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Health Care Compliance  
Association

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## **Navigating Compliance Challenges for Integrated Payer-Provider Systems**

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Privacy Officer at Visiting Nurse Service of New York**

January 27, 2020

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### **Agenda**

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- **Provider-Plan Integration Landscape**
- **Risk-Sharing**
- **Data-sharing**
- **Marketing and Intercompany referrals**

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## Provider-Plan Integration Landscape

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### Current State

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**The bright line that once existed between providers and payers has been blurred by the increase of provider-payer alignment**

**1**

Health systems creating new insurers

**2**

Insurers purchasing providers

**3**

Creation of co-branded offerings

**4**

Providers taking increased risks with insurers

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## Both Payers and Providers See Benefits in Partnership



### Payer

- Payers integrate with provider practices as a means to **improve quality and health outcomes and control cost**
  - Providers support care coordination and integration
  - Expanded access to healthcare for beneficiaries
  - Payers benefit from health system's ability to manage patients to improve outcomes and increase value
- Integration can **increase market strength**

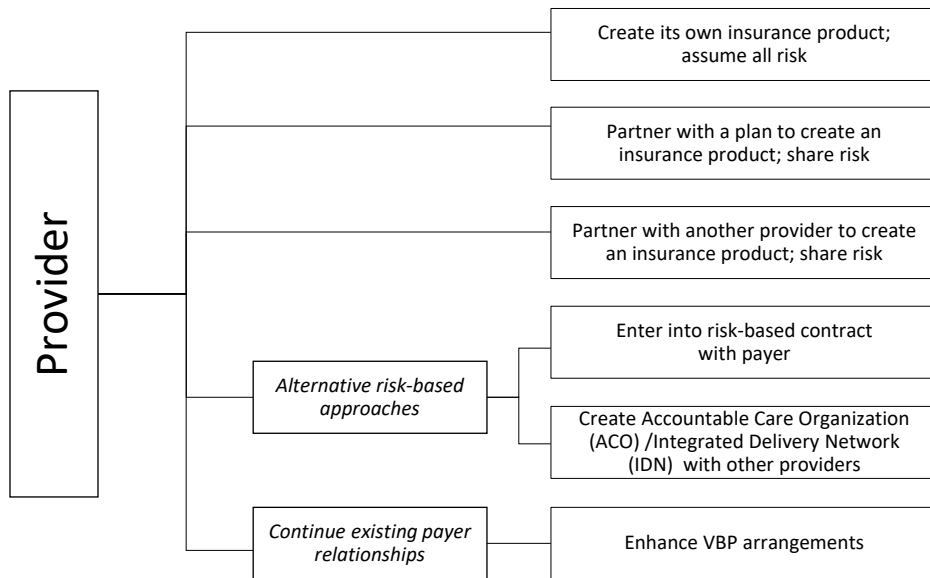


### Provider

- As payers transition from fee-for-service (FFS) models to value-based payment (VBP) models, **providers accept risk for the quality of their care**
  - Providers can increase margins by cutting out insurer overhead costs and profits
  - Providers gain more control over their revenue stream
- Integration can **increase market strength**

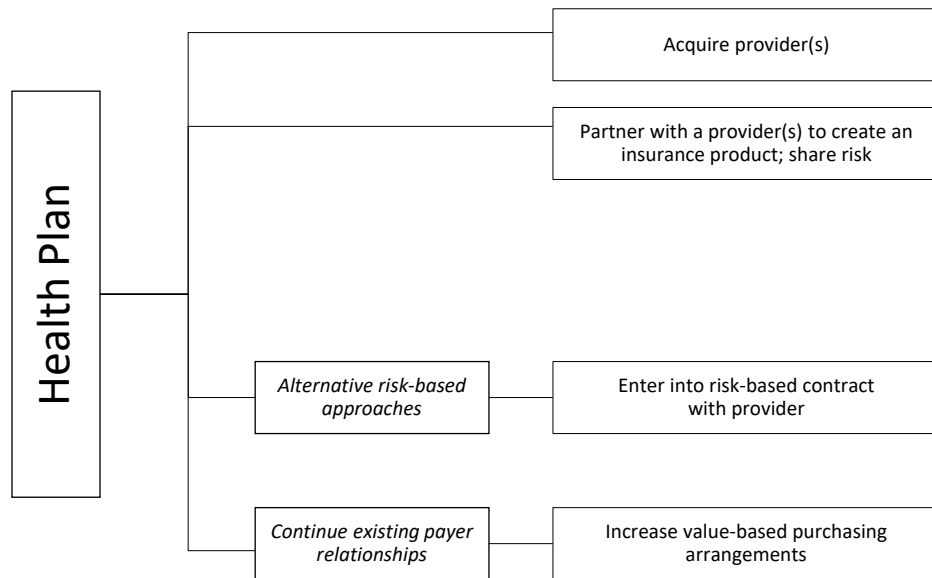
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## Provider Approaches to Integration



