



Legal and Regulatory Issues Facing Insurance Companies In a Changing Market

Presenters: Doug Anderson and Heather Stutz
12:10 p.m. – 1:00 p.m.



Legal and Regulatory Insurance Issues: Agenda



- During my part of the presentation, I will cover the following:
 - Ohio's Small Group Market and MEWAs
 - Referenced Based Pricing
 - Pharmacy Rebates
 - Member Incentive and Reward Programs
 - Holding Company, Transactions among Affiliates, and Financing Deals

Ohio's Small Group Market and MEWAs



Overview of MEWAs

- A multiple employer welfare arrangement (MEWA) is a group health plan that covers members employed by employers that are not all part of the same control group (a.k.a., not affiliated).
- Self-insured single employer plans (i.e., only involving affiliated companies) are subject to ERISA preemption, and state law does not apply.
- Self-insured MEWAs are not subject to ERISA preemption, and therefore state law applies.
- Under Ohio law, MEWAs must obtain a COA to operate in Ohio, meet solvency standards, and follow Ohio's health insurance laws generally.

Ohio's Small Group Market and MEWAs



- Currently, 13 self-funded MEWAs operate in Ohio.
 - 8 Industry, Trade and Professional Group MEWAs
 - Builders Exchange, Cleveland Auto Dealers Assn, Cooperative Group, Ohio Bankers League, Ohio Dental Assn, Ohio Farm Bureau, Ohio Medical Assn, Sequent
 - 5 Chambers of Commerce MEWAs
 - Akron Chamber
 - Canton Chamber
 - Cleveland Growth Assn/COSE
 - Southern Ohio Chamber Alliance
 - Ohio Chamber of Commerce

Ohio's Small Group Market and MEWAs



- As of June 30, 2019, almost 140,000 Ohioans had coverage through self-funded MEWAs.
 - Almost all enrollment is small group members
 - It is growing fast, and likely will continue

- In 2014, less than 15,000 Ohioans has self-funded MEWA coverage
 - This is almost ten-fold growth.

- By the way, does anyone know of a fully-funded MEWA operating in Ohio?

Ohio's Small Group Market and MEWAs



What has changed?

1. The Affordable Care Act placed new limits on small group coverage
2. Grandfathered coverage has become less attractive
3. In 2015, Ohio expanded the type of organizations that can sponsor MEWAs to include chambers of commerce
 - Previously, MEWA sponsors were limited to trade, industry, and professional associations
4. The new federal AHPs have been struck down in the courts

Ohio's Small Group Market and MEWAs



What makes a self-funded MEWA attractive?

1. A self-funded MEWA is not is not subject to the ACA's small group rules
2. It is not required to offer EHB, but is treated like a large or self-funded group
3. It is not subject to the ACA small group rating rules, but only to Ohio's old small group rules (with +/- 40% health-status rating bands)
4. MEWAs generally charge less to healthy groups, in comparison to fully insured small group insurance
5. Average rates tend to be lower than fully insured coverage

Ohio's Small Group Market and MEWAs



What are the barriers?

1. Licensure: MEWAs must obtain licensure, using the same process as insurance companies, which is time consuming and expensive
2. Capital and Cost: Minimum capital requirements are significant, driven by enrollment and RBC
3. Governance and Oversight: MEWA are governed by the plan sponsor and member companies, so considerable investment of time and effort is required
4. Complexity: MEWAs are complex and there is a learning curve
5. Health Benefits: MEWAs are subject to Ohio's health insurance laws

Regulatory Issues: Capitalization

Associations and Chambers do not have the capital to start a MEWA

1. New MEWAs are generally capitalized by surplus notes, which is the only way to put “capital” in a “group health plan” and later take it out
2. Surplus loan agreements can require the MEWA use a specific TPA, but not a specific stop loss carrier.
3. If you are a carrier funding a MEWA, it is better to issue a series of smaller surplus notes, rather than one large note, in order to take money more quickly as as excess surplus becomes available.

