Megatrends Reinventing the Ways Your Patient, Provider and Payer Customers Think

Manatt Health
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Today's Speakers

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Today's Objectives

Megatrends for three customer segments

"Looking ahead" insights

Q&A with Manatt team

Attendee Polling Question - 1

Which of the three customer segments are of greatest concern to you in your current role?

A. Patients

B. Providers

C. Payers

Landscape Overview

The pharmaceutical industry is facing one of the more uncertain political and regulatory environments in recent memory.

CNBC

In the debate over rising drug prices, both drugmakers and PBMs claim innocence

POLITICO

Why hospitals are suing CMS over 340B cuts

CNN Money

Trump: Drug companies 'getting away with murder'

Trump vows to bring drug prices 'way down'

FiercePharma

Democrats target drug pricing—again—with new economic plan. Will it work this time?

Democrats revive calls for Medicare to negotiate drug prices

The New York Times

Ohio Sues Drug Makers, Saying They Aided Opioid Epidemic

Megatrends for Patients

How Are Threats To Copay Assistance Driving Direct-To-Patient Market Innovation?

Drug Copayment Assistance Increasingly Threatened

California Bill AB 265

- California Assembly member Jim Wood introduced legislation in early 2017 that would **ban use of copay coupons in CA when a generic equivalent drug covered by the individual's health plan exists**.
  - **Bill was signed into law by Governor Jerry Brown on Monday, October 9, 2017**
  - Exceptions in the law include HIV and AIDS maintenance drugs, drugs for individuals who have completed required step therapy or other prior authorization requirements
  - Manufacturers can continue to offer products free of cost (to patients and/or insurer); pharmacists can continue to substitute a drug; patients can still obtain assistance through independent charities
  - PhRMA issued a statement following the Governor's signature, stating the law doesn't ensure patients who need branded products over generics will be able to get those drugs

California Bill SB 17

- On the same day Governor Brown also signed into law SB-17, a piece of legislation forcing drug manufacturers to give warning of and explain increased prices of their products

California Legislative Information, AB265: https://leginfo.legislature.ca.gov/faces/billTextClient.xhtml?bill_id=201720180AB265; http://www.fiercepharma.com/regulatory/copay-coupon-bill-signed-california-dealing-double-whammy-to-pharma

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Ongoing Investigations of Patient Assistance Charities Jeopardize Patient Access to Medications

Investigations, subpoenas and inquiries are more widespread.

Investigations into Patient Assistance Programs

- IRS is investigating tax-exempt status of patient assistance charity Good Days—formerly the Chronic Disease Fund (CDF).
- Investigation alleges Good Days' copay assistance program gave "impermissible" benefits to its pharmaceutical company donors by returning money donated as payments for drugs they manufacture.
  - If claims prove true, Good Days could lose its tax-exempt status.
- U.S. Attorney's Office for the District of Massachusetts also conducting separate inquiry into patient assistance groups and their relationships with drug industry.

Life Science Companies Increasingly Receiving Subpoenas

- Support of 501(c)(3) organizations that provide financial assistance to patients (2017)
- Payments to charities that help Medicare patients pay for their drugs (2017)
- Relationship with the Patient Access Network Foundation (PANF) and other nonprofits that offer financial assistance to Medicare patients (2016,2015)
- Alleged collusion with PANF and CDF to boost sales of specific product (2016)
- Funding of co-pay assistance programs (2016)
- Contributions to patient assistance programs (2015)