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## Health Plan Approaches to Integration



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## Emerging Provider-Payer Alignment Initiatives



How common are Provider-payer alignment initiatives?

- Many major health insurance carriers have these arrangements, including:



- These arrangements have increased across all market segments (commercial, Medicare, and Medicaid/CHIP)

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## And the Opposite Is True as Well. . .

As of 2016, nearly 52% of insurance products were represented through plans owned by health systems such as Kaiser, Providence, Geisinger, and Inova.

Sources: Susan Morse, *25 Biggest Provider-Sponsored Health Plans Include Some of the Nation's Biggest Systems*, HEALTHCARE FIN. (Sept. 13, 2016), <https://www.healthcarefinancenews.com/news/25-biggest-provider-sponsored-health-plans-include-some-nations-biggest-systems> ; see also Bob Herman, *More Health Systems Launch Insurance Plans Despite Caveats*, MOD. HEALTHCARE (Apr. 4, 2015), <http://www.modernhealthcare.com/article/20150404/MAGAZINE/304049981>

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## Hospital-Owned and -Operated Health Plan: Texas Children's Health Plan



- Became the **first HMO** in the country created **just for children in 1996**
- Since its creation, Texas Children's Health Plan has **added coverage for pregnant women and adults**
- The plan is currently offered only in the Medicaid managed care and CHIP markets, not commercially or in Medicare
  - Medicaid and CHIP coverage is available for enrollees in 20 counties
- In 2015, the plan was accredited by the National Committee for Quality Assurance (NCQA)

Sources: <http://www.texaschildrenshealthplan.org/> ; <http://www.texaschildrenshealthplan.org/news/releases/ncqa-accreditation/>

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## Insurer-Provider Consolidation: CareMore



In 2011, WellPoint agreed to buy CareMore, a senior-focused multi-specialty healthcare provider, for \$800 million

- CareMore provides managed care to about 54,000 MA beneficiaries through 26 clinics across California, Nevada and Arizona
- CareMore's clinics serve as medical homes, coordinating care for members and managing symptoms and co-morbidities for the chronically ill
- The program has reduced readmission rates and led to lower length of stay and below-average inpatient utilization in a high-acuity population
- The deal gave WellPoint:
  - Control of CareMore's clinics and employment of CareMore's staff, including physicians, nurse practitioners, case managers and other providers
  - An opportunity to test an integrated care approach with a regional provider

Sources: <http://articles.latimes.com/2011/jun/09/business/la-fi-caremore-wellpoint-20110609>;  
<http://www.wsj.com/articles/SB10001424052702304392704576373421615105108>

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## New Insurer: Vivity – Offered by Anthem



At the end of 2014, Anthem Blue Cross and seven competing Los Angeles Hospital systems formed Vivity, a unique, separate LLC

- The joint venture offers an HMO-like plan that allows members to see providers in any of the seven health systems, making it a cost-competitive narrow network product with a broader network than competing plans
  - All partners share in revenue and losses
  - This marks a major departure from industry practice, in which insurers usually bear the financial risk and individually negotiate prices with hospitals
- First customers include the California Public Employees' Retirement System (CalPERS) — the second-largest buyer of health insurance in the U.S. — and two of the participating hospital systems
- Vivity will require a high level of clinical and IT integration between the hospitals' IT systems

Sources: <http://www.vivityhealth.com/>; [http://www.nytimes.com/2014/09/17/business/hospitals-and-insurer-join-forces-in-california.html?\\_r=2](http://www.nytimes.com/2014/09/17/business/hospitals-and-insurer-join-forces-in-california.html?_r=2);  
<http://www.modernhealthcare.com/article/20140917/NEWS/309179965>; <http://www.modernhealthcare.com/article/20140920/MAGAZINE/309209961>

