

# Legal Issues Associated with Multi-Provider Alternative Payment Models

**Manatt Health**

April 19, 2016

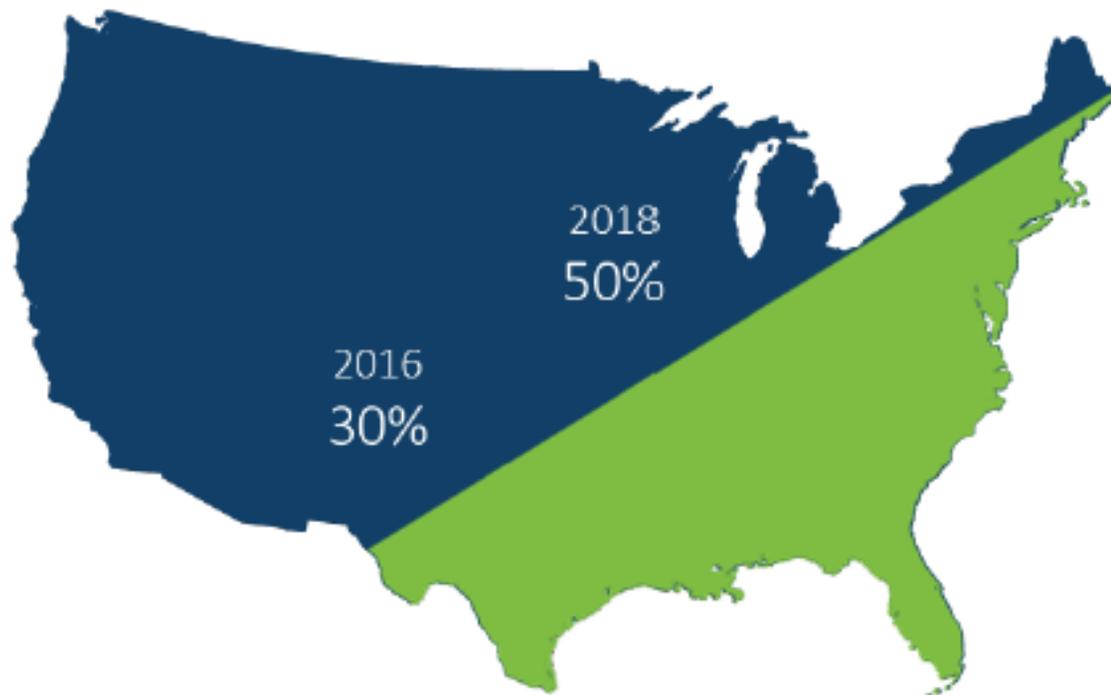
## Alternative Payment Models: an Evolving Landscape