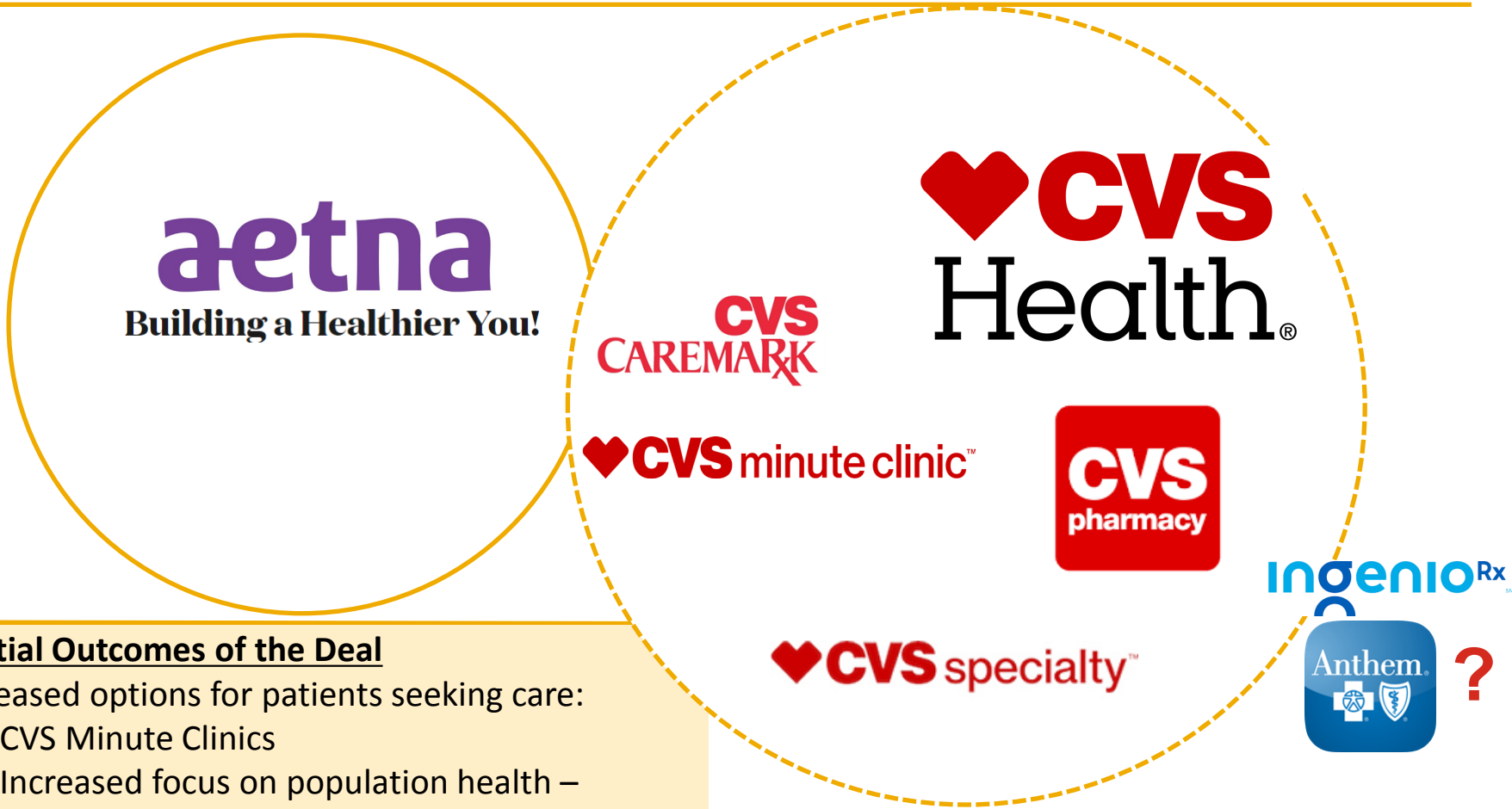
PBMs Are Entering The Drug Discount Program Space

PBMs are developing a more comprehensive menu of consumer-oriented services as a hedge against cost pressures, to create positive press and to leverage their unique role in the supply chain.

	CVS caremark + novo nordisk	+ AARP®
Description	Direct-to-consumer savings program for three Novo insulin products " [Novolin R®, Novolin N® and Novolin 70/30®] where patients forego insurance coverage, if they have it, and pay discounted amount completely out of pocket (cash pay)	AARP members and families receive discounts on medications [FDA-approved generic, brand name, or specialty drugs] not covered by the patient's current prescription plan or Part D plan
Coverage Status	Uninsured or insured who forego use of insurance (cash-paying)	Underinsured

PBM: Pharmacy Benefit Manager; ExpressScripts/Lilly: https://investor.lilly.com/releasedetail.cfm?ReleaseID=1003887; CVS/Novo Nordisk: http://www.prnewswire.com/news-releases/cvs-health-launches-reduced-rx-savings-program-to-give-patients-access-to-more-affordable-medications-300424627.html; OptumRX/AARP: https://advantages.aarp.org/en/offer.aarp-prescription-discounts-provided-by-optumrx.10187.html

Continued Consolidation in the Healthcare Industry



Potential Outcomes of the Deal

- Increased options for patients seeking care:
  - CVS Minute Clinics
  - Increased focus on population health – better outcomes for less cost
- Savings through more efficient formulary design
- More leverage in price negotiations

CVS recently announced next-day delivery of drugs (same day in NYC)

