STRATEGIC HEALTH LAW

The Next Big Thing!

Maintaining Compliance and Managing Risk with Healthcare Startup Vendors and Providers

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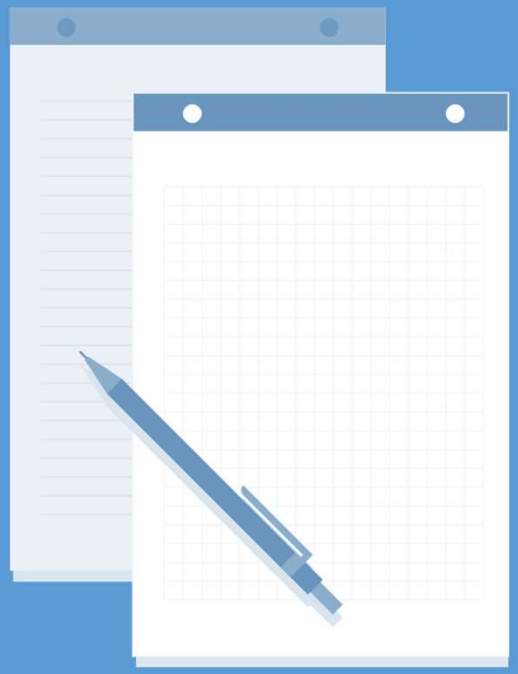
Health Care Compliance Conference Managed Care Compliance Conference
January 31, 2022

