Value-Based Care Fundamentals:

A Guide for Health Law Professionals

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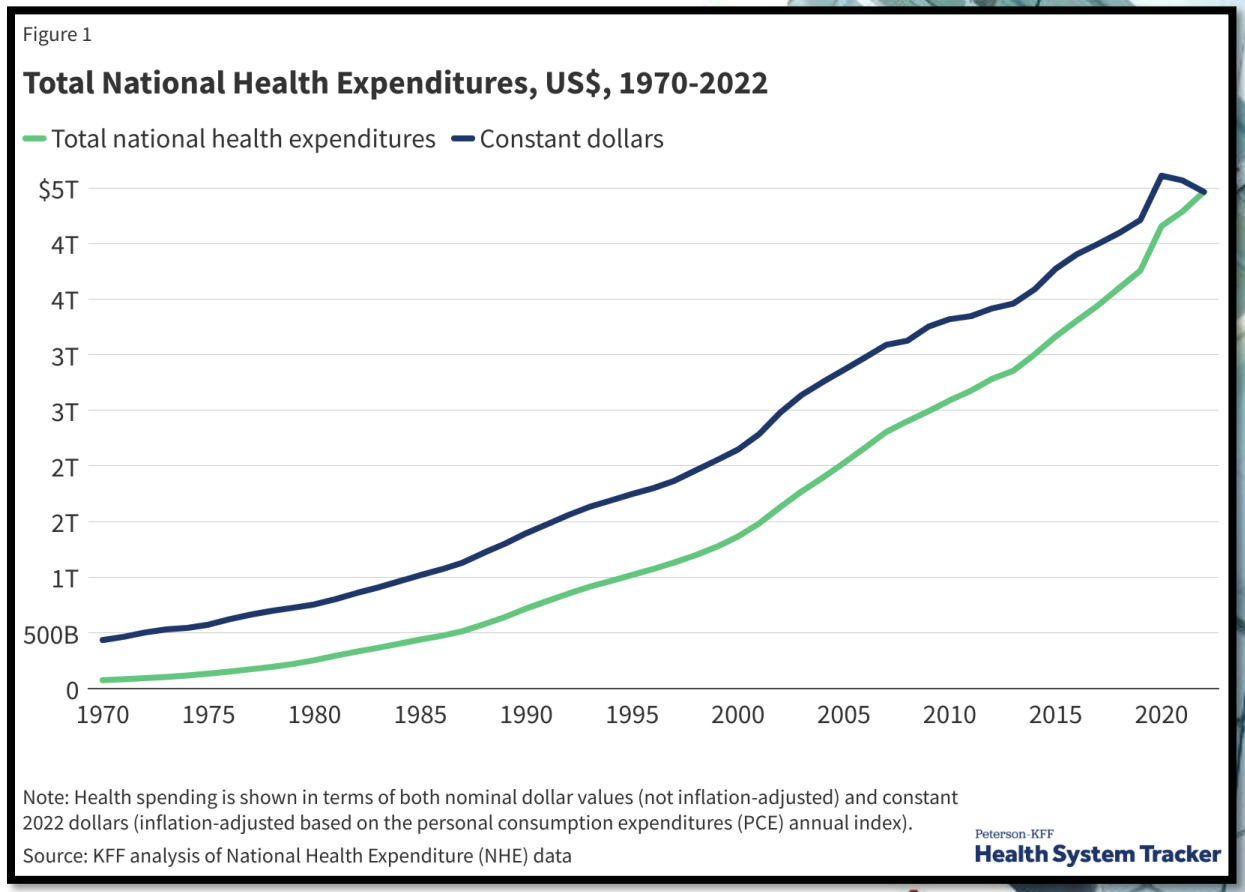
Agenda

1. What is Value-based Care
2. Legal structures and current payor models
3. Regulatory flexibilities
4. Legal and operational issues

What is Value-Based Care?

A Financial Perspective

- Health care costs continue to increase, leading political leaders, providers, and academics to think about how to use alternative payment models to change care delivery and reimbursement to slow health care growth trajectory.



What is Value-Based Care?