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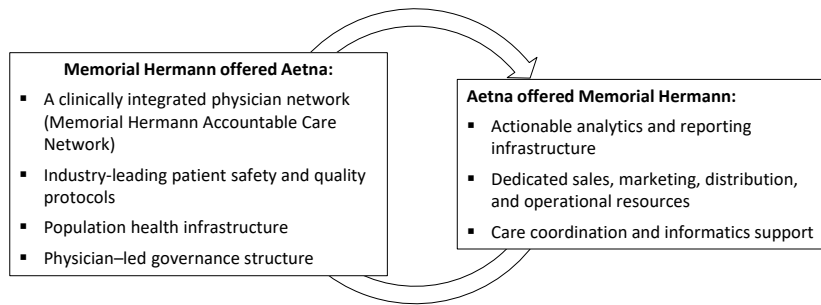
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## Co-Branded Insurance Product: Aetna Whole Health



In April 2013, Memorial Hermann teamed with Aetna to launch a co-branded product – Aetna Whole Health – to employers in the greater Houston market

Memorial Hermann and Aetna took advantage of each organization's unique strengths:



*Under the agreement, Aetna provides financial incentives for Memorial Hermann physicians based on quality, efficiency, and patient satisfaction outcomes*

Sources: <http://www.memorialhermann.org/aetna/>; <https://www.healthleadersmedia.com/finance/aetna-memorial-hermann-aco-year-making>; <https://www.managedhealthcareexecutive.com/managed-care-outlook/hospital-and-insurer-join-forces-launch-co-branded-health-plan>

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## Recent Examples of Payer-Provider Alignment

Just recently, there have been some very big moves in the market.



- Optum acquired DaVita's medical group for **\$4.9B** in December 2018



- Acquired **Kindred Healthcare**, a postacute provider, for **\$4.1B** in December 2018 with two private equity firms
- Same trio bought **Cuo Health Services**, a hospice provider, for **\$1.4B** in April 2019
- Acquired **Family Physicians Group** for **\$190MM** in April 2019



- Announced deal to buy **Community Medical Group**, a primary-care provider, in Florida that employs ~200 physicians and serves 70K patients in March 2019



- Announced deal to buy **Aspire Health**, a palliative care company, in May 2018

Source: <https://www.modernhealthcare.com/article/20180602/NEWS/180609985/reigniting-the-physicians-arms-race-insurers-are-buying-practices?CSAuthResp=1%3A%3A957817%3A1061%3A24%3Asuccess%3A21880D34143486455BBC666F7EBA201>

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## Opportunities and Risks for Provider-Payer Alignment Initiatives



### Opportunities

- Leverage existing experience, infrastructure, and resources, including membership base and reach
- Share risk with provider partners
- Establish a new line of business
- Experiment with innovative delivery and financing strategies (e.g., capitation, pay for performance, telemedicine, ACOs, narrow networks)
- Implement wellness and care management programs to reduce utilization and improve health outcomes
- Pool resources, leveraging strengths and capabilities to create a robust population health infrastructure



### Risks

- Procurement timelines for new market entrants
- Market saturation
- Many of these arrangements require significant investment in care management services and information technology
- Parties must be willing to integrate decision-making
- Requires alignment, cooperation and integration over extended period of time
- New products must meet:
  - Member access requirements (e.g., network adequacy and appointment availability)
  - Licensure and financial requirements (e.g., reserve and deposit requirements)