As Amazon Contemplates Entering the Healthcare Market, A New Frontier Could be Emerging

- Amazon's primary customer is between **30 and 45 years old**
- Amazon is already competing with in-store pharmacies on over the counter medications
- Opportunity to establish in-store pharmacies within Whole Foods with prescription fulfillment through mail-order delivery

https://www.forbes.com/sites/stephenbrozak/2017/10/20/amazons-invasion-looms-over-healthcare/#50d67de56749

Looking Ahead

Pharmaceutical company sponsored patient copayment assistance – through copay cards and giving to charitable foundations – will continue to be threatened

Overlay of state drug pricing transparency legislation (with or without copay bans) adds additional pressure on helping patients in traditional ways

Concurrently, emerging entities are signaling direct-to-patient assistance in new ways

Pharmaceutical companies will need to seek "safe harbors" and pilots to continue traditional model of support while designing innovative ways to engage through emerging partners

Megatrends for Providers

Attendee Polling Question - 2

How does your organization participate in the 340B program?

A. Pharmaceutical manufacturer

B. Hospital or other 340B covered entity

C. Other type of organization or entity

D. My organization does not participate in the 340B program

What is the Future of the 340B Program?

340B Program Overview

Established in 1992, and enables eligible healthcare providers and programs ("covered entities") to purchase outpatient drugs for their patients at discounted prices.

Covered Entities

Covered entities are:

- DSH hospitals, freestanding cancer hospitals and children's hospitals with disproportionate share adjustment percentage > 11.75%
- Sole community hospitals/rural referral centers with disproportionate share adjustment percentage > 8%
- Critical access hospitals
- FQHCs and FQHC look-alikes
- Family planning projects funded under Section 1001 of the Public Health Service Act
- Ryan White clinics
- State AIDS drug assistance programs
- Black lung clinics
- Hemophilia treatment centers
- Native Hawaiian health centers and urban Indian organizations
- Federally funded STD and tuberculosis clinics

Eligible Patients

Patients of a covered entity must meet three requirements to be eligible for 340B drugs:

- Covered entity maintains records of individual's healthcare
- Clinician providing services to individual is employee of covered entity, or provides healthcare under another arrangement so that responsibility for care remains with covered entity
- Other than for hospitals, services must be consistent with the services for which the covered entity receives the grant funding that qualifies it for covered entity status

Individual does not qualify as a patient of a covered entity for 340B purposes if the only healthcare services the individual receives from the covered entity is the dispensing of drugs for subsequent self-administration or administration in the home setting

340B Program Overview *(cont.)*

340B drugs may be dispensed through both in-house and contract pharmacies, but are subject to certain restrictions

Role of Pharmacies

In House Pharmacies

- A covered entity may dispense 340B drugs through in-house pharmacies, if it has in-house pharmacies

Contract Pharmacies:

- In addition to dispensing 340B drugs through in-house pharmacies, a covered entity may enter into "contract pharmacy arrangements" with outside pharmacies

GPO Exclusion

GPO Exclusion

- DSH hospitals, children's hospitals and cancer hospitals that participate in 340B program may not purchase "covered outpatient drugs"—i.e., drugs covered by 340B program—through a GPO.

Prohibition on Duplicate Discounts

Prohibition on Duplicate Discounts:

- A drug may not be subject to both a 340B discount and a Medicaid rebate
- If covered entity uses 340B drugs for Medicaid patients, Medicaid program must be able to identify and exclude such drugs from rebate requests
- 2016 OIG report found most Medicaid programs use provider-level methods to identify and exclude 340B drugs from rebate stream; recommended use of claims-level methods instead
- Drugs dispensed to MCO patients create particular challenges

340B: Impact of the Affordable Care Act (ACA)

- Expanded covered entities to include qualifying children's hospitals, critical access hospitals, free standing cancer hospitals, sole community hospitals, and rural referral centers.
- Exempted orphan drugs from the 340B definition of a "covered outpatient drug" making them ineligible for 340B discounts

Mandated that drugs provided by Medicaid MCOs be included in Medicaid rebate requests, meaning that state Medicaid programs must:

- Track drugs provided through Medicaid MCOs
- Where such drugs are 340B drugs , ensure those drugs are not included in Medicaid rebate requests