Value-based care incentivizes a focus on quality of care and health outcomes rather than volume through a wide range of health care payment/delivery models that:

- Encourage organization and coordination of care across settings to improve care
- Establish quality/cost metrics and benchmarks for research/comparison
- Support providers in collecting/analyzing/managing data to effectively track quality/costs and use it to improve care

Shift to Value-Based Care Models

Indicators of Longevity

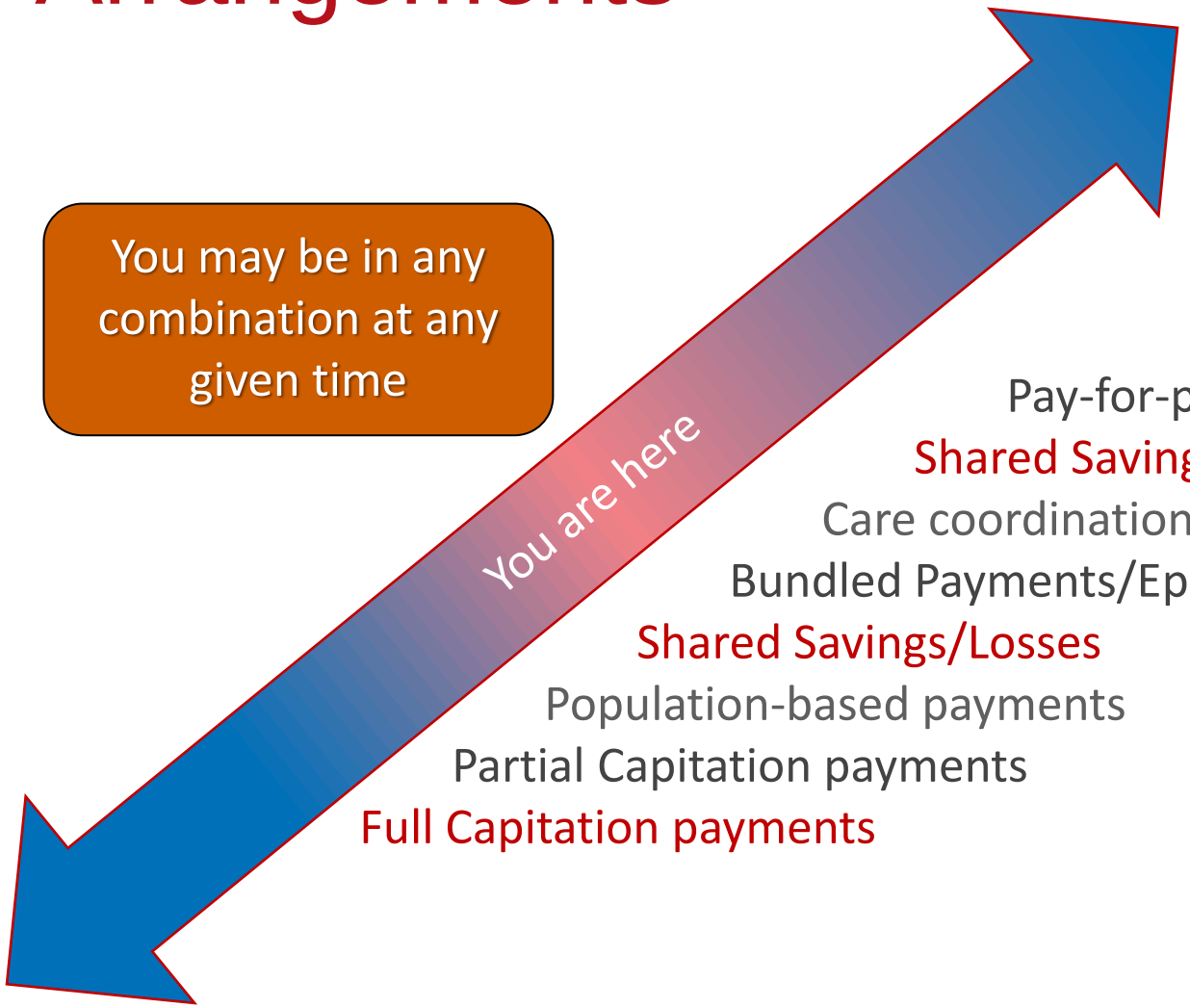
CMS Vision: CMS aims for all Medicare fee-for-service beneficiaries and the vast majority of Medicaid beneficiaries to be in a care relationship with accountability for quality and total cost of care by 2030.