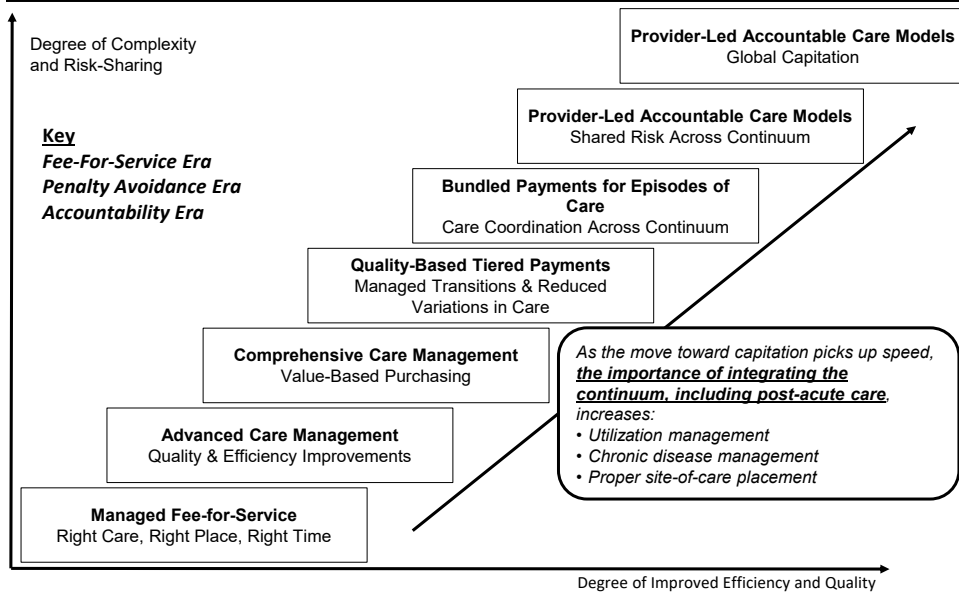
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## Risk-Sharing

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## Value-Based Payment Models Are Closely Tied to Integrated Models of Care



Source: Adapted from Healthcare Financial Management Association- Kentucky, "The Essence of Accountable Care," Numerof, January 24, 2013

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## How Does Risk-Sharing Change Focus of Compliance Programs?

Type of Risk	Fee-for-Service Payments	VBP
<b>Utilization Risks</b>	Monitor over-utilization driven by volume-based payments	Monitor under-utilization driven by cost containment bonuses
<b>Coding Risks</b>	Monitor upcoding under CPT and other billing methodologies	Monitor Hierarchical Condition Categories (HCC) and other clinical coding that drives risk scores tied to medical budget targets
<b>Data Integrity Risks</b>	Ensure medical records support billed services	Ensure reporting and calculation of quality/other metrics are accurate
<b>Hospital-Physician Relationships</b>	Assess whether services are FMV based on amount of time/labor required	Assess whether physician share of network benefits aligns with value of contribution
<b>Patient Inducement Risks</b>	Evaluate whether remuneration fits within exceptions/safe harbors	Evaluate whether waivers or VBP rationale supports innovative incentive programs*

\*Proposed revisions to the Civil Monetary Penalties Laws (CMPL) and Anti-Kickback Statute (AKS) may reduce the risk

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## Risk-Sharing: Legal Considerations

1 Stark Law

2 AKS

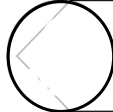
3 CMPL – Gainsharing

4 CMPL – Beneficiary Inducements

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## Fraud and Abuse Laws Implicated by Risk-Sharing Arrangements

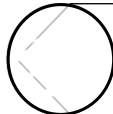
### Stark Law



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.

42 U.S.C. 1395nn

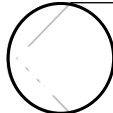
### AKS



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.

42 U.S.C. § 1320a-7b(b)

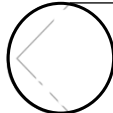
### Gain-sharing



Prohibits a hospital from knowingly making any payment to induce a physician to reduce or limit medically necessary services covered by Medicare or Medicaid.

42 U.S.C. 1320a-7a(b)(1)

### Beneficiary Inducement



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.

42 U.S.C. § 1320a-7a(a)(5)

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## Stark Exceptions and AKS Safe Harbors Relevant to Risk-Sharing

Stark Risk - Sharing Exception	AKS Managed Care Safe Harbor	AKS Health Plan Discount Safe Harbor
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 contractor (such as hospital or IPA) to providers for delivering or arranging for healthcare items and services.	Covers discounts on fees offered by providers to health plans or contracting intermediaries.
Should protect shared savings or similar risk-sharing payments from VBP entity to physicians.	Does not protect commercial plan payments; does not protect marketing or payments or pre-enrollment activities	Protects only discounts from providers, not shared savings or similar risk-sharing payments.
Does not protect VBP investment relationships or care management fees.	Does not protect VBP investment relationships.	Does not protect VBP investment relationships or care management fees.