Fraud and Abuse Considerations

Antitrust Considerations

Case Study

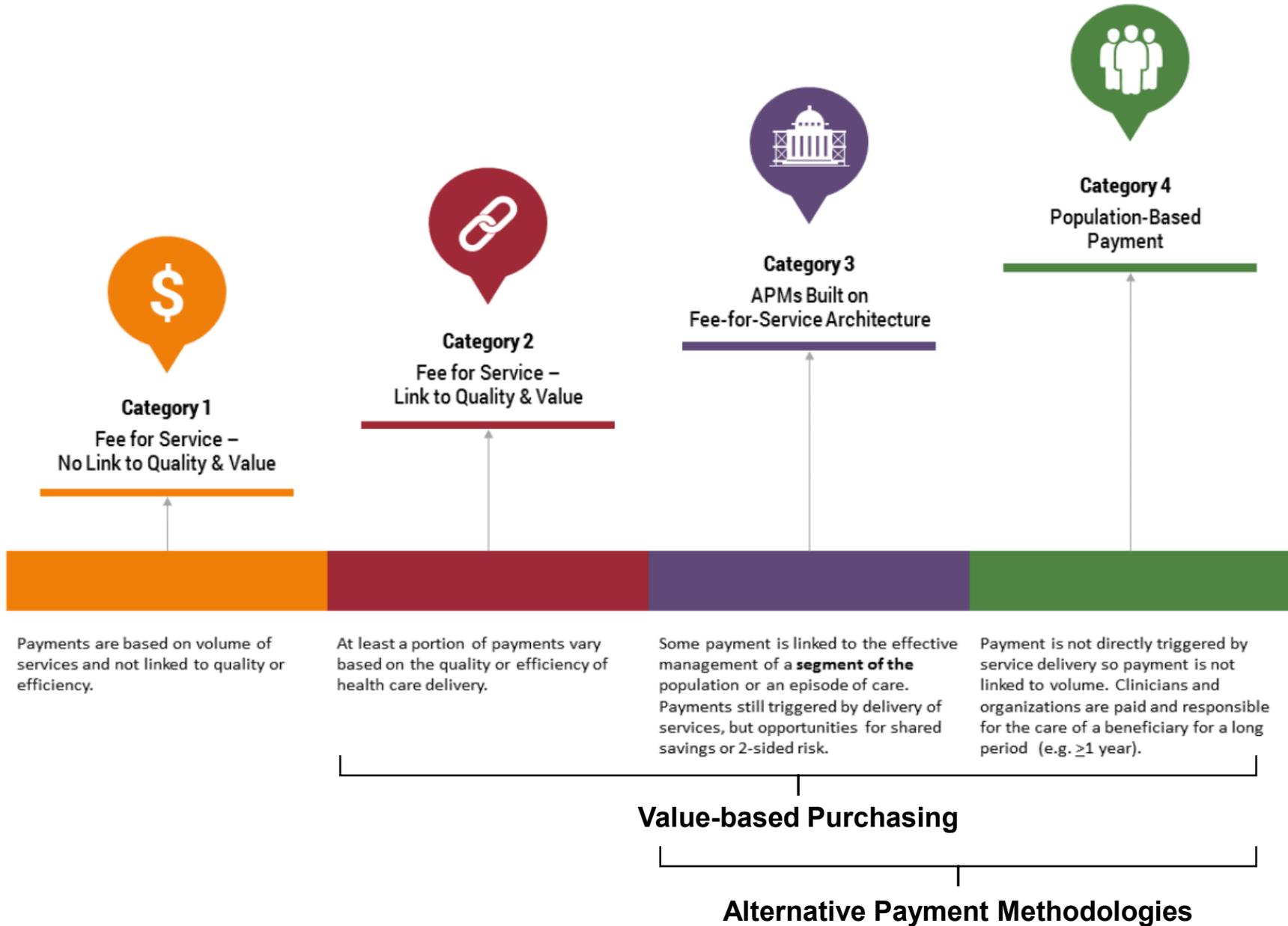
Questions and Discussion



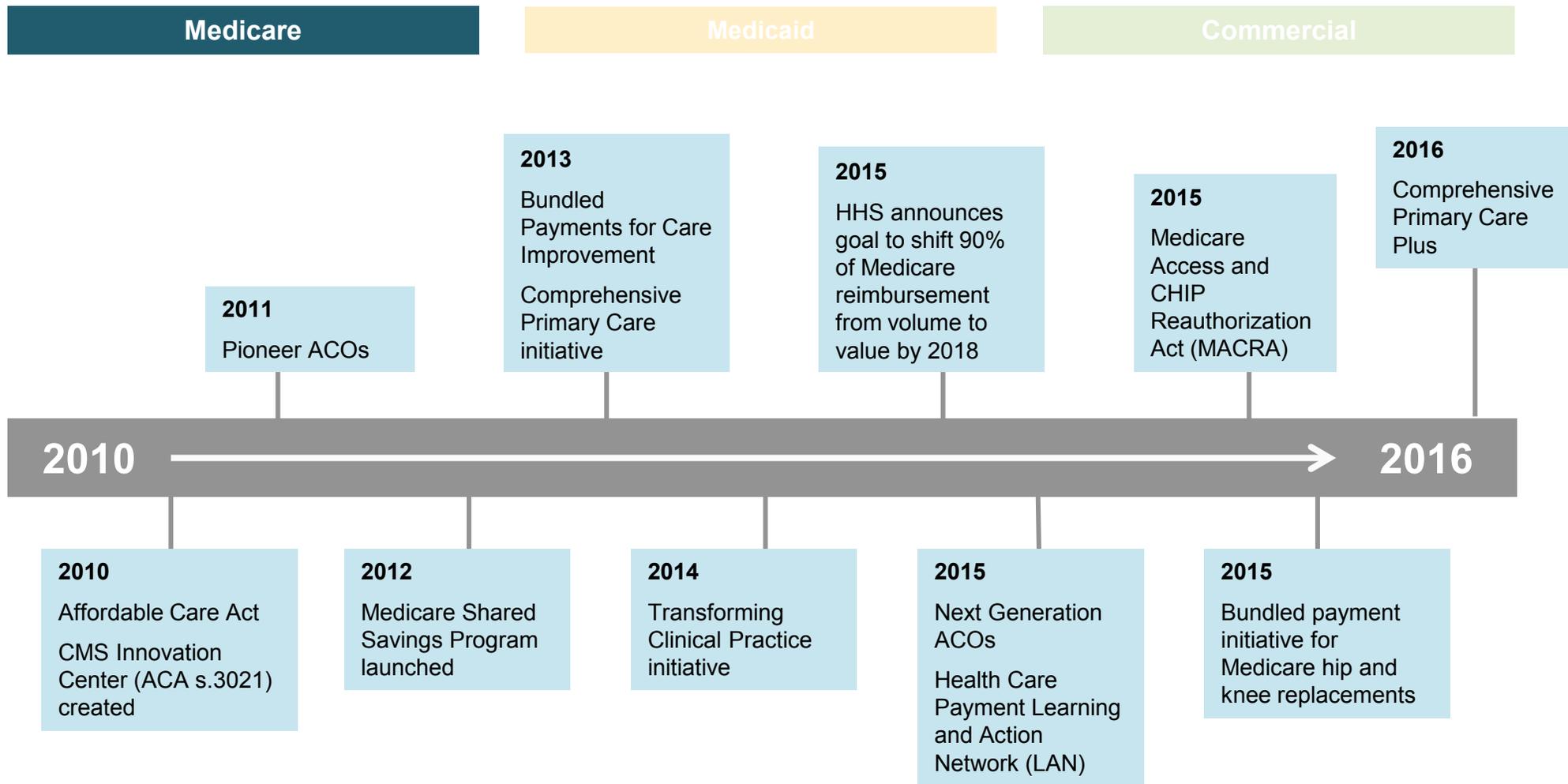
- Alternative Payment Models are payment methodologies that seek to reward value and care coordination—rather than volume and duplication
- HHS has set goals for APM expansion in Medicare, while the multi-sector “Health Care Payment Learning and Action Network” is working towards the same goals across payers

Source: Health Care Payment Learning & Action Network, Alternative Payment Model Framework.

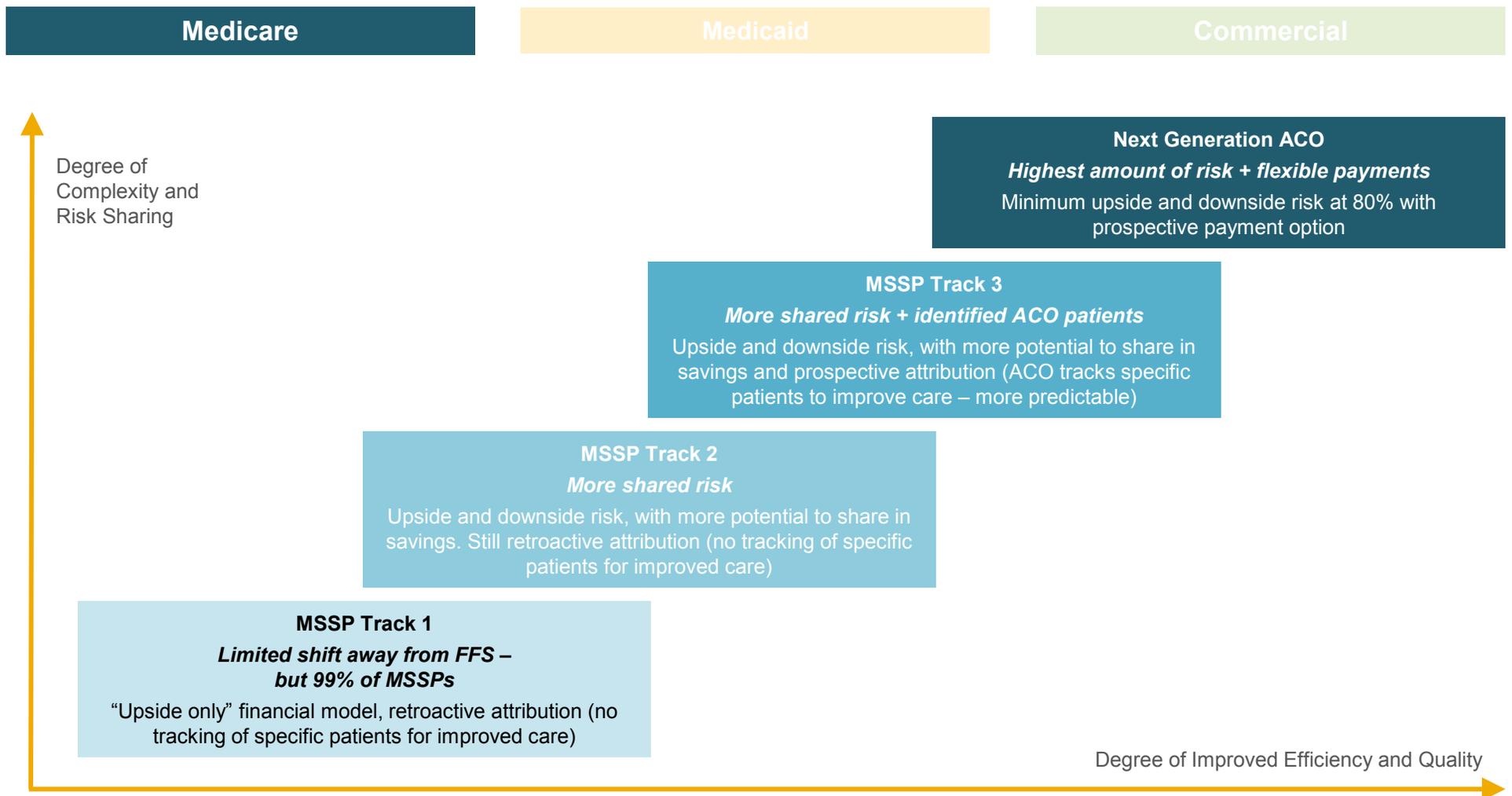
# Alternative Payment Model Categories



# Medicare is a Major Driving Force Behind APMs



# CMS Now Offers Providers Multiple Risk Options



<http://healthaffairs.org/blog/2015/06/16/the-revised-medicare-aco-program-more-options-and-more-work-ahead/>;  
<https://www.advisory.com/daily-briefing/2015/04/27/what-acos-need-to-know-about-cmss-next-generation-model>.