340B: Current Issues

Reductions in Medicare Part B Reimbursement

- **Hospital Outpatient Prospective Payment System Final Rule released 11/1/17:**
  - Effective as of 1/1/18
  - Reduces Medicare Part B reimbursement for 340B drugs from ASP plus 6% to ASP minus 22.5% (excluding pass-through drugs and vaccines).
  - Children's hospitals, free-standing cancer hospitals and sole community hospitals are exempted from the reductions
  - Provides that CMS will establish two modifiers for hospitals to use to identify whether a drug billed under the OPPS was purchased under the 340B program

Other Regulations in Development

- **Civil Monetary Penalties Rule:** *Final Rule published 1/5/17*
  - Will impose civil monetary penalties on pharmaceutical manufacturers that intentionally overcharge covered entities for 340B drugs. Effective 10/1/17.
- **Administrative Dispute Resolution Rule:** *Proposed Rule published 8/12/16*
  - Would establish administrative dispute resolution process to resolve claims by covered entities that have been overcharged for 340B drugs. Not yet finalized.

340B: Current Issues *(cont.)*

340B program has been caught up in debate about prescription drug prices - policymakers have renewed focus on the program, particularly for DSH hospitals:

- June 2017: Leaked executive order from Trump administration suggested 340B Program would start to tie volume of discounted drugs to indigent patient volume.
- October 2017: House Oversight and Investigations Subcommittee held hearing titled, "Examining How Covered Entities Utilize the 340B Drug Pricing Program."
- November 2017: Medicare Part B reimbursement for 340B drugs for most hospitals reduced to ASP minus 22.5%

Scrutiny of 340B program is not new – for example:

- September 2011: GAO report called for increased government oversight over the 340B program
- July 2012: House Ways and Means Health Subcommittee members urged HRSA to issue an updated definition of a patient to limit the program's eligibility for those truly in need and curb any misuse of the program
- March 2013: Senator Grassley asked HRSA to collect data on how the revenue covered entities receive through the 340B program, and how they use such revenue.

340B: Prior concerns led to efforts at reform

Omnibus Guidance

- **Guidance published in August 2015** would have addressed a broad range of topics, including definition of "patient" for 340B purposes.
- **Withdrawn** by current administration on 1/30/17; next steps unclear.

HRSA Covered Entity Audits

- **HRSA began auditing covered entities in 2012**, conducting over 600 audits; nearly 60% were of DSH hospitals.
- **Common audit findings include:**
  1) Having incorrect primary contact,
  2) Providing 340B drugs to inpatients and
  3) Failing to maintain auditable records.
- **Corrective actions** typically involve entity repaying drug manufacturer all the savings and correcting information in HRSA database.

Looking Ahead

Continued focus on pharmaceutical pricing likely to result in continued focus on 340B Program

Medicare Part B reimbursement reduction for 340B drugs to ASP minus 22.5% finalized in recent Medicare HOPPS final rule

Potential changes to patient definition remain in flux; unclear what next steps will be particularly given Trump administration restrictions on issuance of additional regulations

Efforts to repeal ACA could impact 340B provisions implemented by the ACA, such as inclusion of additional covered entities and requirement that state Medicaid programs seek rebates on drugs dispensed to Medicaid MCO patients

Any legislative action will draw strong reactions from powerful pharmaceutical company and hospital lobbying organizations

Megatrends for Payers

Do Value Based Payment Models Encourage The Use of Innovative Products?

Administration Support of Value-Based Payment Models With Changes to Quality Measures

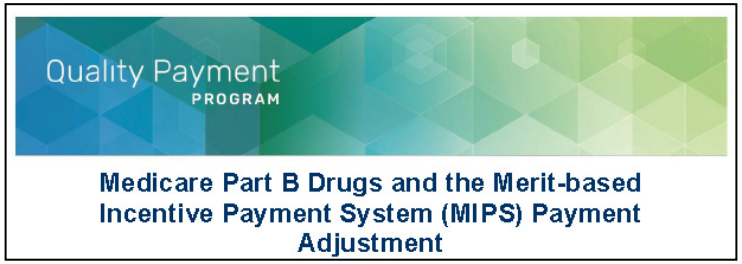
- ***The "move to value is still a strong priority at CMS…. It's not a partisan issue."***

  Kate Goodrich, M.D., Director and CMS Chief Medical Officer, National Quality Forum Annual Conference. April 4-5,2017

- ***"We are revising current quality measures across all programs to ensure that measures are streamlined, outcomes-based, and meaningful to doctors and patients. 'Meaningful Measures' takes a new approach to quality measures to reduce the burden of reporting on all providers. "***