\*Proposed revisions to the Stark Law and AKS provide additional exceptions and safe harbors, respectively

Sources: 42 CFR § 411.357(n)(Stark Law); 42 CFR § 1001.952(h),(t),and (u).

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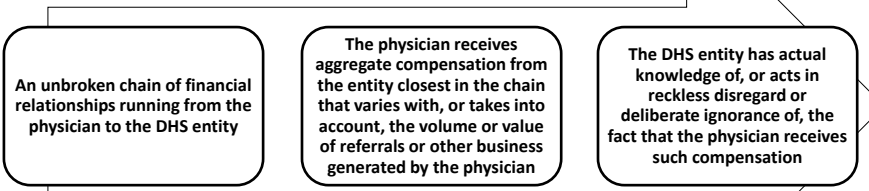
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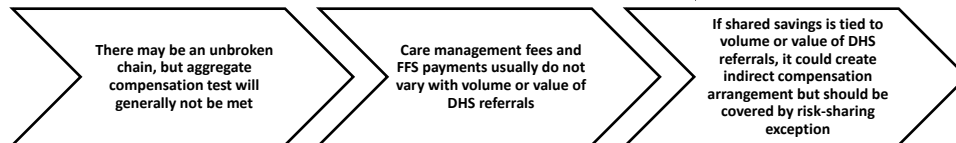
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## Do Risk-Based Payments to Physicians Create Indirect Compensation Arrangement Under Stark?

### Indirect Compensation Arrangement Definition



### Application to Payments to Physicians



Source: 42 CFR § 411.354

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## Gainsharing: VBP Under-Utilization Risks

Type of VBP Program	Potential Risk
Total cost of care tied to shared savings/losses	Reduction in medically necessary hospital admissions, lab tests, imaging services, specialty referrals, etc.
BPCI and similar bundled payment arrangements	Improper discharge of patients to home rather than skilled nursing facility
Hospital-physician gainsharing	Medically inappropriate early discharge of patient from hospital by physician
Medical group capitation	Inappropriate diversion of patients from practice to specialists or emergency room

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## Addressing Social Determinants of Health in a Risk-Sharing Arrangement

**When providers and payers integrate and share risk, they are further incentivized to address the social determinants of health that impact health outcomes and associated cost of care**

Payment reforms such as shared savings/loss arrangements, capitation and bundled payments force providers to reengineer care delivery to improve value, including addressing Social Determinants of Health (SDOH)

Some payer-provider may attract populations that are more likely to be impacted by SODH (i.e. low income populations, minority populations, etc.), and thus higher risk patients

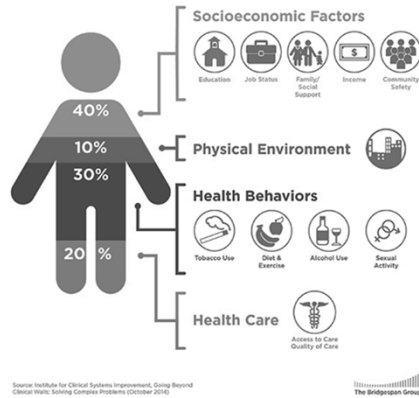
**80% of Payers Aim to Address SHOD,  
according to a 2018 CHANGE Health Care Survey**

Source: <https://www.medtrade.com/news/billing-reimbursement/value-added-services-while-avoiding-prohibited-inducements>;  
<https://healthpayerintelligence.com/news/80-of-payers-aim-to-address-social-determinants-of-health/>

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## Social Determinants of Health: Definition & Impact

SDOH are conditions in the environments in which people are born, live, learn, work, play, worship, and age that affect a wide range of health, functioning, and quality-of-life outcomes and risks.



- Socioeconomic factors, physical environments, and health behaviors collectively drive health outcomes more than medical care
- Having at least one unmet social need is associated with increased rates of depression, diabetes, hypertension, ED overuse, and clinic “no-shows”
- Nearly 80% of physicians believe addressing social needs is as important as medical care, but most do not feel prepared to address them

Source: Institute for Clinical Systems Improvement, Going Beyond Clinical Work: Solving Complex Problems (October 2010)

The BridgeSpan Group

Sources: Booske, B.C., Athens, J.K., Kindig, D. A., et al. *Different Perspectives for Assigning Weights to Determinants of Health*. University of Wisconsin Population Health Institute. February 2010; Bachrach, D., Pfister, H., Wallis, K. and Lipson, M. *Addressing Patients’ Social Needs: An Emerging Case for Provider Investment*. Commonwealth Fund. May 2014; Blendon, R.J., Donelan K., Hill C., Scheck A., Carter W., Beatrice D., Altman, D. “Medicaid beneficiaries and health reform.” *Health Affairs*, 12, no.1 (1993): 132-143.

