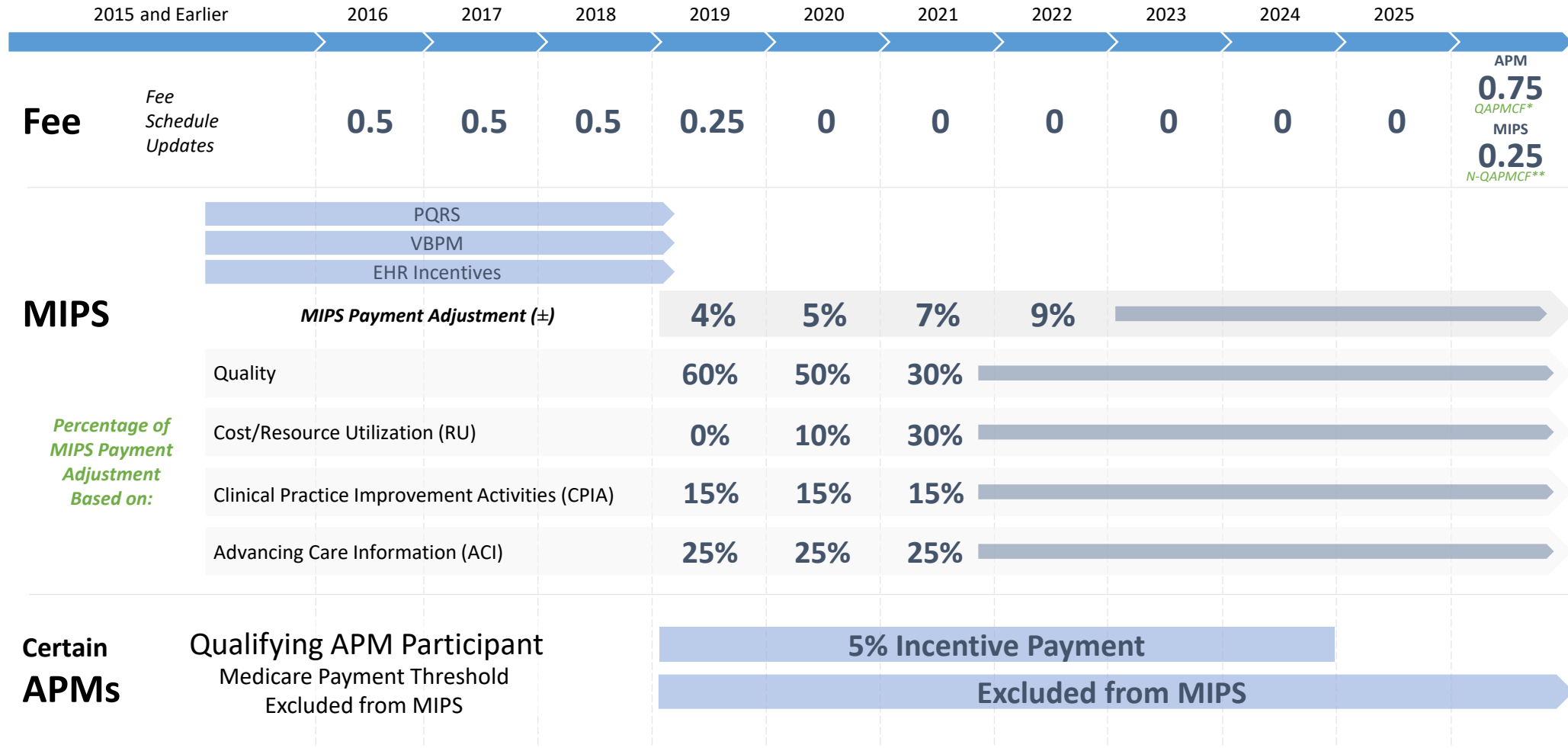
2 Reporting providers will be compared to the CMS-determined performance threshold.

3 Scores above the performance threshold result in an upward adjustment, while scores below it will result in a downward adjustment, where all adjustments are net neutral.



VII. Merit-Based Incentive Payment System

Payment Adjustments Summary



APM
0.75
QAPMCF*
MIPS
0.25
N-QAPMCF**

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

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



VII. Merit-Based Incentive Payment System

Summary of 2018 Changes

The 2018 final rule extended and expanded upon many of the transition features from the 2017 final rule. The Bipartisan Budget Act of 2018 also included a number of revisions to MIPS. A selection of these changes is included below.

The MIPS payment adjustment was limited to professional services only (excludes Part B drugs).

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

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.

Less credit is given for quality measures with incomplete data (1 point versus 3 points in 2017). Additionally, the data completeness standard was increased to 60%.

Different submission methods can be used for each performance category. CMS may consider allowing the use of different submission methods within each category in future years.



VII. Merit-Based Incentive Payment System

Proposed 2019 Changes

Proposed changes for 2019 aim to reduce clinician burden, focus on outcomes, and promote interoperability of EHRs. Comments on the proposed changes were accepted through September 10, 2018.

Low-Value Quality Measures

CMS proposed to remove MIPS process-based quality measures that clinicians have said are low value or low priority. This will allow the program to focus on meaningful measures with a greater impact on health outcomes.