  Seema Verma. Administrator CMS. Health Care Payment Learning and Action Network Fall Summit, October 30, 2017

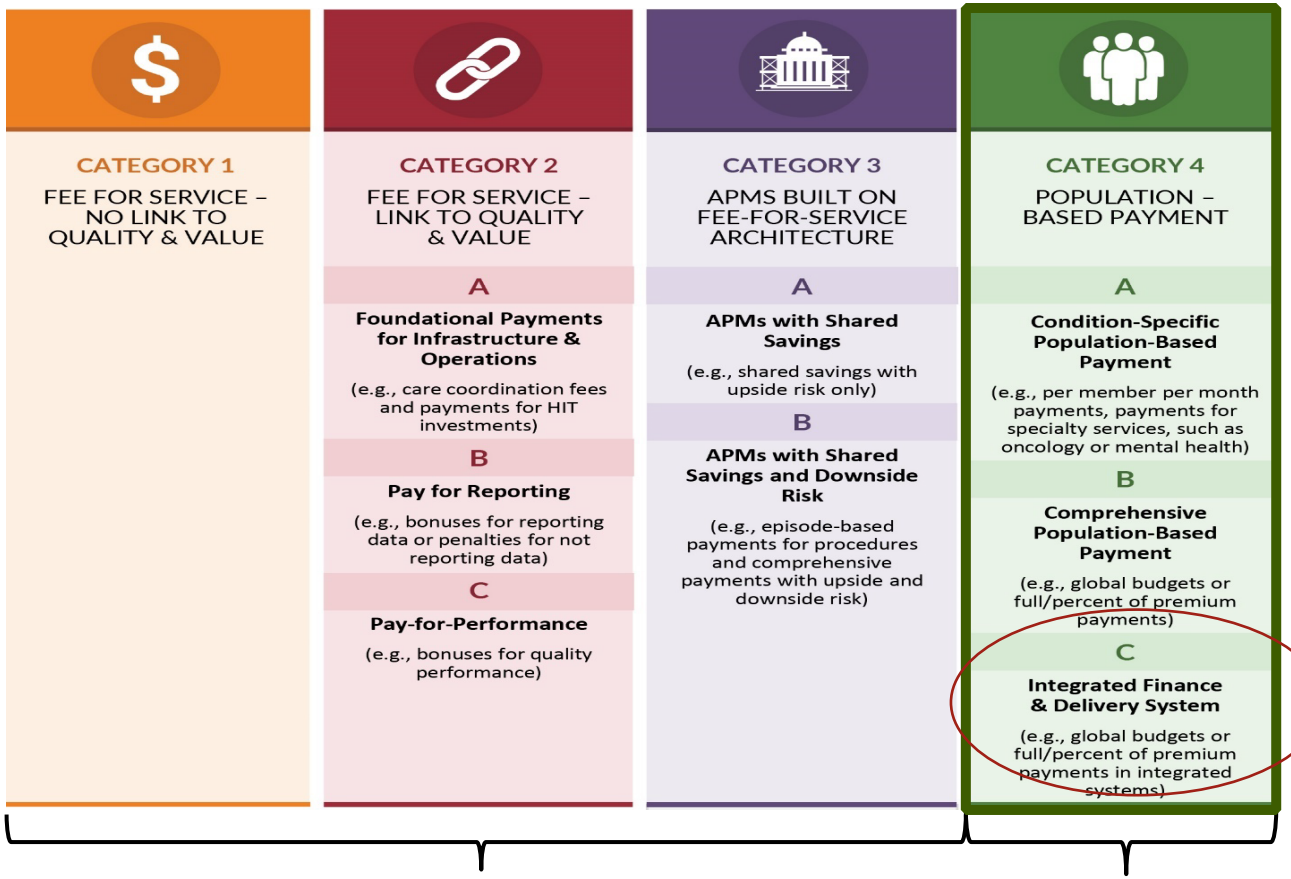
- ***"We will continue to explore methods to add Part D drug costs into cost measures in the future."***



CMS. Quality Payment Program Final Rule. and Part B Drug Fact Sheet (November 2017)

Merit-based incentive payment **adjustments apply to Part B drugs** when the cost of the drug itself and administration of the drug are directly attributed to an eligible clinician.

Value-Based Payment Model Categories Recognize Consolidation of Market Players



Refreshed Alternative Payment Model (APM) Framework
A payment model classification system originally developed by CMS and refined by the Health Care Payment Learning Action Network.