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## Beneficiary Inducements

A person who offers or transfers to a Medicare or Medicaid beneficiary any remuneration that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of Medicare or Medicaid payable items or services may be liable for civil money penalties (CMPs) of up to \$10,000 for each wrongful act.

Exceptions to this prohibition include (without limitation):

- Exception for items of **nominal value**
  - Nominal value means the items (or services) must have a retail value of no more than \$15 per item or \$75 in the aggregate per patient on an annual basis.
- Incentives given to individuals to **promote the delivery of preventive care services**
- **Exception for financial hardship** that includes the provision of items reasonably connected to a particular patient’s medical care
- **Promotes access to care and poses a low risk of harm**

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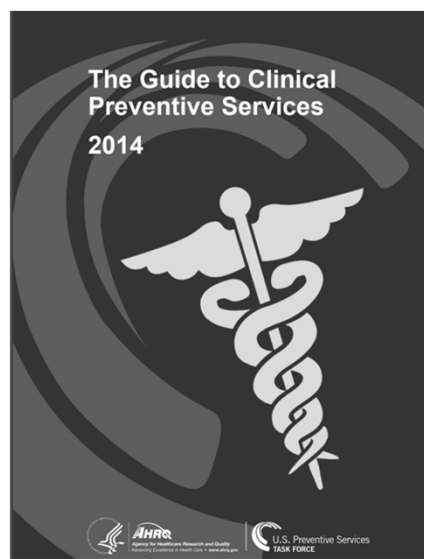
## Financial Hardship Exception

- The offer or transfer of items or services for free or less than fair market value **does not constitute “remuneration”** under the CMP **if the items or services**
  - **are not** offered as part of **any advertisement or solicitation**;
  - the items or services **are not tied** to the provision of **other services** reimbursed in whole or in part by **Medicare or Medicaid**;
  - there is a **reasonable connection** between the **items or services** and the **medical care** of the individual; **and**
  - the **provider determines in good faith** that the individual is in **financial need**.
- The OIG has clarified that for remuneration to be “reasonably connected” to medical care, it must be reasonable from a medical perspective and reasonable from a financial perspective.
- This **determination requires an individualized assessment**, made in good faith and **on a case-by-case basis**, of the patient’s financial need.

## Incentives Given to Individuals to Promote the Delivery of Preventive Care Services

A provider is permitted to **offer incentives** to beneficiaries, if the incentive **promotes the delivery of preventive care services** where the delivery of such services is not tied (directly or indirectly) to the provision of other covered services that are reimbursed in whole or in part by a Federal Health Care Program.

**Preventive care is defined in 42 C.F.R. § 1003.101** as items and services that (a) **are covered by Medicare or Medicaid**, and (b) are **described in the Guide to Clinical Preventive Services published by the U.S. Preventive Services Task Force**.



## Remuneration That Promotes Access to Care and Poses a Low Risk of Harm

"We recognize that there are socioeconomic, educational, geographic, mobility, or other barriers that could prevent patients from getting necessary care (including preventive care) or from following through with a treatment plan. Our interpretation of items or services that 'promote access to care' encompasses giving patients the tools they need to remove those barriers." - OIG

"Promote access to items or services that are payable by Medicare or a State health care program" and

Poses a low risk of harm:

- be unlikely to interfere with, or skew, clinical decision making;
- be unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and
- not raise patient-safety or quality-of-care concerns.