# Medicare and CHIP Reauthorization Act (MACRA) of 2015 Provides New Incentives for Providers to Move “Up Risk”

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Medicare

Medicaid

Commercial

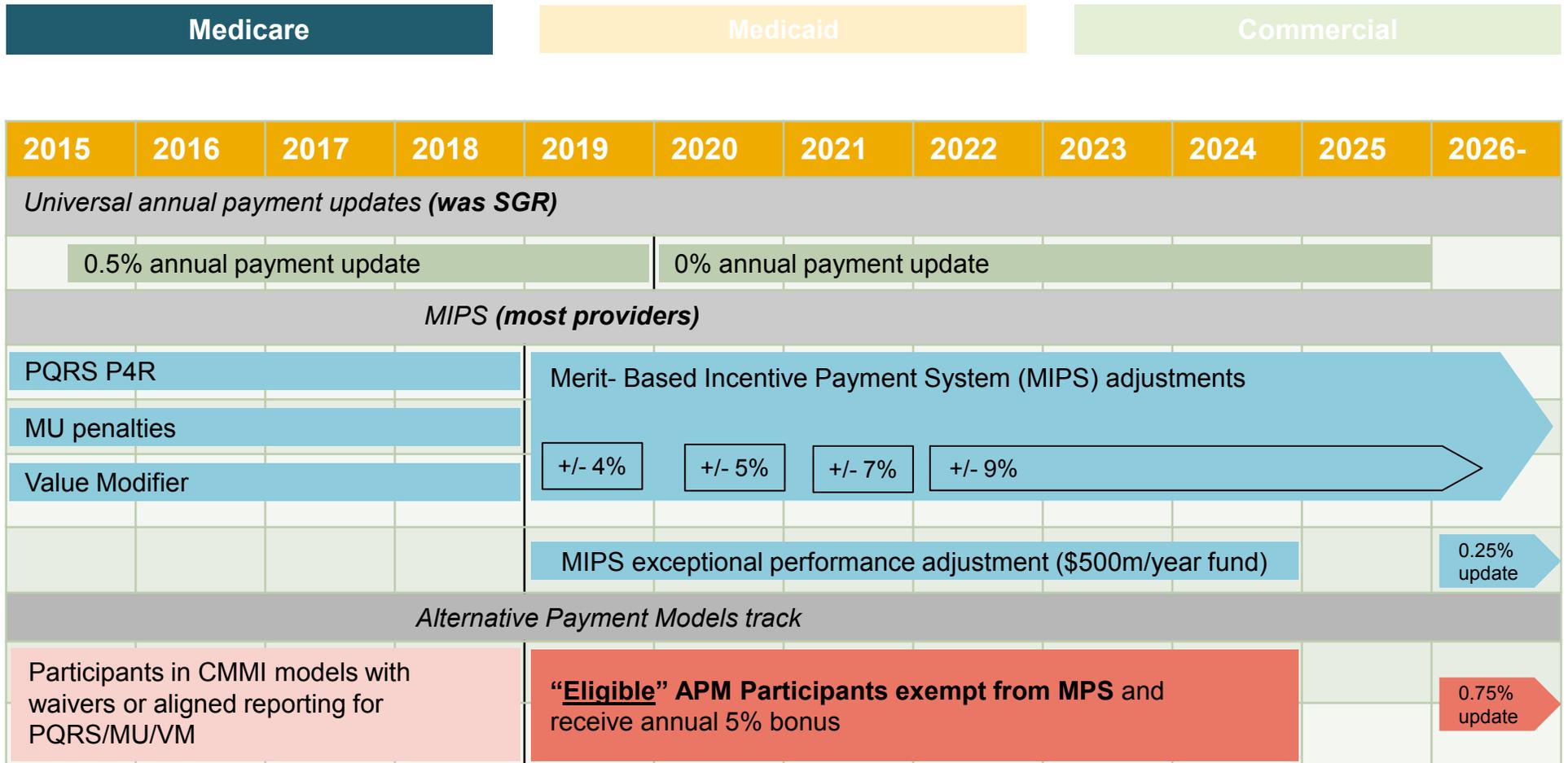
## Passed in April 2015, MACRA articulates a 10 year payment reform agenda for how Medicare FFS reimburses practitioners

- Annual Medicare updates replaced by the Merit-Based Incentive Payment System (MIPS) under which annual adjustments tied to performance
- Provides new incentives to participate in APMs
- Legislation is a framework with large policy discretion for CMS to clarify in implementing regulations expected to be released Spring 2016



### “Eligible” APMs

- Providers implement APMs, which:
  - Report on quality
  - Bear more than nominal financial risk OR act as a medical home “expanded under CMMI”
  - Make up 25% of Medicare payments by 2019-2020, increasing to 75% of all payer payments in 2023+
- 5% payment bonus each year, and providers are exempt from MIPS



Medicare

Medicaid

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- States increasingly focusing on delivery system reform and use of APMs
  - 70 million covered and rising
  - Spurred by SIM grants, demonstrations for dual eligible
  - ACA Medicaid changes are “turning the corner”
- Broad array of approaches depending on state-specific environment and priorities
  - Require/encourage MCOs to develop APMs
  - Require use of state-developed APMs
  - Episode-based payments
  - Provider-level capitation payments
- Medicaid-specific issues and APMs
  - Strong focus on social determinants of health
  - Behavioral health plays particularly important role
  - Intersection with Medicaid managed care

# Medicaid Driving State Payment and Delivery System Reforms: State Examples

Medicare

Medicaid

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## State Examples

### Require MCOs to Develop APMs

*Massachusetts and South Carolina*



In 2012, MA decided to require the Medicaid agency to move 90% of payments into APMs.



South Carolina has implemented a requirement that MCOs pay 20% or more of providers using APMs.

### Require Use of State Developed APMs

*Minnesota*



All Medicaid MCOs in MN must participate in Medicaid ACOs called Integrated Health Partnerships (IHPs). IHPs are paid using a capitated gain/risk sharing arrangement where the total costs for caring for Medicaid enrollees are measured against cost and quality targets. ACOs have flexibility to pay for enhanced services and to integrate social, behavioral, and medical care.

### Multi-Payer Episode-Based Payments

*Arkansas*



AR implemented a multi-payer, episode-based payment program for 16 episodes of care. Providers are accountable for the total cost of an episode of care, and receive bonuses if they meet established cost thresholds and quality targets or penalties if they exceed cost thresholds.

### Provider-level Capitation Payments

*Ohio*



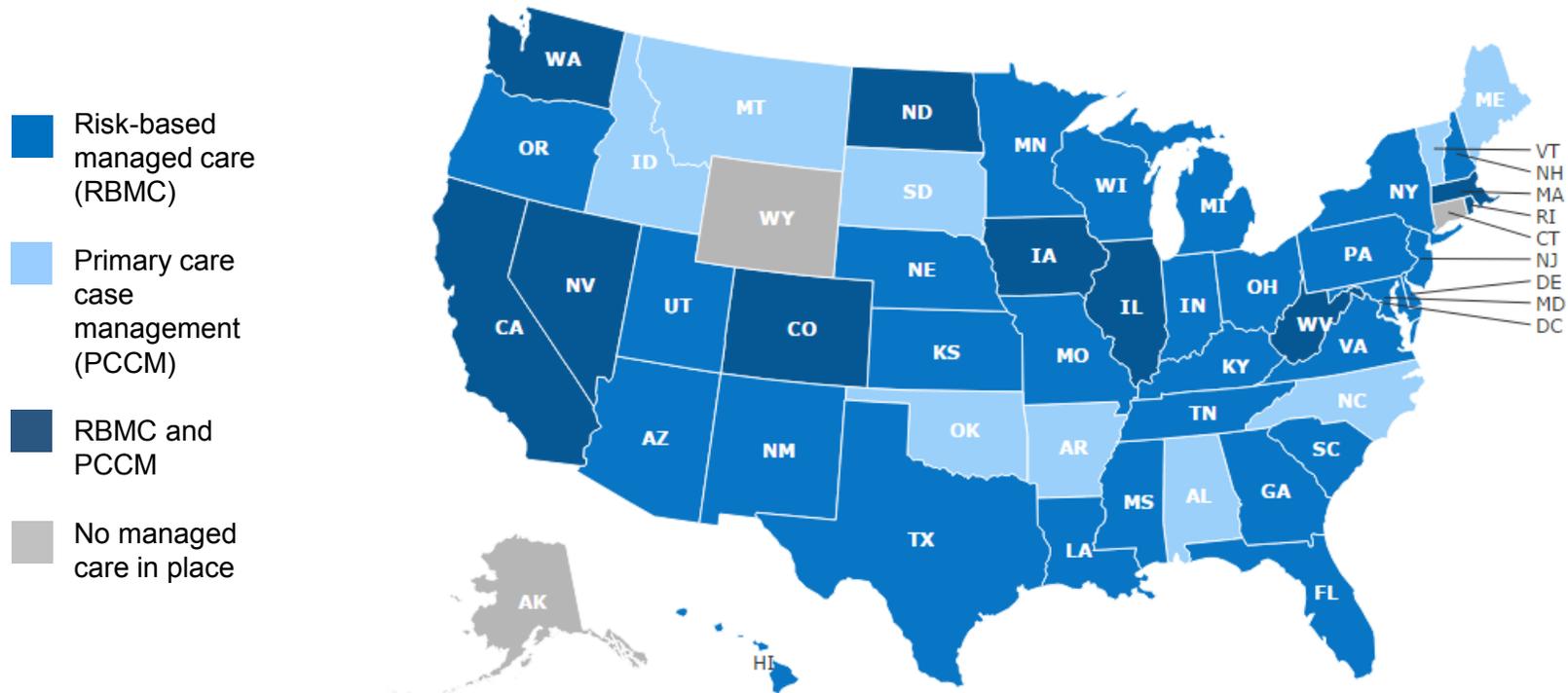
Cincinnati Children's Hospital Medical Center formed an ACO that receive a risk-adjusted PMPM from the MCOs it contracts with (currently 2 of 5 total). The ACO uses robust care management teams to improve quality, better manage care and connect family with social services. Providers are reimbursed on a fee-for-service basis, but can earn incentive payments for meeting quality metrics.