HCP-LAN goal: 50% of commercial payments and 100% of MA through two-sided risk alternative payment models by 2030.

Private equity investment in companies that focus on quality over volume increased more than 400% between 2019 and 2021, according to a 2022 McKinsey analysis.

Examples of Value-Based Arrangements

You may be in any combination at any given time



Pay-for-performance *(reporting; quality)*

Shared Savings *(upside only)*

Care coordination/care management payments

Bundled Payments/Episode payments

Shared Savings/Losses

Population-based payments

Partial Capitation payments

Full Capitation payments

Primary Legal Structures

Accountable Care Organization (ACO)

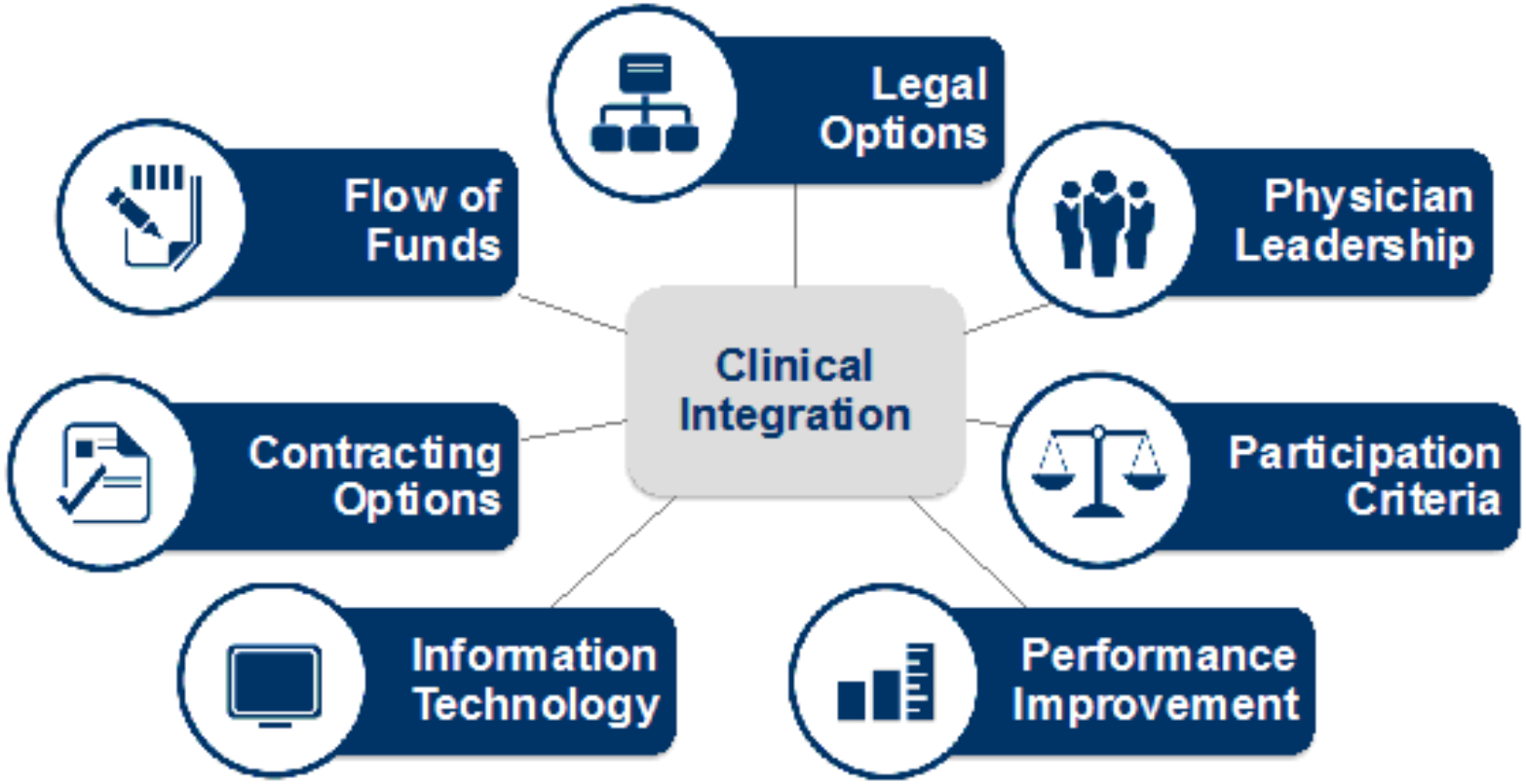
- Accountable Care Organizations (ACOs) are groups of doctors, hospitals, and other health care providers, who come together voluntarily to give coordinated high-quality care to the patients they serve.
- Product of Affordable Care Act in original Medicare
- ACO may be eligible to share in savings it achieves for a payor for its attributed population; it may also be responsible for increases in costs.
- Requires distinct governance structure.