Ohio's Small Group Market and MEWAs



Regulatory Issues: Growth

If a new MEWA grows quickly, premium may not be enough to support RBC. There are two ways to address this situation:

1. More surplus notes
2. Move to a quota share reinsurance agreement
 - Aggregate stop long not less than 125% of claims is required by law, but does not necessarily provide credit for reinsurance
 - Quota share reinsurance automatically gives “credit for reinsurance”, reducing liabilities, and helping meet RBC requirements

Regulatory Issues: Fiduciary Status and Prohibited Transactions

Under ERISA, trustees, officers are fiduciaries who must act in the best interest of members with no conflicts of interest. Certain transactions (including transaction involving TPAs) are prohibited.

1. Do not use trust fund dollars to pay people who work for the MEWA sponsor or a participating employer
2. Trust fund dollars may only pay for services at “fair and reasonable” rates
3. The MEWA sponsor can bear some costs, and be reimbursed by participating employers through access fees, without the funds going through the trust
4. Only use funds in the trust for necessary expenses associated with providing benefits
5. No self-dealing or commissions from MEWA transactions for trustees or officers

Regulatory Issues: Fiduciary Status and Prohibited Transactions

TPA compensation must be disclosed in the administrative services agreement because, under prohibited transaction rules, fees must be fair and reasonable, including:

- Administration Fees
- Drug Rebates
- Interest earned on Funds Held
- Other Fees or Earnings

Regulatory Issues: Responsibility for Compliance

- Self-Funded MEWAs are treated as insurance companies in and of themselves.
- They must make their own financial statement filings, submit their own forms and rates in SERFF, are subject to ODI direct examination and enforcement authority.
- Notwithstanding, it is the insurers that administer MEWAs that have the knowledge and experience to comply with the insurance laws, and MEWAs rely heavily on insurers to do so

Member Incentives and Rewards



Member Incentives and Reward Examples

- Wellness Incentives
- Free downloadable apps
- Telematics and connected devices
- Wearables
- Medical devices to track conditions
- Software
- Rewards to incentivize conduct
- Implementation Credits

Member Incentives and Rewards



Applicable Ohio Law

Ohio Rev. Code 3933.01 prohibits an insurer from offering any rebate, advantage, or valuable consideration as an inducement to insurance not plainly specified in the policy.

ODI Bulletin 2019-05 - ODI does not interpret the offer of an item with a fair market value of less than \$50 to violate the rebating statute if not tied to the purchase of insurance.

ODI Bulletin 2019-04 - ODI does not interpret the offer of a rate reduction, loss control, and/or loss mitigation value added product at no or reduced cost to violate the rebating statute if the product is: (1) Directly related to the purchase of insurance; (2) Intended to mitigate risks or reduce rates; and (3) Offered in a fair and nondiscriminatory manner.

Member Incentives and Rewards



Compliance Tips

The BEST WAY to avoid the illegal rebating statute is include a provision in the insurance contract mentioning the types of rewards, items, and devices the insurer may provide.

Such language in coverage documents can be written broadly, in anticipation of new incentive programs being later developed

Incentives must be on a non-discriminatory basis and in compliance with the wellness regulations

Pharmacy Rebates



Pharmacy rebates are amounts received by insurer, TPAs, PBMs, or plans related to utilization of drugs contained on a plan formulary.

“Meet the rebate, the new villain of high drug prices.”

“Every day, Americans—particularly our seniors—pay more than they need to for their prescription drugs because of a hidden system of kickbacks to middlemen.”
Secretary of HHS Azar.