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**38 states contract with Managed Care Organizations, covering 90% of all U.S. Medicaid beneficiaries**



Source: <http://kff.org/interactive/delivery-system-and-payment-reform/>.

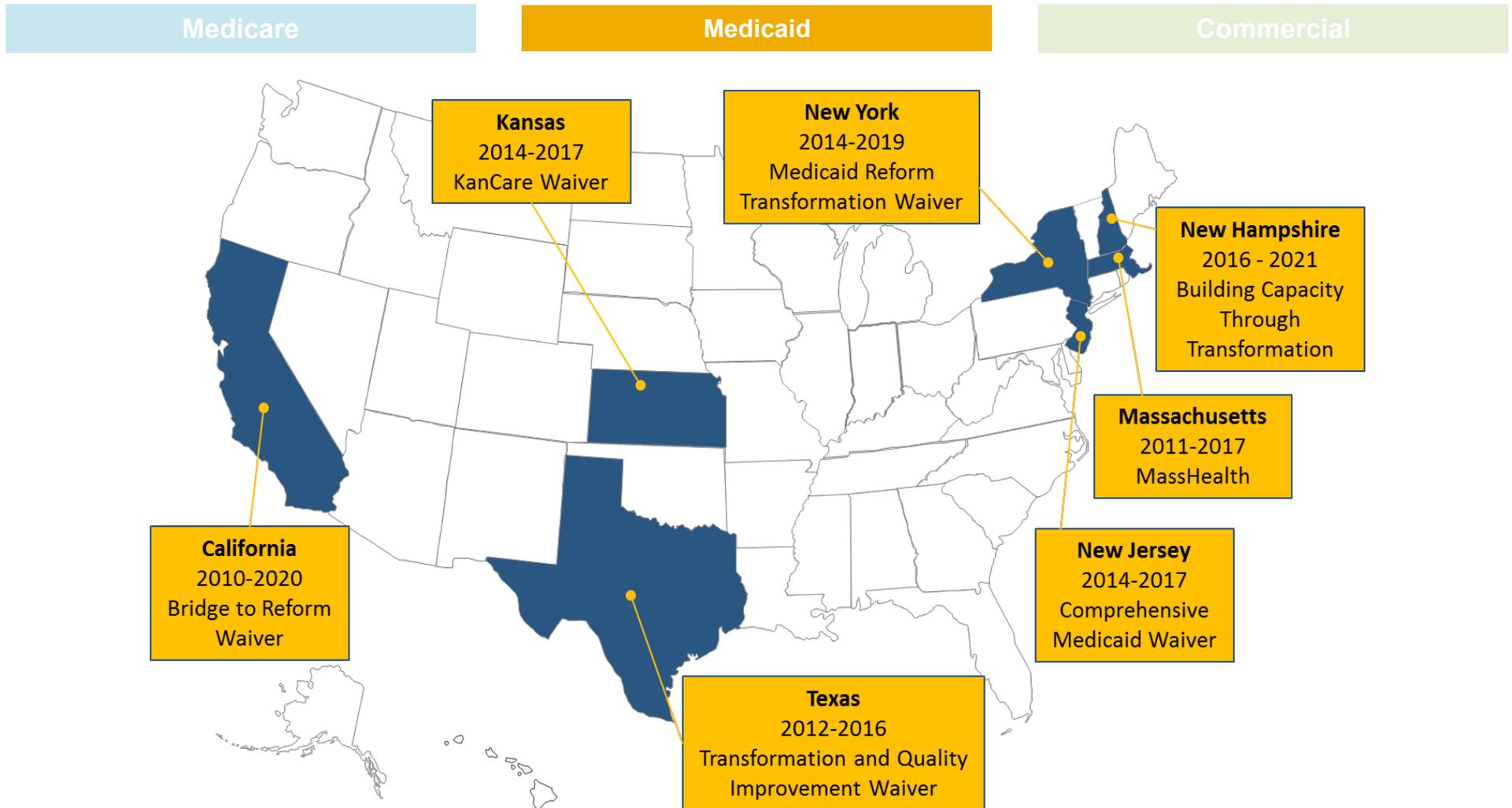
Medicare

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- Some states relying on Delivery System Reform Innovation Program (DSRIP) waivers to pursue greater use of APMs
  - Funding significant - \$600 million to \$11 billion over a period of up to 5 years
  - Requires “budget neutrality” for federal government
  - Time-limited
- CMS increasingly expecting states to establish sustainable financing for DSRIP waivers through use of APMs
  - New York must move 80% of Medicaid managed care payments to APMs
  - New Hampshire and California also facing requirements to expand use of APMs

# DSRIP “Health System Transformation” Waivers Have Accelerated Value-Based Payment Trends in Medicaid



Source: <http://kff.org/report-section/an-overview-of-delivery-system-reform-incentive-payment-waivers-issue-brief/>.

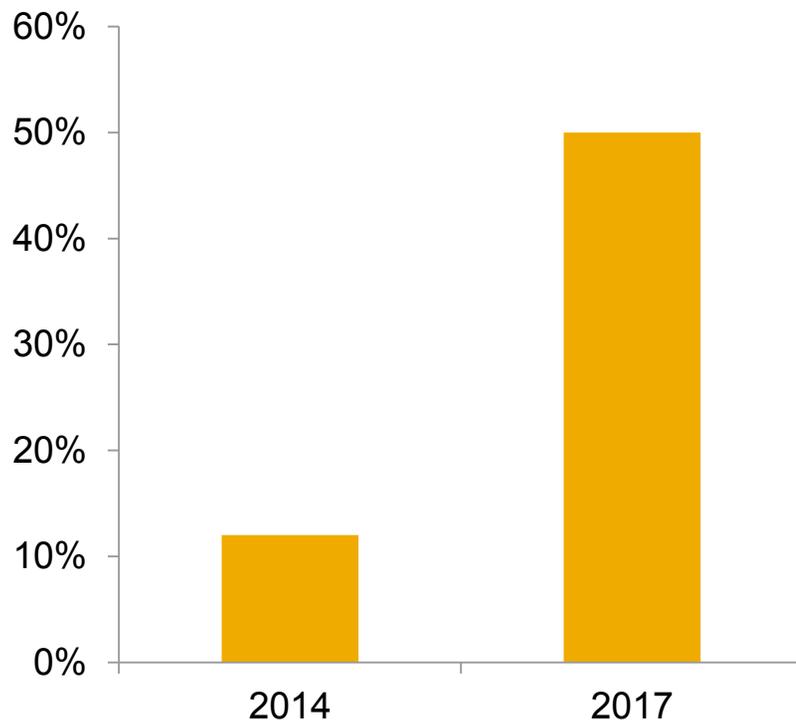
# Value-Based Payment Arrangements Have Also Increased in the Commercial Sector