Performance Category Weighting

CMS proposes to increase the cost category weight to 15% (up from 10% in 2018) while lowering the quality category weight to 45% (down from 50% in 2018).

Promoting Interoperability

CMS proposed to transition the Advancing Care Information category into a new Promoting Interoperability category, which promotes patient engagement and the electronic exchange of health information using CEHRT.

MIPS Requirement Waivers

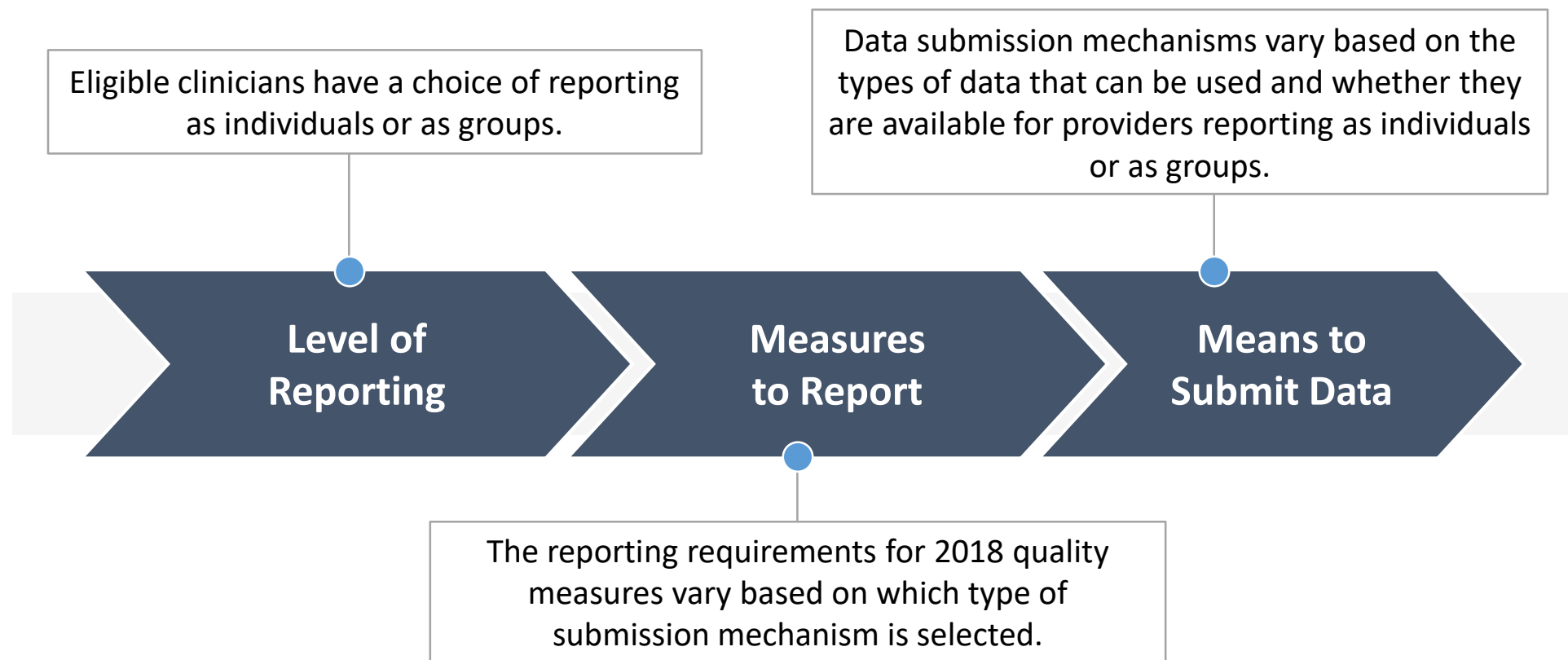
CMS proposed to test a demonstration called Medicare Advantage Qualifying Payment Arrangement Incentive, which would waive MIPS reporting and payment adjustments for clinicians who participate sufficiently in Medicare Advantage arrangements that are similar to Advanced APMs.

Source: <https://www.cms.gov/newsroom/fact-sheets/proposed-policy-payment-and-quality-provisions-changes-medicare-physician-fee-schedule-calendar-year-3>.

VII. 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.



VII. Merit-Based Incentive Payment System

Reporting-Level Considerations

	<i>Individual Reporting</i>	<i>Group Reporting</i>
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.