PBMs protect their practices “with greater secrecy than HBO is guarding the ending of Game of Thrones.” Sen. Ron Wyden, D-Oregon

Pharmacy Rebates



Reporting Rebates

Compliance with state and federal laws related to rebates begins the reporting rebates as required by laws, including as follows:

1. To ODI as part of premium rate and financial statement filings;
2. To HHS, as part of the MLR reporting;
3. To HHS, in connection with QHP products;
4. To CMS, in relation to the MA bid and cost reconciliation reporting process;
5. To ODM, in relation to Medicaid managed care plans; and
6. To groups and members, in relation to individual and group insurance

Pharmacy Rebates



Anti-Kickback Statutes

Insurers must comply with federal and state anti-kickback laws. The federal Anti-Kickback Statute states:

It is unlawful for any person to knowingly and willfully offer, pay, solicit, or receive remuneration, in cash or in kind, to induce or reward a person for purchasing, ordering, recommending or arranging for the purchase of any product or service paid for by a federal health care program. 42 USC § 1320a-7b (b)(1, 2).

Pharmacy Rebates



Anti-Kickback Statutes

Related to pharmacy rebates, there is an important exception, which provides that the following is not prohibited:

A discount or other reduction in price obtained by a provider of services or other entity under a federal health care program if the reduction in price is properly disclosed and properly reflected in the costs claimed or charges made by the provider or entity 42 U.S.C. § 1320a-7b (b)(3)(A); 42 C.F.R. 1001.952(h).

Under this exception, if an insurer, TPA and PMB accurately report the pharmacy rebates it receives as required by law, the rebates will not be considered anti-kickback violations.

Pharmacy Rebates



Proposed Changes, to the Federal Anti-Kickback Rules, which were Abandoned

On March 1, 2019, HHS proposed to subject drug rebates to anti-kickback scrutiny in the following circumstances:

1. As related to Medicare Part D and Medicaid Managed Care plans
2. As related to private pay plans if such rebates were conditioned on the product's favorable formulary placement across all plans (including Part D plans)

On July 11, 2019, HHS withdrew the Proposed Rule:

“Based on careful analysis and thorough consideration, the President has decided to withdraw the rebate rule,” White House spokesman Judd Deere.

Ohio's Anti-Kickback Statute applies to Commercial Insurance

No person shall pay or receive a “kickback” or “rebate” in return for referring an individual for the furnishing of a health care service or good, for which reimbursement is made by a health care insurer, “except as authorized by the health care or health insurance contract, policy or plan.” Ohio Rev. Code 3999.22 (B).

Notably, this Ohio statute does not apply to:

1. “[d]iscounts or similar reductions in prices” or
2. “[a]ny amount paid as part of a bona fide lease, management, or other business contract.” *Id.*

Pharmacy Rebates



Ohio's Anti-Kickback Statute

Pharmacy rebates do not violate Ohio's anti-kickback laws if the insurer discloses the receipt of pharmacy benefits as required by law and receipt of the rebates are permitted by the "health care contract, policy or plan."

Arguably, organizations that contract with drug manufacturers for rebates are excepted from the Ohio anti-kickback because such rebates are "discounts" and provided pursuant to "business contracts", but compliance risk is mitigated if the rebates are disclosed and permitted by the applicable health care contract, policy and plan.

Pharmacy Rebates



Legal Requirements and Best Practices

1. Ensure rebate data is reported as required by law
2. Disclose rebates in all health care contracts, policies and plans
3. Disclose to customers the estimated or actual amount of rebates received during the contract period
4. Have customers acknowledge that the receipt of rebates is part of the reasonable compensation to a TPA or PBM for services
5. Share rebates with customers, with disclosure as the amount of rebates shared and received

Reference Based Pricing

Background

Reference Based Pricing (“RBP”): A provider reimbursement rate that is based on a percentage of a reference rate, such as a percentage of Medicare rates.