Medicare

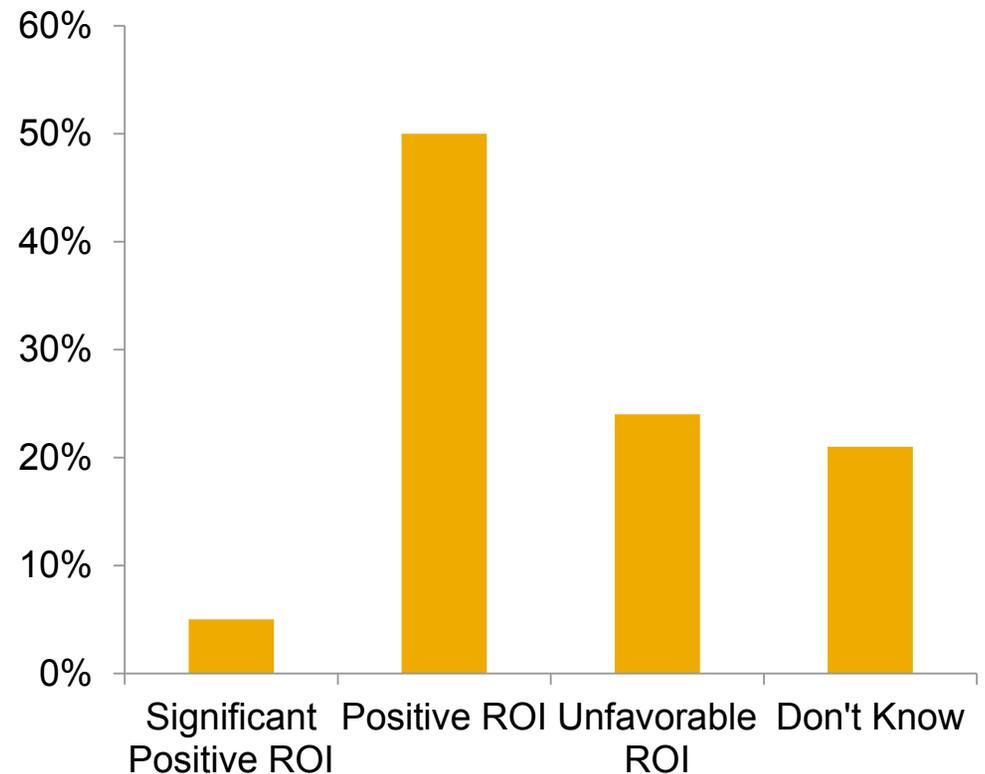
Medicaid

Commercial

### Anticipated Penetration of Commercial VBP Among Hospital Executives



### Anticipated Positive Return On Investment From Commercial VBP Among Hospital Executives



Source: <https://www.hfma.org/value-basedpaymentreadinesssurvey/>

- Government, insurers and providers are all looking for alternatives to traditional managed care
- The medical model is changing from a reactive, episodic treatment-based approach, to a proactive, population health-based prevention paradigm
- Providers are assuming new levels of risk for patients they treat—this requires much stronger partnerships between insurers and providers, and between providers and other providers, to align payment with health outcomes
- Complex questions are arising over the legal implications of the new relationships among providers, between payers and provider, risk-sharing arrangements, and clinical protocols

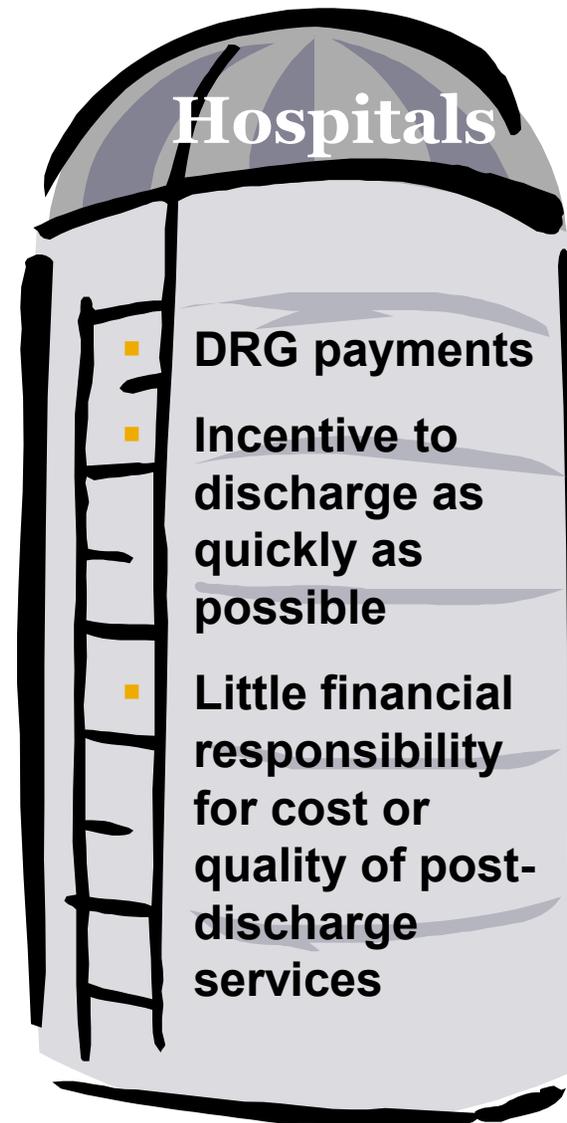
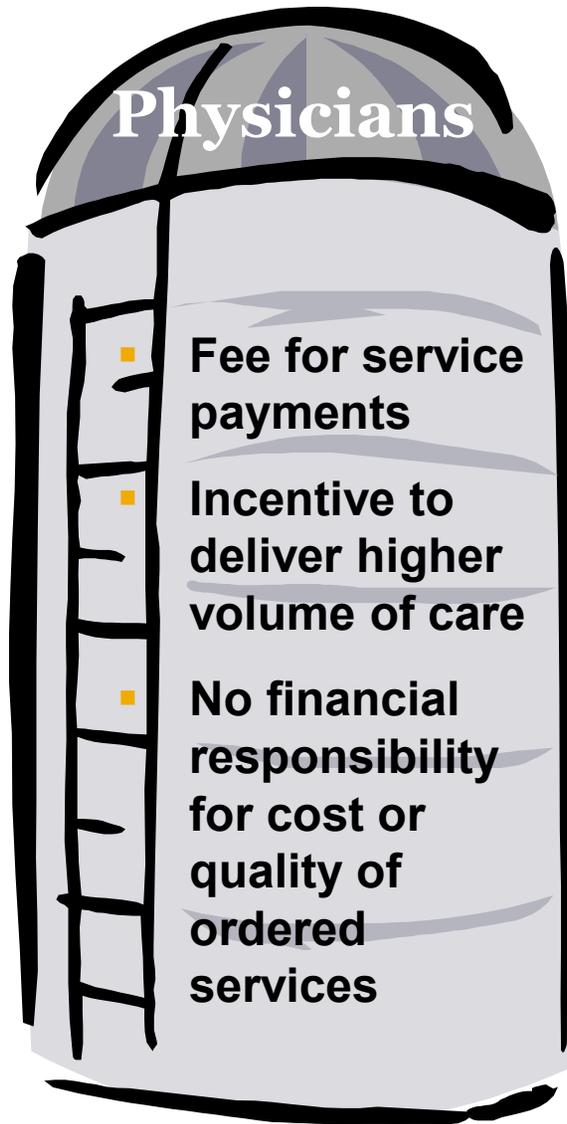
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# Complementary Strengths and Weaknesses Drive Joint Hospital-Physician Collaboration in APM Arrangements

	Strengths	Weaknesses
Hospitals	<ul style="list-style-type: none"><li>▪ Capital for infrastructure development</li><li>▪ IT sophistication</li><li>▪ Compliance capabilities</li></ul>	<ul style="list-style-type: none"><li>▪ Limited capacity to control non-hospital expenses</li><li>▪ Limited capacity to engage patients</li></ul>
Physicians	<ul style="list-style-type: none"><li>▪ Significant opportunity to control non-physician expenses</li><li>▪ Best positioned to engage patients</li></ul>	<ul style="list-style-type: none"><li>▪ May be isolated in small practices with limited capital</li><li>▪ Weak IT capacity</li><li>▪ Lack of compliance sophistication</li></ul>