Examples of ACO Models:

- Medicare Shared Savings Program
- ACO REACH

Clinically Integrated Network (CIN)

- Integration model designe d to manage antitrust risk
- FTC/DOJ - “An active an ongoing program to evaluate and modify the practice patterns by the network’s physicians and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality.”



Value-Based Enterprise (VBE)

- Product of CMS and OIG Final Rules creating Value-based Exceptions and Safe Harbors for Stark Law and Anti-Kickback Statute
- Two or more VBE participants collaborating to achieve
  - at least one value-based purpose
  - with an accountable body or person responsible for financial and operation oversight of the enterprise, and
  - a governing document that describes the enterprise and how the participants intend to achieve their purpose(s).
- Not required to be a separate legal entity.

Current Value-Based Models

Medicare Accountable Care Models

- MSSP
- ACO REACH
- Making Care Primary Model
- Kidney Care Choices
- And coming soon…ACO Primary Care Flex!

Medicare Disease-Specific & Episode-Based Models

- Enhancing Oncology Model
- BPCI Advanced
- ESRD Treatment Choice
- GUIDE Model
- And coming soon…TEAM!

Other Models

- MA Value-Based Insurance Design
- Many commercial and MA products in the market

Medicare Shared Savings Program (MSSP)

- Medicare's flagship ACO program
  - No end date; annual application cycle
  - Accountable for the quality, cost, and care experience for attributed Medicare population
  - Total cost of care for Parts A and B expenses; risk-adjusted based on CMS HCCs
  - Agreement period is at least five years.
- Two participation tracks
  - BASIC (Levels A through E) – glide path toward additional risk and greater savings
  - Enhanced (offers highest level of shared savings/risk)
  - Options to select risk-sharing path; can remain in upside-only track for up to 7 years
- Beneficiary assignment
  - Voluntary alignment
  - Claims-based alignment