How is referenced based pricing used:

1. For network plans as to contracted in-network benefits
2. For network plans for payment out-of-network benefits
 - a) With the member paying any balance due; or
 - b) With the member being held harmless for any balance due
3. For plans with no network or a network for only some services, for benefits not subject to the network under the plan

Alternative “4” is normally discussed in terms of a RBP plan being an innovated way to reduce the cost of health coverage for employers

Reference Based Pricing



Problems with Reference Based Pricing

1. There is no guarantee any provider will accept the RBP without a contract to do so
2. There is no prohibition on balance billing a member for amounts in excess of the RBP

Recognizing this, consultants acknowledge that members covered by RBP plans should educate themselves as to which providers charge reasonable rates, before go see any providers

Reference Based Pricing

RBP and Out of Pocket Limits

- The ACA requires all individual and group plans to have a maximum OOP expenses limit
- Deductibles, coinsurance, copayments, and similar charges count toward the OOP limit
- Once the OOP limit is reached, the plan must contain pay 100% for the covered services
- Balance billing for “non-network services” do not count to OOP limits

Question: How does OOP limits apply to a RBP plans?

- Generally, providers who accept RBP are considered in-network, whereas providers who don't are considered out-of-network, but there are requirements to this approach

Reference Based Pricing



As to OOP limits for RBP plans without networks, HHS has issued FAQs, which state as follows:

- Any RBP approach must enable plans to cover services from high-quality providers at reduced costs, and should not function as a subterfuge for limiting coverage
- RBP plans may only treat providers that accept the reference amount as the only in-network providers under the plan, if the member has time to choose providers that accept the RBP
- Limiting or excluding cost-sharing from counting toward the OOP limit with respect to providers who do not accept the RBP is not reasonable as to emergency services
- Plans should ensure that an adequate number of providers that accept the RBP are available
- Upon request, the plan must give consumers a list of providers who accept the plan's RBP

See, <https://www.dol.gov/sites/dolgov/files/ebsa/about-ebsa/our-activities/resource-center/faqs/aca-part-xxi.pdf>

Reference Based Pricing

RBP to negotiate high cost out-of-network services

Consultants often approach insurers, proposing to negotiate down out-of-network charges using a RBP approach

As to these arrangements, review the contracts carefully with respect to:

1. Whether members will be held harmless by the RBP approach
2. If the member is to be held harmless, who bears the risk if the provider will not accept the RBP
3. Any appeals process as to provider acceptance of RBP, so as to be consistent with prompt pay, internal appeals, and external review rights of members
4. Terms of coverage document, so as to be consistent with the RBP approach
5. Implications for maximum OOP limits

Holding Companies, Transaction Among Affiliates, and Loans



Holding Company Entities under common control, one being an insurer

Affiliate An entity that controls, is controlled by, or is under common control with an insurer

Transactions within or involving the holding company system are governed by:

Form A: Prior approval by ODI a change of control of an insurer

Form B: A Registration Statement to be filed annually and updated as necessary during the course of a year

Form D: Prior approval by ODI for certain transactions between an insurer and an affiliate

Holding Companies, Transaction Among Affiliates, and Loans



Common Circumstance

A holding company wants to finance operations, including the operations of an insurance company.

- First, determine if the insurer needs to be a party to the transaction
 - If not, avoid it, and no Form D applies
- Second, don't pledge the assets of the insurer as part of the transaction
 - Doing so would make the insurer a party to the transaction and also a pledge may impact the "admitted" nature of the asset pledged
- Third, if appropriate, the parent company may pledge the stock of the insurer
 - This does not trigger Form D, but requires a Form B filing update after-the-fact

Holding Companies, Transaction Among Affiliates, and Loans



Common Circumstance

A holding company wants to finance operations, including the operations of a insurance company.