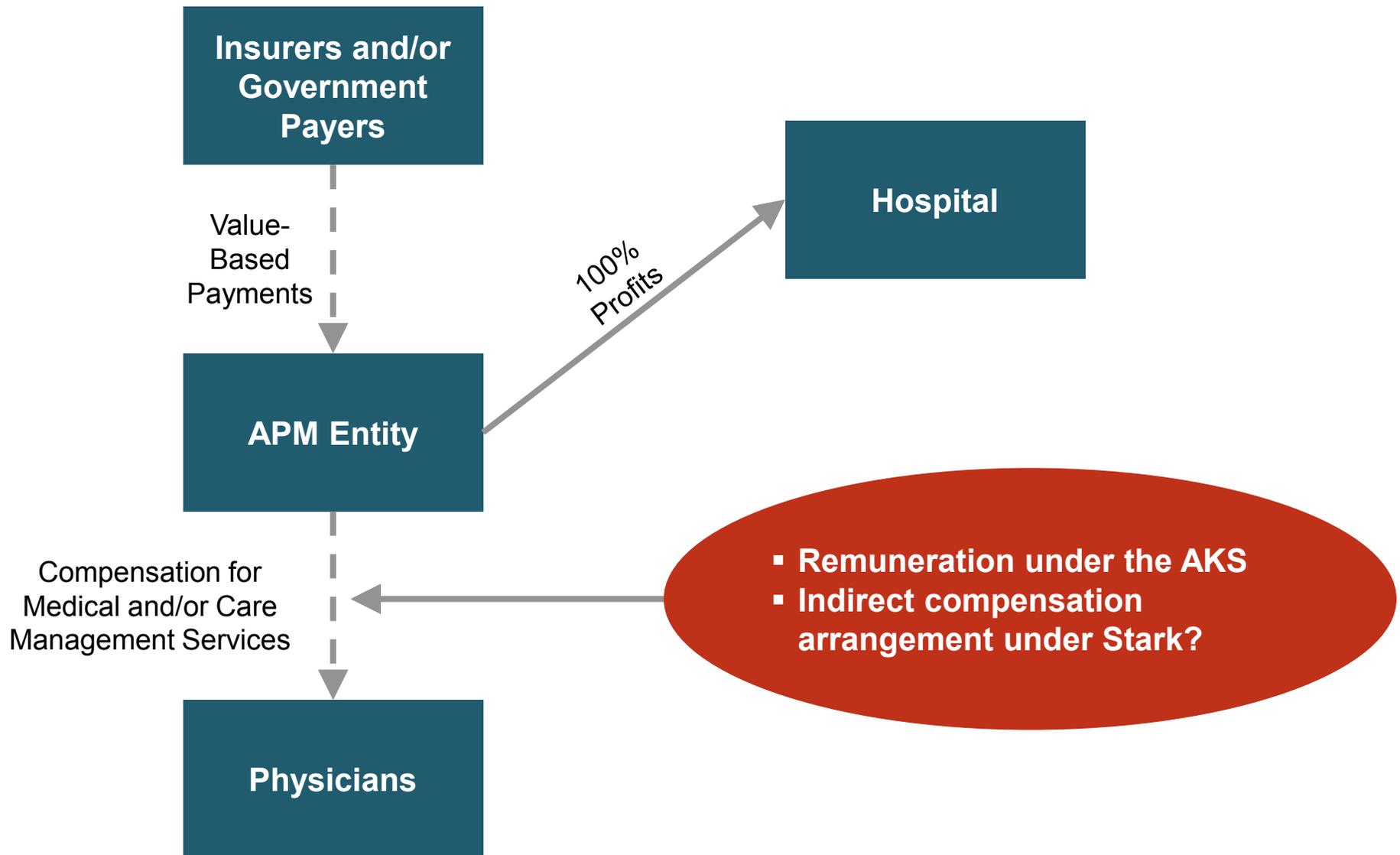
**Need for collaboration is in tension with fraud and abuse laws that are designed to keep hospitals and physicians at arm's length**

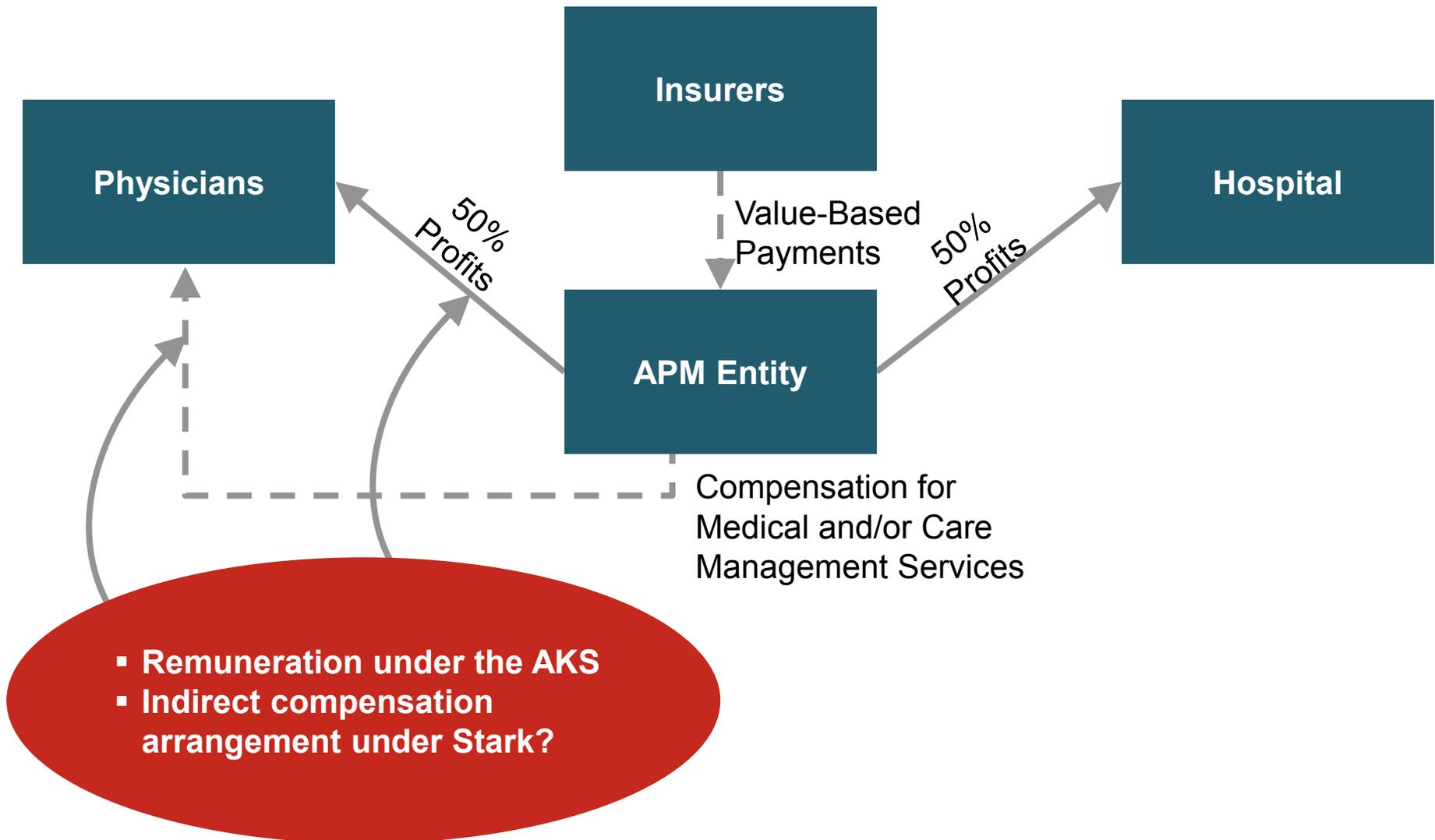
# Fraud and Abuse Laws Implicated by Hospital-Physician Collaboration in APMs

Statute	Key Restriction
Stark Law	Prohibits a physician from referring a patient for inpatient, outpatient or other “designated health services” covered by Medicare to a hospital or other entity with which the physician has a financial relationship, unless the relationship satisfies a Stark exception
Anti-Kickback Statute	Makes it illegal for any person to knowingly and willfully exchange remuneration for the referral of a patient for items or services covered by a federal health care program
Anti-Inducement Law	Prohibits a person from providing remuneration that he or she knows is likely to influence a patient’s selection of a provider or supplier for services covered by Medicare or Medicaid
Gainsharing Law	Prohibits a hospital from knowingly making any payment to induce a physician to reduce or limit <u>medically necessary</u> services covered by Medicare or Medicaid

<b>Stark</b>	<b>Anti-Kickback Statute</b>
Applies to referrals by physicians for designated health services	Applies to referrals by any person for any items or services covered by a federal health care program
Strict liability law—the law is violated if a financial relationship does not fit within an exception	Intent-based law—the law is violated if a person intended remuneration to serve as an inducement (one-purpose test)
Compliance with an exception is required	Compliance with a safe harbor is voluntary
Direct and indirect financial relationships treated differently	Direct and indirect financial relationships generally subject to same analysis
Civil penalties only	Civil and criminal penalties
Enforcement increasingly through False Claims Act	Enforcement increasingly through False Claims Act