VII. 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.



VII. 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

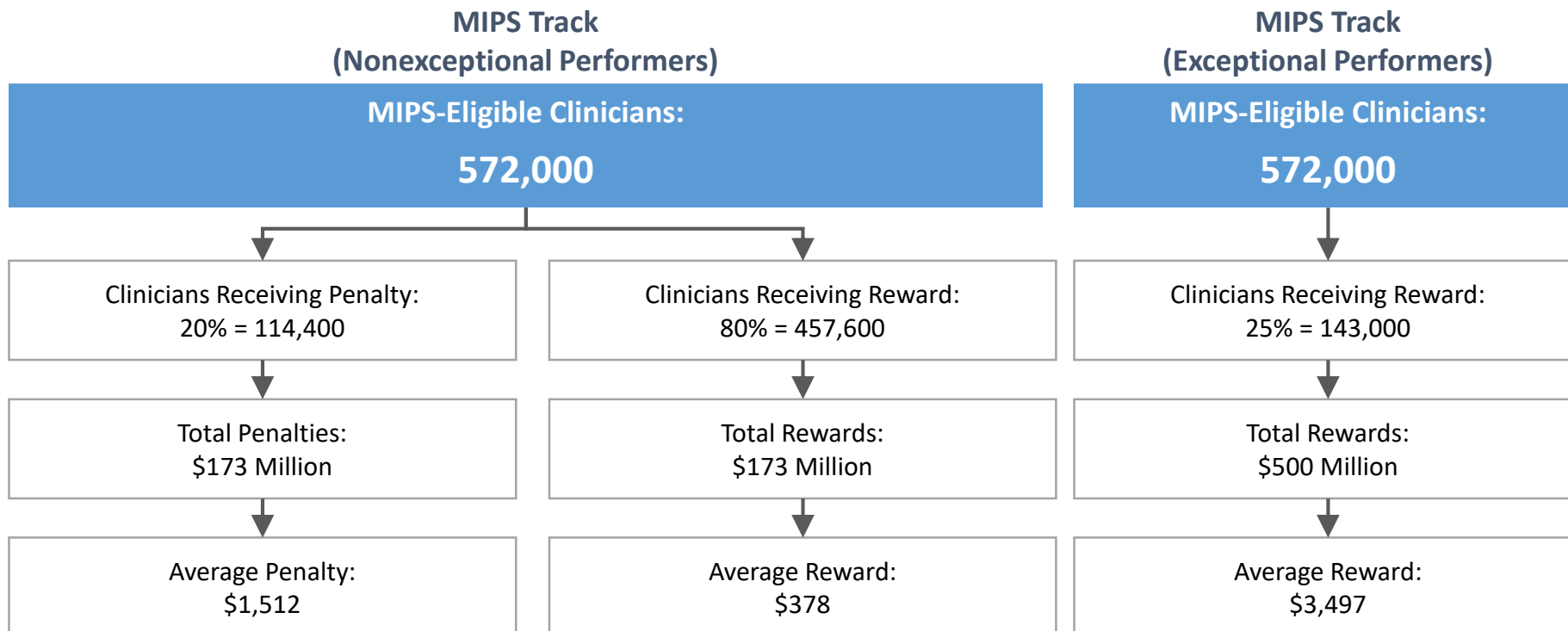


Setting your strategy based on your organization's traditional reporting methods

VII. 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.



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.

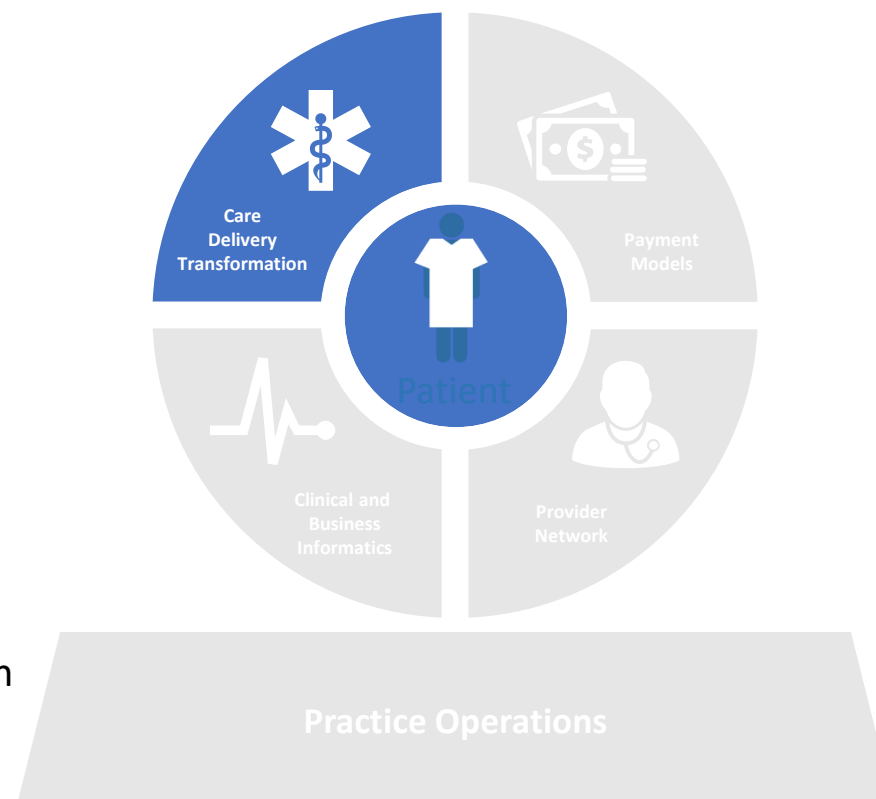


VIII. Takeaways

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 their licenses.
- Standardize processes, roles, and expectations across work areas.
- Eliminate non-value-added operations.

Questions & Answers



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