*Example: A primary care group practice might purchase and make available to its diabetic patients a subscription to a web-based food and activity tracker that includes information about healthy lifestyles.*

Source: <https://oig.hhs.gov/fraud/docs/advisoryopinions/2017/AdvOpn17-01.pdf>

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## Beneficiary Inducements

- Beginning in 2020, MA Plans may offer supplemental benefits that address SDOH
  - Example: May offer air filters to persons with asthma
- An MA plan may create one or more Rewards and Incentives (RI) Programs that provide rewards and/or incentives to enrollees in connection with participation in activities that focus on promoting improved health, preventing injuries and illness, and promoting efficient use of health care resource
  - Example: May reward members for reporting their weight and blood pressure at regularly intervals or members for reporting they are smoke-free after the completion of smoking cessation program
- Medicaid managed care may have similar flexibility

Sources: <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf>; Medicare Managed Care Manual, Ch. 4, Sec. 100, available at <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/mc86c04.pdf>

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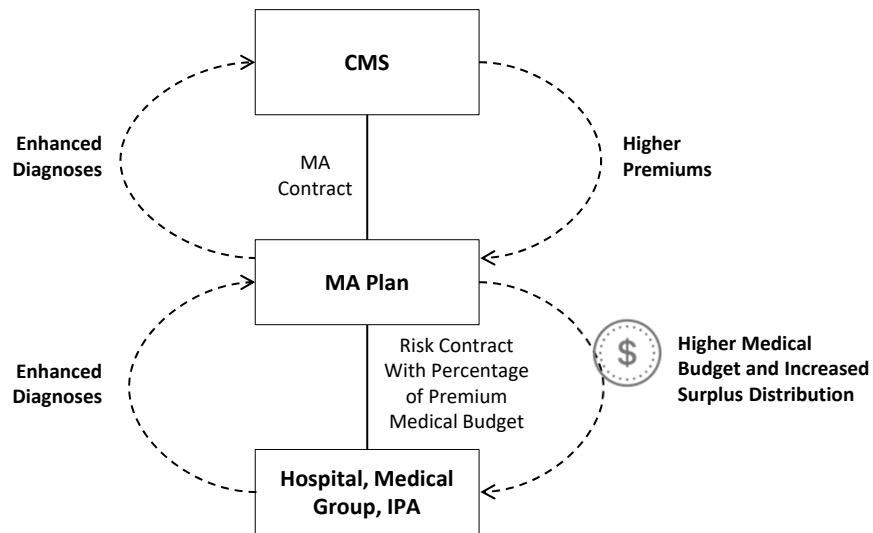


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## Other Risks: Provider HCC Coding Risks Tied to VBP



*Medicare Advantage plans face primary False Claims Act and external audit risks for HCC coding errors.*

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## Data-Sharing

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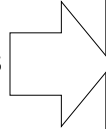


## Opportunities and Risks for Provider-Payer Alignment Initiatives



### More data should yield more insights

Providing broad access to claims and clinical data where possible helps create a complete picture of a patient's history and health status, helping physicians and care managers provide needed care and reduce wasteful spending



#### Shared data can be leveraged to:

- **Complete actuarial analysis** to determine high-risk patients and develop approach to manage their needs
- Provide **insight into health plan's performance** across service lines and populations
- Identify **opportunities to improve** clinical operations and management
- **Analyze population health trends** that can be targeted to improve health outcomes and reduce costs

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## Data Sharing: Relevant Regulations & Legal Considerations

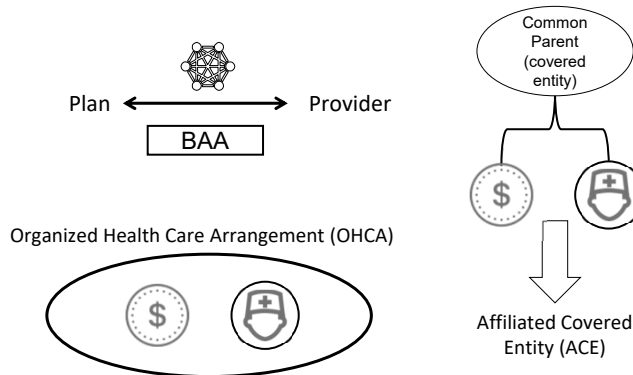


### There are limits what data can be shared and how data can be shared between plans and payers under HIPAA and Part 2

In general, **HIPAA prohibits the sharing** of protected health information **between a provider and a plan**, except for **payment and health care operations**

- Treatment
- Payment
- Health Care Operations

#### Patient Consent



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## Emerging Provider-Payer Alignment Initiatives



### What is marketing under HIPAA?

- “A **communication** about a **product** or **service** that **encourages recipients** of the communication to **purchase or use** the product or service”  
**Patient authorization is generally required**
- “An **arrangement** between a **covered entity** **and** any other entity whereby the covered entity discloses **PHI** to the other entity, **in exchange for direct or indirect remuneration**, for the **other entity** or its affiliate to **make a communication about its own product or service** that encourages recipients of the communication to purchase or use that product or service.”