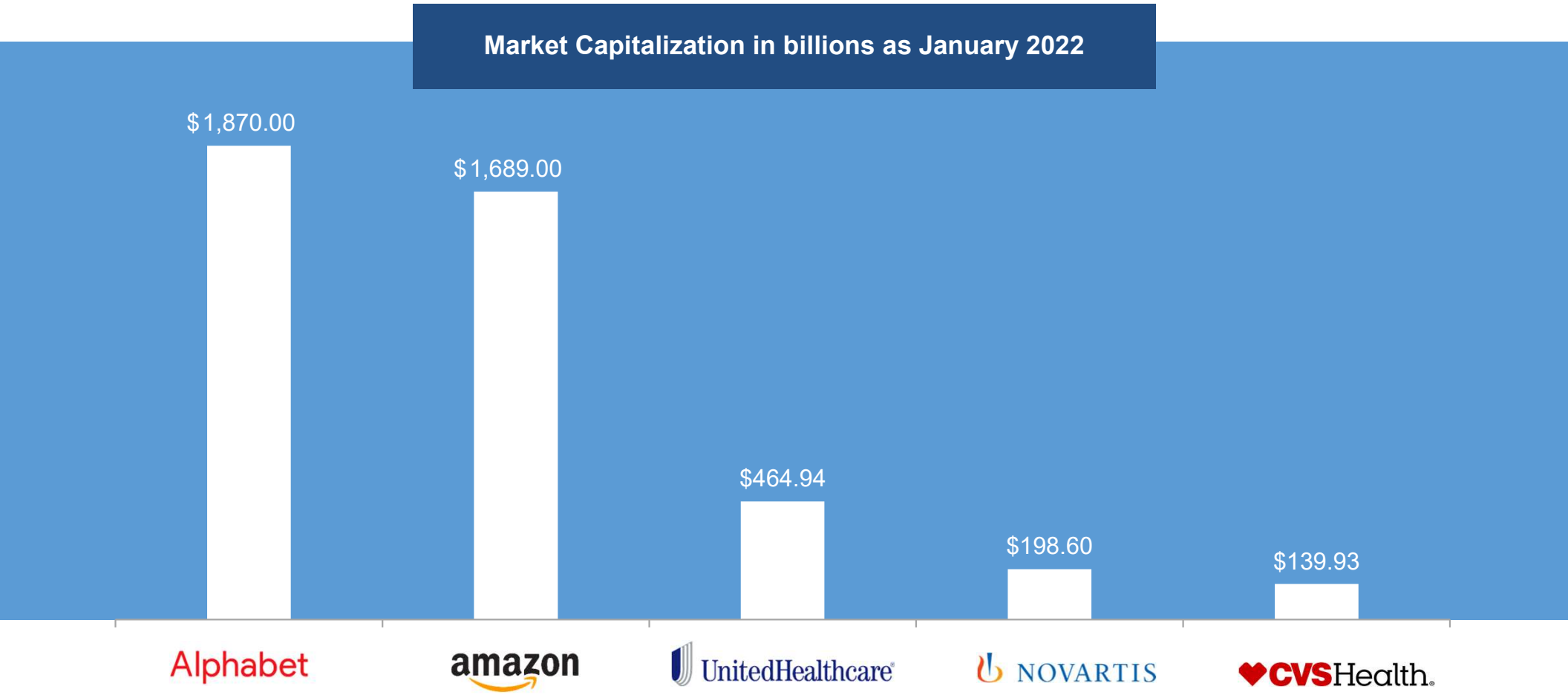
Agenda



- Private Equity and Venture Capital in Healthcare
- Key Legal Risks
- Practical Strategies and Best Practices

Private Equity and Venture Capital in Healthcare

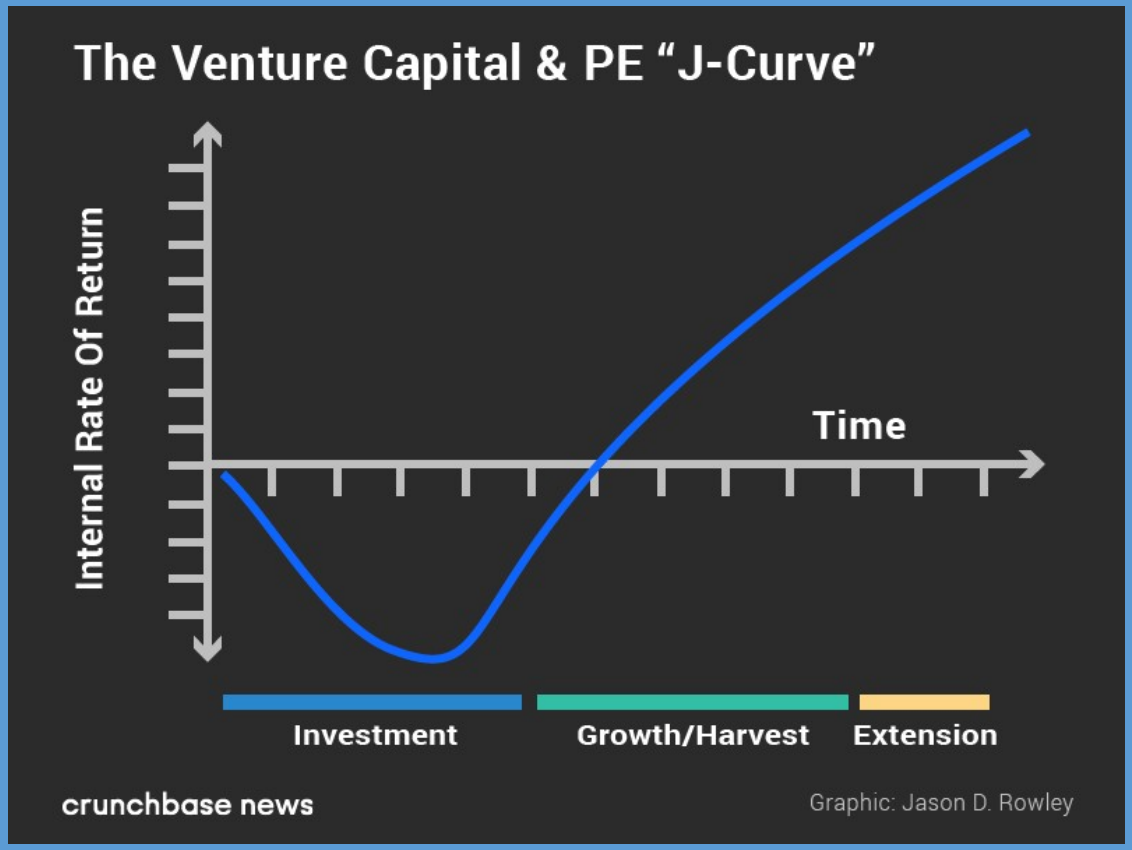
Tech Companies: They're big, and they are investing in healthcare.



What's Private Equity (PE)?