Regulatory Flexibilities

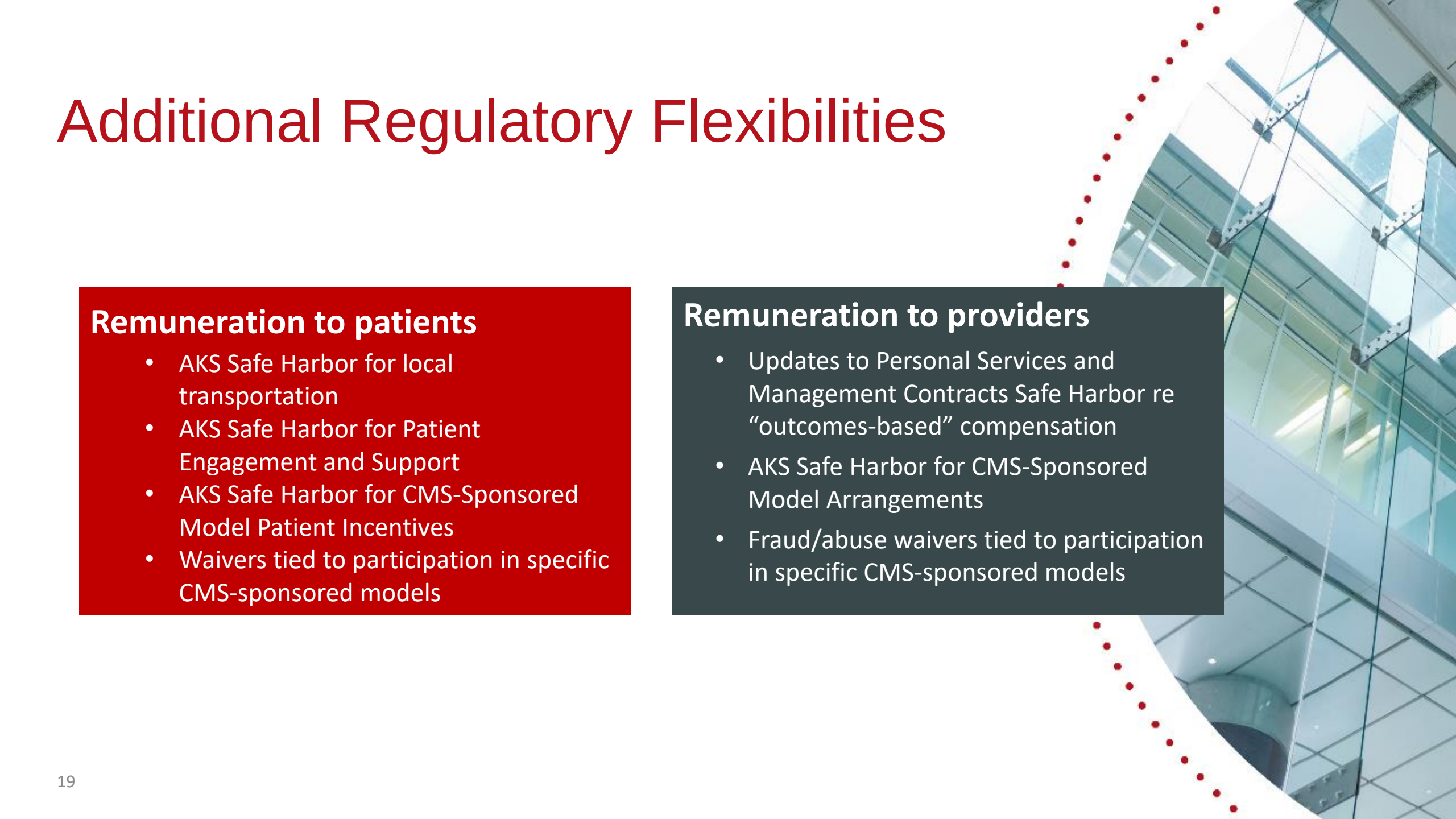
	New Stark Exceptions	New AKS Safe Harbors
Full Risk	Protects payments by VBEs that are fully responsible for the cost of all patient care items and services covered by a payor prospectively	Protects payments by VBE when VBE participant has assumed financial responsibility for cost of all patient care items and services covered by a payor on a prospective basis
Meaningful or Substantial Downside Risk	Protects payments by VBEs when physicians take on the required level (equal to or greater than 10%) of downside financial risk (i.e., may repay or forgo money)	Protects remuneration exchanged when VBEs assume a percentage of downside financial risk, and VBE participants meaningfully share a percentage (5%) of that risk
No Risk	• Protects payments for value-based activities • No mandatory risk levels • Annual monitoring requirements • Must be terminated if ineffective	• Protects in-kind remuneration connected to coordination and management of care for the TPP • Recipient must pay 15%.