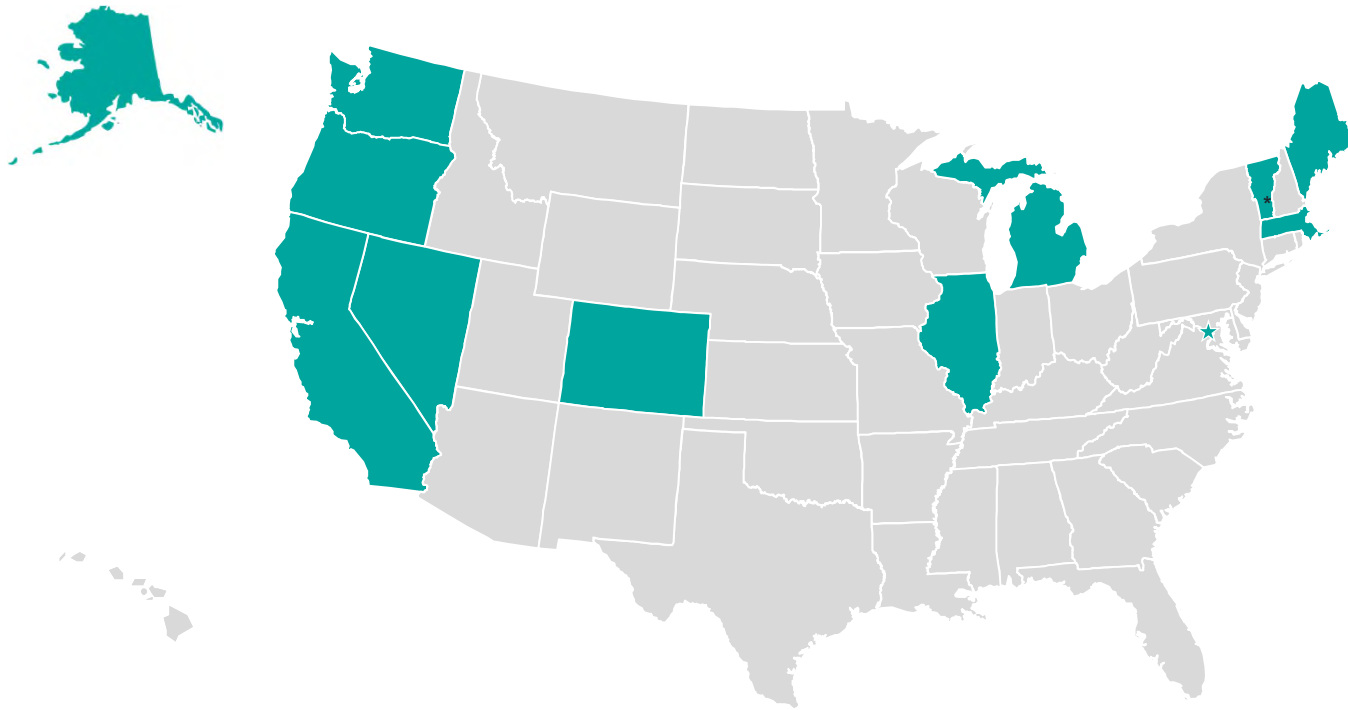
- Once a parent company receives loaned funds, it can contribute it as capital to the insurer, either directly or via a surplus note
- As to the pledge of the insurer's stock, the loan agreement must be clear the lender must go through a Form A process (change of control) before taking ownership of the stock upon default
- TIP – Always assess whether an insurer needs to be part of a transaction involving its holding company or is there another way meet the objective.

Cannabis Law Update

Heather L. Stutz
Partner
Squire Patton Boggs



States with legal
recreational and medical
marijuana



Ohio Law

- Effective September 8, 2016
- Two years to make operational

Department of Commerce:
cultivators,
processors,
laboratories

Board of Pharmacy:
dispensaries

Ohio Medical Board:
physicians,
patients

21
medical conditions

NO
smoking

Edibles, oils,
tinctures, capsules,
patches, vaporizing



Marijuana Still Illegal Under US Federal Law



Marijuana Still Illegal Under US Federal Law... Sort of

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OHP
Ohio Association of Health Plans

- Controlled Substances Act
- Farm Bills
- Enforcement
- Banking



Not Your Problem Yet?