<b>“Hospital Subsidiary Model”</b>	<b>“Joint Venture Model”</b>
<ul style="list-style-type: none"><li>▪ APM entity contracting with third-party payers is the hospital or an entity wholly owned or controlled by the hospital</li></ul>	<ul style="list-style-type: none"><li>▪ APM entity contracting with third-party payers is an entity owned and/or controlled jointly by the hospital and physicians who are not hospital employees</li></ul>
<ul style="list-style-type: none"><li>▪ Physicians may be represented on board or advisory body of AMP entity, but are appointed by hospital</li></ul>	<ul style="list-style-type: none"><li>▪ Physicians appoint representatives to board of APM entity</li></ul>
<ul style="list-style-type: none"><li>▪ Hospital provides all or nearly all investment capital</li></ul>	<ul style="list-style-type: none"><li>▪ Investment capital provided by hospital and physicians</li></ul>
<ul style="list-style-type: none"><li>▪ Physicians receive compensation under participation agreements signed with APM entity</li></ul>	<ul style="list-style-type: none"><li>▪ Physicians may receive compensation for services under participation agreements signed with APM entity and/or through profit or surplus distributions made by entity to its owners</li></ul>





<b>Stark Risk Sharing Exception</b>	<b>AKS Managed Care Safe Harbor</b>	<b>AKS Health Plan Discount Safe Harbor</b>
Covers any “risk-sharing arrangement” between an MCO or IPA and a physician (either directly or through an intermediary such as a hospital) for services provided to enrollees of a health plan	Covers payments made by Medicare Advantage or Medicaid managed care plan to provider for delivering or arranging for health care items and services	Covers discounts on fees offered by providers to health plans
Should protect shared savings or similar risk-sharing payments from APM entity to physicians	Does not protect commercial health plan payments	Protects only discounts from providers, not shared savings or similar risk-sharing payments
Does not protect APM investment relationships or care management fees	Does not protect APM investment relationships	Does not protect APM investment relationships or care management fees

- May be possible to avoid financial relationships under Stark due to quirks in how “indirect compensation arrangement” is defined
- Even if Stark is not applicable, kickback issues will remain
- Kickback safe harbors will likely not protect commercial APM arrangements
- Absent application of an MSSP waiver, best protection may be demonstration of fair market value. But there are challenges in showing FMV:
  - How is FMV measured when paying for a physician’s effectiveness in achieving APM goals rather than paying for a physician’s time?
  - Will FMV be benchmarked against what health plans pay for comparable services? For example, if a plan pays an APM entity a care management fee of \$5 PMPM, can the APM entity pay a fee of \$10 PMPM to physicians?
  - Does the APM entity’s compensation arrangements with physicians have to track the arrangement between the entity and the health plan? For example, can the VBP entity (i.e., the hospital) assume downside risk from the plan but have a shared savings only arrangement with physicians?

- Proposed CMS Rule, 80 Fed. Reg. 41927-41930 (July 15, 2015)
  - Recognizes Medicare AMP program, CMMI initiatives, MSSP and similar commercial insurance efforts are changing landscape that previously required financial separation of hospitals and physicians
  - Notes that “entities furnishing DHS face the predicament of trying to achieve clinical and financial integration with other health care providers, including physicians, while simultaneously having to satisfy the requirements of an exception . . . .”
  - Solicits comments on a wide range of issues, including:
    - Does the “volume or value” standard require clarification or modification?
    - Is there a need for new exceptions covering alternative payment models?
    - Should existing exceptions be expanded to better align with alternative payment models?

Waiver	Key Terms
Pre-participation Waiver	<ol style="list-style-type: none"><li>1. Covers “start up arrangements” pre-dating MSSP participation agreement</li><li>2. Good faith intent to participate in MSSP</li><li>3. Diligent steps to develop ACO in target year</li><li>4. Bona fide determination by ACO governing body that arrangement “reasonably related to purposes of MSSP”</li><li>5. Documentation</li><li>6. Public disclosure</li></ol>
Participation Waiver	<ol style="list-style-type: none"><li>1. ACO participates in MSSP</li><li>2. ACO satisfies MSSP governance and management rules</li><li>3. Same as items 4-6 in pre-participation waiver</li></ol>
Shared Savings Waiver	Covers distribution of shared savings by Medicare ACO to its participants

- “Although we are not providing a specific waiver for private payer arrangements at this time, we believe avenues exist to protect flexibility for ACOs participating in commercial plans. First, nothing precludes arrangements ‘downstream’ of commercial plans (for example, arrangements between hospitals and physician groups) from qualifying for the participation waiver . . . . The participation waiver does not turn on the source of the funds for the arrangement.”
- “Arrangements with similar purposes but that are unrelated to the Shared Savings Program are not covered by the term ‘purposes of the Shared Savings Program.’ Arrangements that involve care for non-Medicare patients as well as Medicare beneficiaries are eligible for the waiver.”

*Preamble from CMS on MSSP Waivers, 76 Fed. Reg. 67992 (11/2/2011)*

## ■ Anti-Kickback Statute Exceptions

- Waiver or reduction of inpatient hospital PPS cost sharing if not claimed as bad debt, offered without regard to type of admission, and other conditions satisfied
- Waiver of Medicaid cost sharing by FQHCs and similar entities
- Cost sharing differentials part of a health plan benefit design

## ■ Anti-Inducement Law Exceptions

- Items of nominal value (\$10 per item, \$50 per year)
- Non-routine cost sharing waivers after determination of financial need or failure of reasonable collection efforts
- Non-cash incentives to promote prenatal services or a post-natal well-baby visits or clinical services described in U.S. Preventive Services Task Force's Guide to Clinical Preventive Services
- Any practice protected by a kickback safe harbor

- **Complementary Transportation.** Provided by hospitals or physicians to established patients within 25 miles. Provider may restrict transportation to patients who require frequent appointments but not to patients requiring lucrative services. Excludes air, luxury and ambulance transportation.
- **Access to Care With Low Risk of Harm.** Remuneration that improves a beneficiary's ability to obtain medically necessary services. Low risk of harm if it is unlikely to skew clinical decision making or increase federal health care program costs, and does not raise safety or quality concerns. Examples include lodging assistance provided by hospitals and the provision of items necessary to record and report health data. Rewards offered for compliance with treatment regimes could also fall within this exception.
- **Financial Need.** Non-advertised items/services not tied to the provision of services reimbursed by Medicare or Medicaid where there is a reasonable connection between items/services and patient's medical care and patient has a financial need. Examples include pagers for patients with chronic medical conditions to alert them to take their drugs.

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- Policy Rationale

- Antitrust laws aim to protect and enhance competition for the benefit of consumers, not competitors
- Presumes that competitive process leads to lower prices, better quality, more innovation
- Potential tension with healthcare policy, which many view as encouraging consolidation

- Key Antitrust Statutes

- The Sherman Act
- The Federal Trade Commission Act
- The Clayton Act
- State Antitrust Laws (generally mirror the federal antitrust laws)

“Every contract, combination . . . or conspiracy in restraint of trade or commerce among the several States, or with foreign nations is declared to be illegal.”