New: "Integrated Finance & Delivery System"

Reliant on Fee-for-Service Architecture: Generally tied to existing codes, coverage, and payment policies unless specifically "waived"

Population-based payment: More flexibility

"Alternative Payment Models (APM) Framework: Refreshed for 2017". July 10, 2017.

Attendee Polling Question - 3

In which of the more advanced value-based payment model categories are you currently exploring potential arrangements? (choose any that apply)

A. **Category 3:** Advanced Payment Models Built on Fee-for Service Architecture

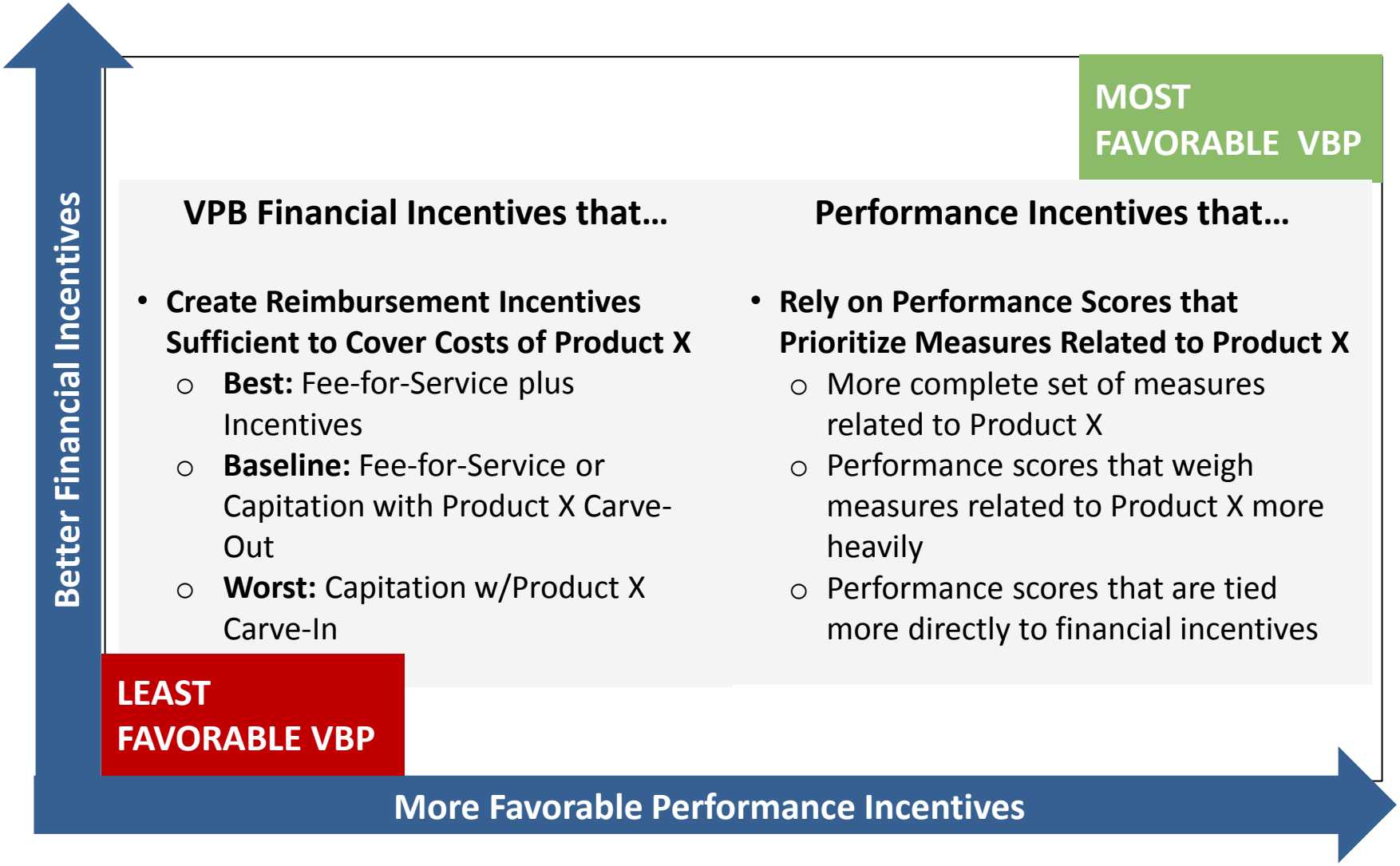
B. **Category 4:** Population-Based Models (e.g., PMPM, global budgets)

C. **None** of the above

Do Alternative Value-Based Payment Models (VBP) Encourage Use of Innovative Medications?