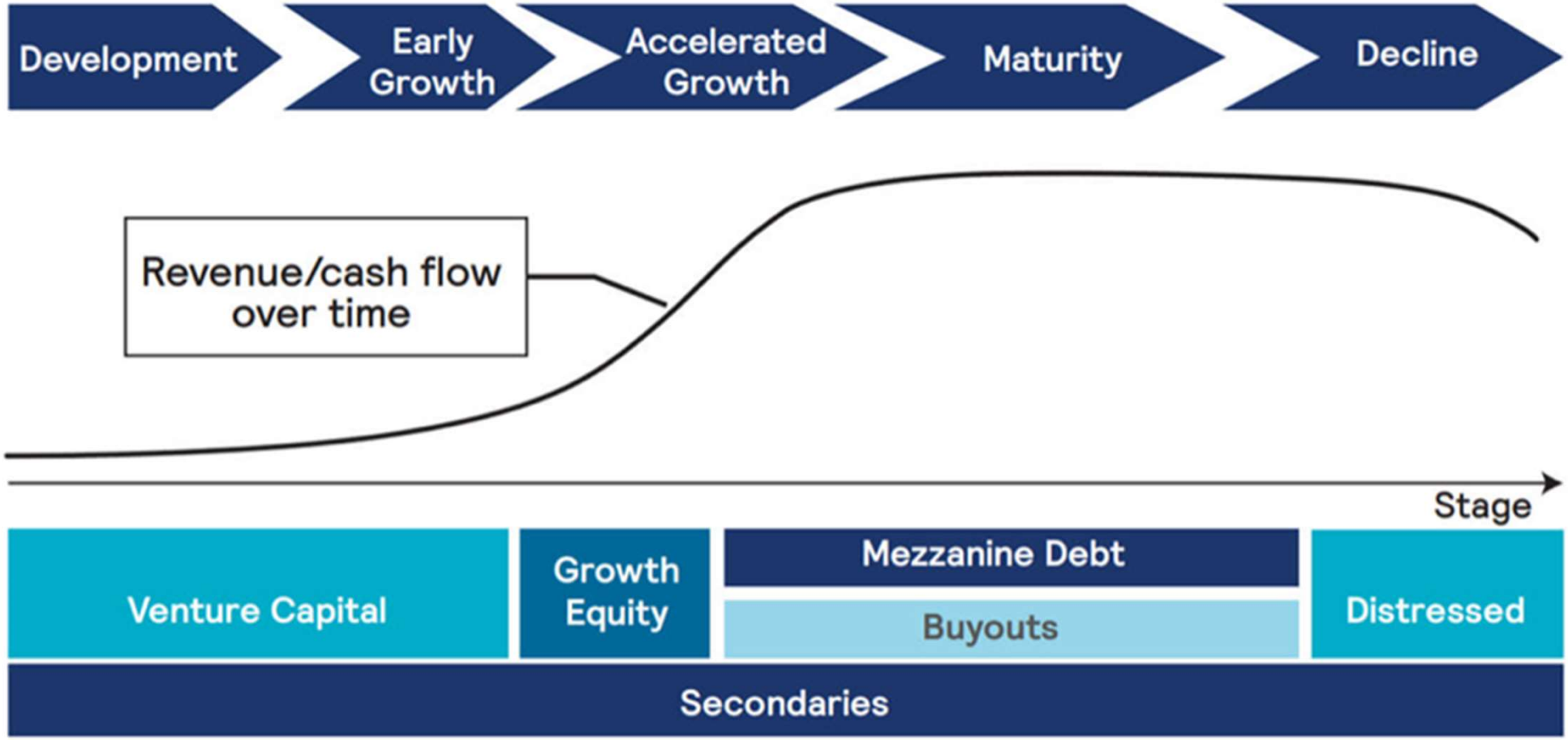
A non-publicly tradeable investment	Not liquid	More control over a company than other investors
Fund often controls board of directors	Capital calls in first few years in addition to management fees	Often generate much higher returns than publicly traded stocks

PE Time Horizon and the “J-Curve”



Term of typical PE fund is 10 years plus additional time to complete liquidation

Private Equity Landscape in the Busines Cycle Framework



From *Understanding Private Equity: A Primer*, by Michael Forestner, 2015. Copyright 2015 by Mercer. Reprinted with permission.