15 U.S.C. § 1

- **Per se** violations: agreements whose nature and necessary effect are so plainly anticompetitive that no elaborate study of the industry is needed to establish illegality
  - Include: naked agreements among competitors to fix prices; allocation or division of markets; and group boycotts/concerted refusals to deal
- All other conduct alleged to violate antitrust laws is analyzed under the **rule of reason**
  - Consider anticompetitive effect of conduct and procompetitive efficiencies

**“Every person who shall monopolize or attempt to monopolize or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations shall be deemed guilty of a felony.”**

**15 U.S.C. § 2**

- To prove monopolization claim, need to show:
  1. Possession of monopoly power in a relevant market; and
  2. Exclusionary conduct (i.e., willful acquisition or maintenance of monopoly power as distinguished from growth or development as a consequence of a superior product, business acumen or historic accident)

- **Price-fixing:** Provider networks may want to engage in collective price negotiations with payers and enter into joint price agreements not ancillary to efficiency-enhancing clinical or financial integration
- **Market allocation:** Hospitals in a network may want to agree on areas of specialization or geographic focus, agreeing not to compete with one another
- **Market power:** Provider networks that combine large local players may leave few market alternatives for consumers and payers
- **Collateral restraints:** Provider networks may want to include restrictions, such as exclusivity provisions
- **Spillover effects:** When the provider network members continue to compete in areas outside the network, the information flow or collaboration may spill over into the other areas and diminish competition

- FTC and DOJ have recognized that while multi-provider networks can offer significant procompetitive benefits, they can also present antitrust issues
- Any collaboration of competitors needs to be analyzed under Sections 1 and 2 of the Sherman Act
  - Most healthcare collaborations will be analyzed under rule of reason and procompetitive impact taken into account
- FTC and DOJ have provided guidance on antitrust issues and the means to avoid concerns

- Where otherwise competing providers are **financially** or **clinically** integrated, joint contracting will not be subject to per se condemnation under the antitrust laws
- *Arizona v. Maricopa County Medical Society* (1982)
  - Supreme Court made clear that physicians in independent practices are supposed to compete; when physicians collectively set the prices at which they sell their individual services, they can be guilty of illegal price fixing
  - To avoid condemnation as an illegal price-fixing conspiracy, the Supreme Court said, the agreement needs to be:
    - “. . . analogous to partnerships or other joint arrangements in which persons who would otherwise be competitors pool their capital and share risks of loss as well as the opportunities for profit”

- Requires that a network of otherwise independent providers share financial risk in such a way that each member has an economic incentive to ensure that the network as a whole generates efficiencies that benefit consumers
- Some examples:
  - Capitation
  - Percentage of premium or revenue
  - Withholds
  - Global fees or all-inclusive case rates
- Financial integration is not an end in itself; the goal is to create a meaningful prospect of:
  - Improving efficiency in the delivery of care
  - Controlling costs
  - Better managing utilization, or
  - Improving the quality of care

- “[A]n active and ongoing program to evaluate and modify the practice patterns [of physicians] and create a high degree of interdependence and cooperation among the physicians to control costs and ensure quality”
- The goal is to create a meaningful prospect of:
  - Jointly improving efficiency in the delivery of care
  - Controlling costs
  - Better managing utilization
  - Otherwise improving the quality of care
- Any agreement on price must be “reasonably necessary” to realize the efficiency, cost, and quality goals

- No single way to structure a CI program—and no FTC mandates
- Common features include:
  - Mechanisms to monitor and control utilization & costs, and assure quality
  - Selectivity choosing providers committed to the program
  - Significant investment, both monetary and human
  - Use of common information technology
  - Development and adoption of clinical protocols
  - Performance review based on implementation of protocols
  - Mechanisms to ensure adherence to protocols

- Even if the primary area of collaboration passes antitrust muster, other agreements between the parties or even unpoliced information exchanges could draw antitrust scrutiny
- Such side-effects outside the direct scope of the collaboration are known as “spillover effects,” because they spill over into the parties’ otherwise competitive activities
- Healthcare guidelines set out restrictive safe harbor for information exchanges to avoid antitrust concerns:
  - The collection of information is managed by a third-party;
  - The information provided is based on data more than 3 months old; and
  - There are at least five reporting entities upon which each disseminated statistic is based, no individual entity's data represents more than 25 percent on a weighted basis of that statistic, and any information disseminated is sufficiently aggregated such that it would not allow recipients of the data to identify the prices charged by any particular entity

- Information exchanges to avoid:
  - Competitively sensitive information
  - Prices or price formulas
  - Terms and conditions of sale
  - Current or future costs
  - Managed care strategy
  - Marketing and strategic plans
  - Employee wages
  - Market allocation
  - Hospital service line or geographic expansion plans

- The ACA provides that groups of providers “meeting the criteria specified by [HHS] may work together to manage and coordinate care for Medicare . . . beneficiaries through an [ACO]” and “may receive payments for shared savings if the ACO meets certain quality performance standards”
- The Medicare Shared Savings Plan (MSSP) is similar to traditional clinical integration programs in terms of goals and means—they require:
  - Legal structure to receive and distribute shared savings
  - Sufficient PCPs for assigned beneficiaries (minimum of 5,000)
  - Agree to participate for at least 3 years
  - Management structure including clinical and administrative systems
  - Defined processes to promote evidence-based medicine, report data to evaluate quality and cost measures, and to coordinate care
  - Meets “patient-centeredness” criteria

- Safety Zones
  - Combined shares of not more than 30% for each common service
    - “Market and “Service” defined specifically (but not necessarily as defined by law)
  - Hospitals and ASCs must be non-exclusive
  - Physicians may be exclusive unless have more than 50% market share
- ACOs that fall outside safety zones will be analyzed under rule of reason
- Policy statement applies to collaborations among independent providers that:
  - Meet CMS’ eligibility criteria and participate in SSP; and
  - Operate in commercial markets

- Exclusivity/non-exclusivity
  - Under Policy Statement, hospitals and ASCs must be non-exclusive
  - Any ACO participant with more than 50% share in its PSA must be non-exclusive
- Improper sharing of competitively sensitive information
  - Can lead to “spillover effects”
- Conduct by ACOs with high PSA shares or other indicia of market power

- Consider carefully (and possibly avoid) the following:
  - Preventing or discouraging private payers from directing or incentivizing patients to choose certain providers outside the ACO
    - Examples—anti-steering, anti-tiering and guaranteed inclusion rules and MFN clauses
  - Tying sales of ACOs services to purchase of services from other providers outside the ACO
  - Exclusive contracting with ACO physicians, hospitals, ASCs or other providers, discouraging those providers from contracting with private payors outside the ACO or through other ACOs
  - Restricting a private payer’s ability to make available to its health plan enrollees information on cost, quality, efficiency and performance

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Hospital establishes a physician hospital organization (PHO) to contract with MA, Medicaid managed care, and commercial insurers.



Hospital (not physicians) invests in care management and IT infrastructure to operationalize the PHO. PHO expects to be clinically integrated in about 18 months.



The PHO's physicians will include both physicians employed by Hospital and voluntary physicians on Hospital's medical staff. All physicians except voluntary specialists will be exclusive.



Hospital is one of two in the service area. The physicians participating in the PHO account for 35% of the service area's primary care providers and between 10–40% of the service area's specialists.

**PHO is an LLC. Hospital A is the LLC's sole member. The LLC's operating agreement requires that at least 50% of the LLC's board members consist of participating physicians.**

**Hospital A developed a three stage value based purchasing business plan for the PHO that will be phased in over 5 years.**

- 1** **Phase 1:** PHO will not negotiate underlying FFS rates for Hospital A or the PHO's physicians. Instead, it will negotiate a care management fee and a percentage of shared savings. A portion of the shared savings and the entire care management fee will be passed down to PHO physicians
- 2** **Phase 2:** Shared savings will be coupled with downside risk, subject to cap
- 3** **Phase 3:** PHO will negotiate not only shared savings and downside risk, but also underlying FFS rates for Hospital A and all PHO physicians



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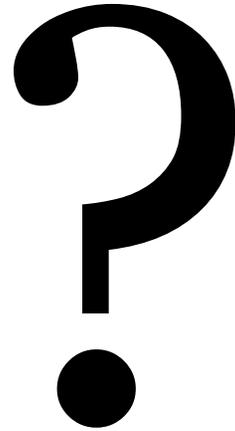
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an Evolving Landscape

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Multi-Provider APMs: Antitrust Considerations

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## Thank You!

### **Presentation developed by:**

Bob Belfort | Partner | [RBelfort@manatt.com](mailto:RBelfort@manatt.com)

Lisl Dunlop | Partner | [LDunlop@manatt.com](mailto:LDunlop@manatt.com)

Jocelyn Guyer | Managing Director | [JGuyer@manatt.com](mailto:JGuyer@manatt.com)

Edith Coakley Stowe | Senior Manager | [ESTowe@manatt.com](mailto:ESTowe@manatt.com)

Spencer Manasse | Senior Analyst | [SManasse@manatt.com](mailto:SManasse@manatt.com)