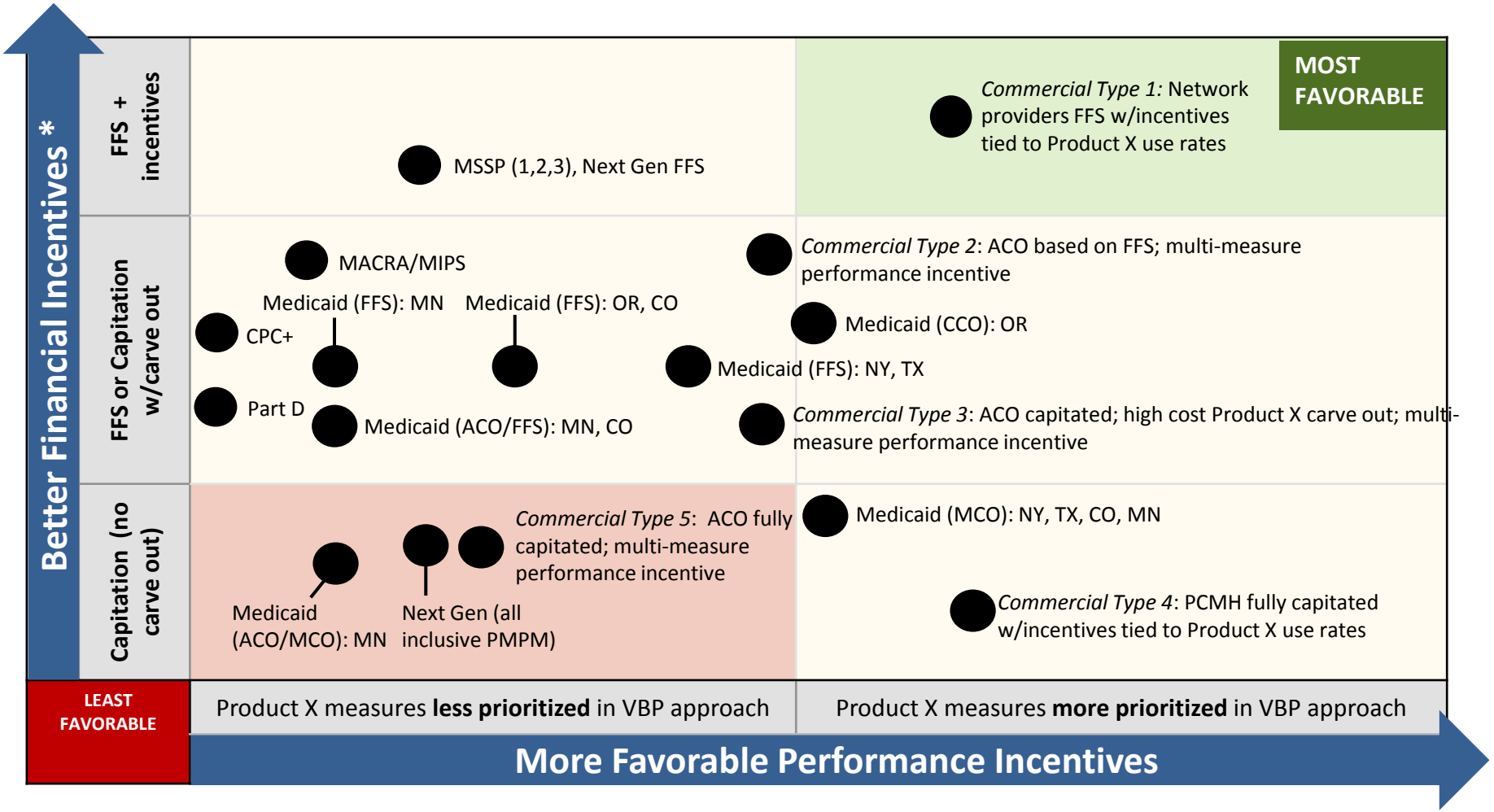
1. What are the dominant reimbursement methods for Product X within value-based payment (VBP) models? Are there bonuses/losses tied to the Product X?
2. Which VBP models include quality measures relevant for Product X?
3. What are the statutes/regulations that guide coverage and patient cost-sharing for Product X that the value-payment payment models must comply with?
4. Do VBP models include provider and patient education on use of Product X?

Product X Radar Mapping - Example
What VBP Design Features Incentivize Use of Product X?