PE-Backed Health Plans

oscar

Founded: **2012**

Total funding amount: **$1.3B**

Clover

Founded: **2013**

Total funding amount: **$925M**

bright HEALTH

Founded: **2015**

Total funding amount: **$440M**

DevotedHealth

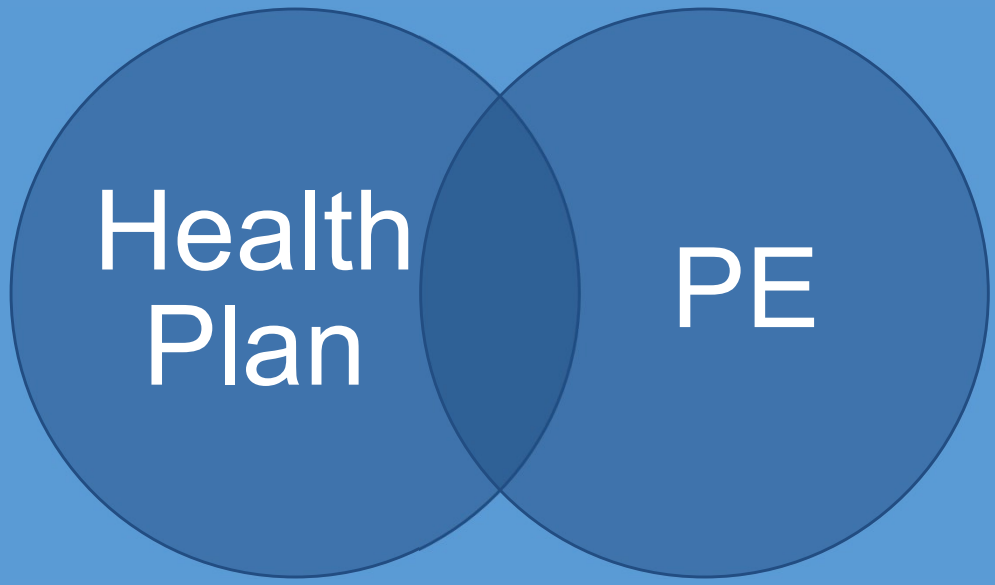
Founded: **2017**

Total funding amount: **$362M**

Source: www.crunchbase.com (accessed 3/11/2019)

What Health Plans Need to Remember When Working with PE-Backed Companies

- Time Horizon
- Risk Tolerance
- Background and Expertise
- Legal and Compliance Framework
- Core Values



Top Uninsurable Risks

Reputational risk	Regulatory risk	Cyber risk	Political risk	Pandemic risk
• Data breach, marketing, customer service	• CMS, OIG, FTC, FDA	• 'How did you get the information?'	• Federal scrutiny, relationships with local regulators	• Force majeure clauses insufficient, shifting local requirements

Key Legal Risks: Anti-fraud Laws, Agent Sales, HIPAA Data Use

Anti-Kickback Statute

Makes it a crime to:

Offer, pay, solicit, or receive

- Any "remuneration," meaning anything of value
- Directly or indirectly, overtly or covertly

To induce

- Referrals of items or services reimbursable by federal healthcare programs

Anti-Kickback Statute

Actual knowledge of the AKS or intent to violate the law not required

"One purpose" test means that inducing referrals can be one of a number of purposes (including noble ones).

Penalties:
Up to $50,000 per kickback
and 5-10 years incarceration

Beneficiary Inducement Statute

Prohibits giving a gift to a Medicare or Medicaid beneficiary that the benefactor should know is likely to influence the beneficiary's selection of a particular provider or supplier for anything reimbursable.

Civil Monetary Penalties ranging from $55,000 to $100,000+ for each act, depending on the conduct

Possible exclusion from federal health care programs

False Claims Act

Prohibits:

- Submitting false claim for payment to the federal government
- Making false records or statements that are material to a false claim
- Retaining overpayments from the federal government ("reverse false claims")

Intent can be actual knowledge or reckless disregard – no requirement of actual intent to defraud

FCA Penalties

Treble damages plus penalties between $11,665 and $23,331 per violation

Criminal sanctions in the most serious cases

Plus: Whistleblowers

- FCA allows *qui tam* lawsuits filed by employees or others (called “relators”)
- *Qui tam* relator may collect 15-30 percent of the damages