**This is called a subsidized communication. Patient authorization is always required.**

**Unsubsidized communications are excluded from the marketing definition if:**

- The communication describes a health-related product or service (or payment for such product or service) that is provided by, or included in, a plan of benefits of the covered entity making the communication
- The communication is for the treatment
- The communication is for case management or care coordination, or to direct or recommend alternative treatments, therapies, providers or settings of care to the individual

Source: <https://www.hhs.gov/hipaa/for-professionals/privacy/guidance/marketing/index.html>

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## Part 2

**Some types of data related to substance use disorder (“SUD”) services are subject to 42 C.F.R. Part 2**

**Part 2** Programs include any organization that “*holds itself out*” as providing, and provides, *SUD diagnosis, treatment or referral for treatment* **and receives federal assistance**

**Part 2 is known as a strict privacy regulation because a patient’s written consent generally is required prior to disclosing Part 2 data.**

In contrast to HIPAA, there is **no exception to Part 2 that allows disclosures without consent for purposes of treatment or care coordination**, nor is there a consent exception that allows a provider to disclose Part 2 data to a health plan in order to **obtain payment**.

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## Part 2

A provider may receive Part 2 data from a health plan

Health plans may hold data that is subject to 42 C.F.R. Part 2.

Health plan discloses the data to provider and tells the provider its Part 2 data

Provider **must** protect the data as Part 2 data

Prohibited from re-disclosing that patient data unless consent is obtained

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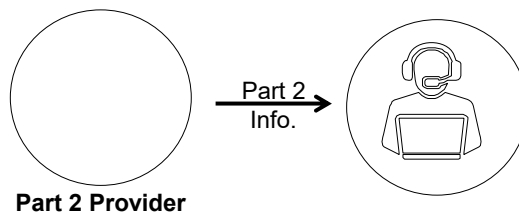
## Part 2 and Qualified Service Organizations

A Qualified Service Organization (QSO) is a contractor to a Part 2 program that provides services on behalf of that program.

Similar to a business associate

But a QSO must directly contract with a Part 2 provider

If you are a QSO then patient consent is not required to disclose the Part 2 information to the QSO



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## Marketing & Intercompany Referrals

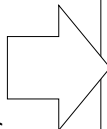
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## Opportunities for Marketing and Intercompany Referrals



### Intercompany referrals can help increase market strength

Often, providers and payers understand integration as a means to grow their market share by merging their patients and beneficiaries into a larger consumer pool



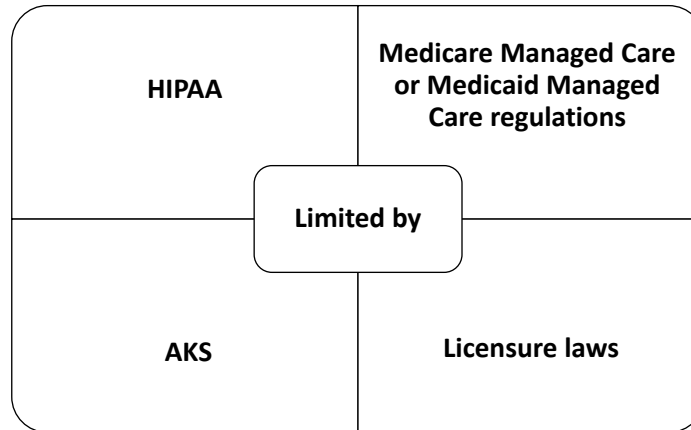
### Intercompany referrals can be leveraged to:

- **Increase enrollment** in health plan
- **Increase volume** of health system or particular service line of health system
- **Strengthen brand** for either the payer or provider side

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## There Are Limitations on How Integrated Companies May Market or Refer to One Another

Cross-marketing is highly regulated



and always subject to patient/member choice

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## Questions?



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