Value-Based Payment Models on the "Product X Radar"

Value-based payment models vary widely on how strongly they incentivize Product X



* MCO: Managed Care Organizations; CCO: Coordinated Care Organization

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Looking Ahead

Move towards more integrated, risk-based and value-based payment and delivery will not change

Understand which value-based payment models and to what extent these models encourage use of medical innovations generally, and which type of medical innovations are encouraged

Continue to shape environment for value-based arrangements, including provisions to protect access to medical innovations

Engage in development and encourage the inclusion of performance measures to address the "Value" of Product X, with more attention to outcomes, population health measures and resource use measures

Engage providers who are often confused about VBP and impact of the use of Product X

What Is The Potential Impact of CMMI RFI?

CMMI is the Medicare and Medicaid R&D Lab

The Center for Medicare and Medicaid Innovation (CMMI) is an independent office at CMS that experiments to increase quality and reduce costs in Medicare, Medicaid and CHIP

- Created under the Affordable Care Act
- Budget of $10 billion for every 10 years
- Can waive Medicare, CHIP and some Medicaid requirements

The CMMI Model Life Cycle

Testing:

CMMI runs small-scale pilot programs

Evaluation:

Pilots' effect on cost and quality measured through independent analysis

Expansion:

Programs made permanent if they improve quality or decrease cost

Recent RFI Announces "New Direction" for CMMI

"This administration plans to lead the Innovation Center in a new direction. … We are issuing a 'request for information' to collect ideas on the path forward."

- CMS Administrator Seema Verma

- RFI Announces "guiding principles" for new model tests (and rethinking of old ones) under current leadership.
- Advertises priorities and hints at specific new model tests.
  - Priorities can change – HHS Secretary & CMMI Director positions vacant.
- Seeks comments and ideas for tests by November 20, 2017: innovation.cms.gov/initiatives/direction

Response is chance to suggest specific policies, influence direction of CMMI, and position responder as partner for innovation with CMS

CMMI RFI Proposes Overarching Principles for New Model Tests

These principles reflect administration's priorities and its critique of past CMMI activities. They are not specific to any particular model test.

1. Choice and competition in the market
2. Provider choice and incentives (esp. *voluntary* tests)
3. Patient-centered care
4. Benefit design and price transparency
5. Transparent model design and evaluation
6. Small-scale testing

CMMI will promote these general themes across all new models

CMMI Highlights Drug Models in RFI

Quotes from RFI…	…their potential meaning
"test new models for prescription drug payment in Medicare Part B and Part	Need solutions to reduce drug costs in Medicare and Medicaid
"Novel arrangements between plans, manufacturers, and stakeholders" including value based purchasing"	Want to encourage value-based purchasing
"increase drug pricing competition while protecting beneficiaries' access to drugs."	Considering formulary flexibility in exchange for cost reduction, but need mechanisms to protect beneficiaries

CMS Will Focus on Prescription Drugs Using All Available Tools

CMMI has limited waiver tools on prescription drug costs, as it lacks authority to waive the Medicaid best price rule, frequently cited as a barrier to value-based contracting. Expect CMS to use other tools to promote value-based contracting.

Example: The Kymriah "Deal"

- Novartis announces agreement with CMS for gene therapy "focused on improving efficiencies in current regulatory requirements" to permit indication-based pricing.
- CMS does not confirm, but states it is "continuing to explore the development of payment models and arrangements for new and potentially life-saving treatments."
- Arrangement may be that CMS will provide separate J codes/HCPCS codes for each Kymriah indication.
- CMS promises to issue "future guidance to explain how pharmaceutical manufacturers can engage in innovative payment arrangements."

The "future guidance" may shed light on how to report prices of drugs in value-based arrangements so as to not trigger best-price obligations.

Looking Ahead

CMMI will survive in new administration, but direction still in flux

Request for Information reveals CMMI's interest in reducing prescription drug costs: Potential willingness to experiment with consumer incentives, value-based purchasing and formulary flexibility

Expect prescription drug activity across CMS, not just from CMMI

CMS guidance on value-based contracting, if/when released, will shed light on agency priorities and methods in prescription drug contracting

Attendee Polling Question - 4

Which of the megatrends discussed do you believe will most impact your organization in the next three years?

A. Direct-to-patient innovation

B. 340B changes

C. Value-based payment

D. CMMI demonstrations

Manatt Panel Roundtable

Questions and Discussion

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Thank you from the Manatt Team

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