Threshold Terms/Definitions

Potential Uses of Value-Based Rules

- Physician organization agrees that its physicians will abide by hospital's care protocols for a period of two years.
    - Hospital pays physicians $10 every time they order dual-modality screening instead of single-modality screening.
- Incorporating value and quality metrics into arrangements with employed or contracted physicians
- Payments from ACO to its participating providers for "gap closure" and follow-up communications to patients
- Providing care coordinators to a physician or physician practice to help manage a target patient population

Additional Regulatory Flexibilities



Remuneration to patients

- AKS Safe Harbor for local transportation
- AKS Safe Harbor for Patient Engagement and Support
- AKS Safe Harbor for CMS-Sponsored Model Patient Incentives
- Waivers tied to participation in specific CMS-sponsored models

Remuneration to providers

- Updates to Personal Services and Management Contracts Safe Harbor re "outcomes-based" compensation
- AKS Safe Harbor for CMS-Sponsored Model Arrangements
- Fraud/abuse waivers tied to participation in specific CMS-sponsored models

Legal and Operational Issues in Value-Based Care

Key Contract Terms and Operational Matters

Payor Contract Dynamics

- Type of value-based arrangement
- Scope of managed population and attribution methodology
- Selection of quality/cost measures
- Data sharing/access/use
- Calculation of savings/losses
- Risk adjustment
- Narrow network/exclusivity
- Term and termination rights
- Dispute resolution and appeal rights

Participant Operations Matters

- Data sharing among network and participants
- Reporting quality data to payor
- Auditing accuracy of new kinds of payment information
- Care management/coordination
- Physician buy-in
- Network management/adequacy
- Communicating with patients (and incentivizing adherence to care regimen)

Risk Adjustment Coding

- MAOs/ACOs/VBEs increasingly attempting to engage providers to code more accurately and comprehensively
- Inaccurate coding and/or lack of documentation to support the diagnosis can lead to a false claim submission under the MA program, and potentially under Medicare/Medicaid value-based programs
- Non-comprehensive coding can also lead to loss of revenue
- To compensate or not compensate providers for coding efforts, and how to structure these payments
- Civil suit against Aledade highlights risk to ACOs

Risk Adjustment Coding

05/2023: Complete Physician Services (a primary care provider) settled a False Claims Act case for $1.5 million plus interest for allegedly submitting inaccurate diagnosis codes (e.g. submitting codes for morbid obesity and COPD where such diagnoses were not supported by patient records).

07/2023: Martin's Point Health Care (MA plan) settled a False Claims Act case for $22.5 million for allegedly submitting inaccurate diagnosis codes.

09/2023: The Cigna Group, in its role as a Medicare Advantage plan provider, settled a False Claims Act case for $172 million for allegedly submitting and failing to withdraw inaccurate and untruthful diagnosis codes for its enrollees via inadequate confirmation of diagnoses in their "chart review" program.

10/2023: The DOJ brought criminal charges against former HealthSun Director of Medicare Risk Adjustment Analytics for allegedly orchestrating a scheme to submit fraudulent diagnostic information for certain MA enrollees to increase company profits and her own compensation. The DOJ declined to prosecute the HealthSun corporation based on its voluntary self-disclosure and voluntary repayment of $53 million in overpayments.

01/2024: The FCA suit against ACO Aledade was unsealed, revealing allegations that their billing apps and other software and guidance provided to doctors improperly boosted revenues by adding overstated medical diagnoses to patients' electronic medical records. The whistleblower is continuing to pursue the suit, despite the DOJ declining to intervene.

07/2024: In 2017, the DOJ intervened in a False Claims Act suit against UnitedHealth Group based on allegations that UHG disregarded information about beneficiary medical conditions to artificially inflate risk adjustment payments. As of July 2024, the parties have filed cross motions for summary judgment, and the case is likely to proceed to pre-trial conferences in Fall of 2024. This is the one of the first Medicare Advantage lawsuits to reach this stage of litigation.

Changes to Antitrust Enforcement

Feb 3, 2023, DOJ withdrew from three longstanding antitrust policy statements.

"The healthcare industry has changed a lot since 1993, and the withdrawal of that era's out of date guidance is long overdue," said Assistant Attorney General Jonathan Kanter of the Justice Department's Antitrust Division. "The Antitrust Division will continue to work to ensure that its enforcement efforts reflect modern market realities."

July 14, 2023, FTC withdraws from longstanding antitrust policy statements.

The FTC has determined that the withdrawal of the two statements is the best course of action for promoting fair competition in health care markets. Much of the statements are outdated and no longer reflect market realities in this important sector of the economy.

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Thank You

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