Plan Kickback/False Claims Risks

Traditional Risks

- Offer of value to a provider to reward steering patients to the plan
- Transfer of value to a payer for referral of patients to the provider

More Complex Arrangements

- Rebates for preferred formulary placement
- Inflated capitated payment to providers and vendors
- Incentive payments for unmet performance metrics
- Shared savings

Non-Traditional Functions

- Charitable donations
- Plan investment in start ups with providers

Considerations in Evaluating an Arrangement Under the AKS/FCA

Will the arrangement:

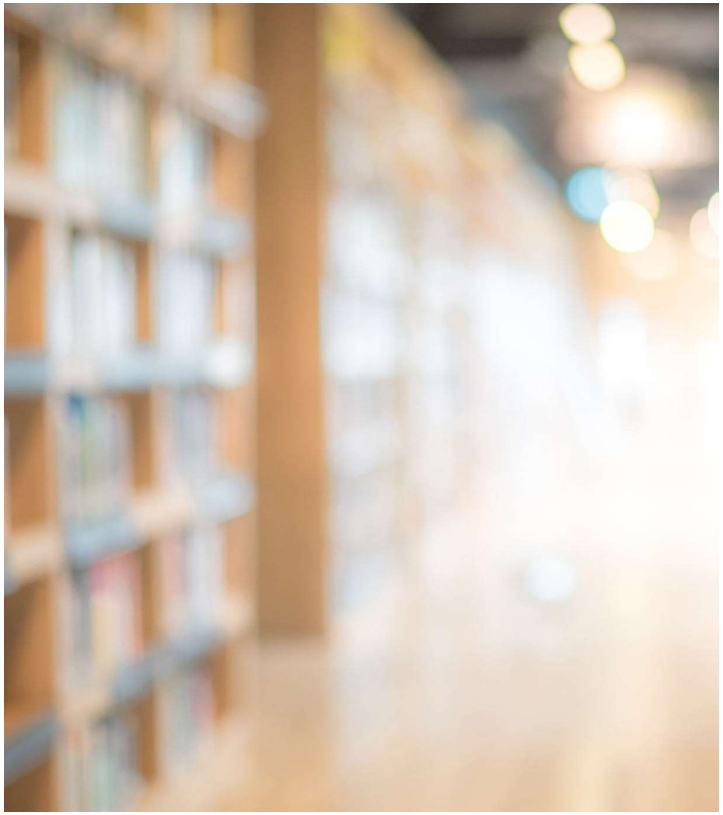
- Influence a person to select a particular provider or include the selection of an item or service reimbursable by Federal health care programs?
- Improve the health of patients and protect the quality of care?
- Reduce overall costs to Federal healthcare programs?
- Lead to an increased risk of overutilization?
- Include appropriate safeguards?
- Operate transparently?

Carve Outs for Federal Health Programs

"**The OIG has a long-standing concern about arrangements under which parties "carve out" referrals of Federal health care program beneficiaries or business generated by Federal health care programs from otherwise questionable financial arrangements**. Such arrangements implicate, and may violate, the anti-kickback statute by disguising remuneration for Federal health care program business through the payment of amounts purportedly related to non-Federal health care program business."

OIG Advisory Opinion No. 13-03

Medicare Marketing Requirements



- Regulations in 42 CFR Part 422, Subpart V and 42 CFR Part 423, Subpart V (**Communication Requirements**)
- Preamble to January 19, 2021 Final Rule, 86 Fed. Reg. 5684 (**Current Guidance**)
- 2018 MCMGs (**Arguably outdated but still in manual**)
  - As modified by August 6, 2019 HPMS Memo, "Medicare Communications and Marketing Guidelines"

October 8, 2021 HPMS Memo on "Third Party Marketing"

- Plans responsible for FDR compliance
- Materials do not need to mention a specific plan to be **marketing**
- Concern about beneficiary confusion
- Clear warning from CMS
  - ***We are also working with other federal agencies regarding the appropriateness of the content of certain advertisements***

HIPAA Permitted Uses: Marketing

Marketing means making a communication about a product or service that encourages recipients to purchase or use the product or service.

- Prior authorization required (unless an exception applies).

Marketing also means an arrangement between a covered entity sells PHI (e.g., patient/member lists) to a third party for that party's own purposes.

- Includes business associates
- No exceptions – individual authorization always required

Exceptions for face-to-face communications and promotional gifts of nominal value

- No authorization required even if marketing

What Is Not Marketing?

Marketing – Prior Auth Needed

- Communication from hospital informing patients about cardiac facility that can perform EGK for $39
- Communication from health insurer promoting a home and casualty insurance product offered by the same company
- Health plan sells list of members to company that sells blood glucose monitors, which intends to send members brochures

Not Marketing – No Prior Auth

- Communication from hospital announcing arrival of a new specialty group or equipment through general mailing
- Communication from health plan to subscribers approaching age 65 with materials describing its Med Supp plan and an application form

Strategies to Support Compliance (Help for the Health Plan Compliance Professional)

Listen to Your Instincts and Ask Questions

I didn't ask questions of the developer, his team or the realtors. I thought if I asked for help, I would be perceived as weak, imperfect. I didn't listen to my gut, because I didn't want to know the answers. I didn't want to lose my biggest client. . . . I wanted to continue providing for my children and sending them to the best schools, to live in a nice home in a fabulous Miami neighborhood and I wanted to keep up appearances.

My inner voice screamed "be careful," "ask for a second opinion," "are you sure this is okay?" Instead, I felt flattered and like I belonged in the big leagues. I convinced myself I was smart enough to do the right thing and I never considered I could be doing something wrong.

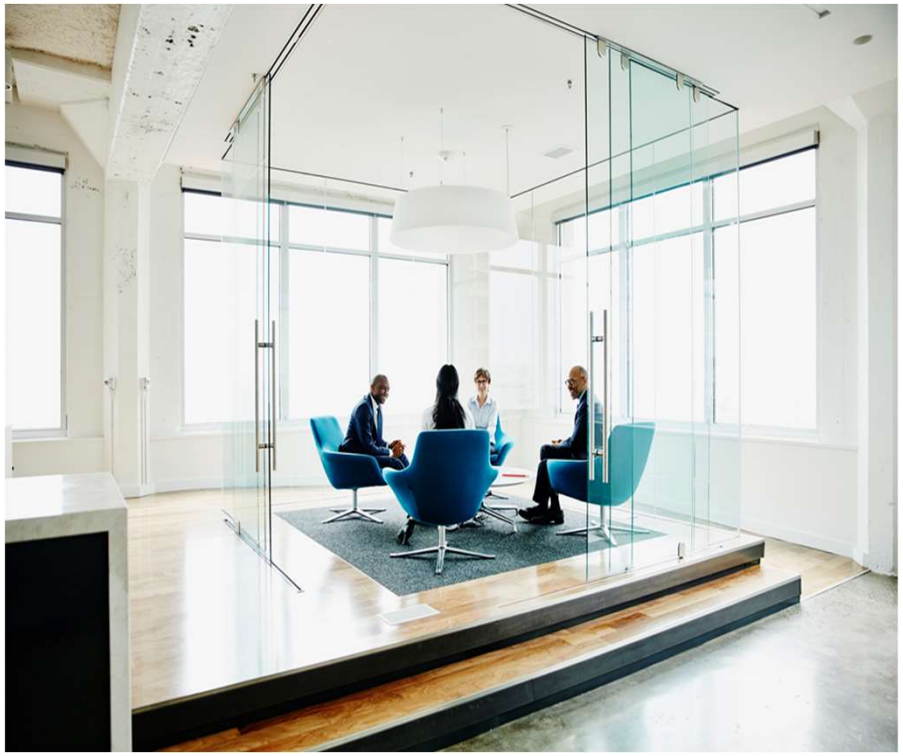
Rashmi Airan, "I was a wealthy suburban woman. Then I went to federal prison for bank fraud," Washington Post (Feb. 20, 2020).

Best Practices for Working With Venture-Backed Providers and Vendors

Involve	Involve counsel early and often in negotiations
Add	Add compliance language to NDAs
Consider	Consider compliance training for significant partners
Ask	Ask as many questions as you need to
Structure	Structure arrangements to fit into safe harbors
Document	Document intent and compliance with all requirements

Scenario 1: Working with a Venture Backed Provider

Proposed investment in new provider clinic



Practical Strategies for Counseling Internal Business Clients

Scenario 2: Working with Your Internal Business Client

- Proposed provider advertising initiative

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