Not quite.

Americans with Disabilities Act (ADA)

The ADA prohibits covered employers from discriminating against qualified individuals on the basis of a disability and requires such employers to provide reasonable accommodations to employees with disabilities so that they can perform the essential functions of their job

Does marijuana use for medicinal purposes count?



What do the
Courts say?


The ADA does not protect against discrimination on the basis of marijuana use, even medical marijuana in accordance with state law, unless authorized by federal law.



What does Ohio say?

Employers do not have to accommodate medical marijuana, but may choose to do so, except:

- Federal contractors
- Safety-sensitive positions



What does Ohio say?

Most state laws say employers are not required to make any accommodation of the use of medical marijuana on the property or premises of the place of employment... **BUT**

In **Nevada** and **New York** – the law specifically provides that employers have a duty to accommodate the use of medical marijuana.

In **Massachusetts** – where medical marijuana is the most effective medication for the employee's debilitating medical condition, an exception to an employer's drug policy to permit its use is a facially reasonable accommodation.

Pre-Employment Marijuana Testing Bans On the Rise

Nevada

Effective January 1, 2020

The law makes it unlawful for any employer to fail or refuse to hire a prospective employee because the prospective employee submitted to a blood, urine, hair, or oral fluids drug test and the results of the screening test indicate the presence of marijuana.

New York City

Effective May 10, 2020

The law makes it an unlawful discriminatory practice for an employer, labor organization, employment agency, or agent thereof to require a prospective employee “to submit to testing for the presence of any tetrahydrocannabinols or marijuana in such prospective employee’s system as a condition of employment.”

Expect to see many more popping up all around the country.

The background of the slide is a photograph of several glass jars filled with dried cannabis buds. One jar in the foreground is tipped over, with buds spilling out onto a wooden surface. The buds are green with some brown and orange hues, indicating they are dried. The lighting is bright, highlighting the texture of the buds.

Insuring the Industry

**> 131
Employers**

Cannabis Law Update

Heather L. Stutz
Partner
Squire Patton Boggs



Legislative & Regulatory Developments In Ohio

Miranda Creviston Motter, President and CEO of the Ohio Association of Health Plans
1:00 p.m. – 1:50 p.m.



New Administration & General Assembly



- Governor Mike DeWine was sworn into office.
 - Immediately signed a number of Executive Orders focused on priority issues
 - 24 new cabinet members plus Director of Children’s Initiatives and Director of Recovery Ohio
 - State of the State - March 5
 - Governor DeWine unveiled his proposed budget – March 15
 - Clear set of priorities

- The 133rd Ohio General Assembly convened
 - New House Speaker & new House Leadership Team
 - New Senate Leadership Team

Legislative Developments

- “It’s the Budget, stupid....”
 - Ohio’s Transportation Budget – The Honeymoon is over....
 - The FY 2020-2021 Biennial Budget (House Bill 166) was unveiled by the Governor on March 15. Language introduced on March 25
 - House consideration began immediately
 - House approved on May 9
 - Senate consideration on May 13
 - Senate approved on June 20
 - Continuing Budget Resolution until July 17
 - Conference Committee Report on July 17
 - Governor’s signature on July 18

FY 2020-2021 Budget (HB 166)



■ Pharmacy Reforms

- Gag clause/claw back provision (ORC 1739.50, 1751.92, 3923.87, 395912, 3959.20, 4729.48 and Section 739.20)
- Prescription Drug Transparency & Affordability Council (ORC 125.95)
- Pharmacy Dispensing Fees (Section 333.280)
- Single PBM (ORC 5167.122, 3959.01, 5167.01, 5167.24, 5167.241, 5167.243, 5167.244, 5167.245)
- Drug Spend Cap (ORC 5164.7515)
- Drug Claim Processing Pilot (Section 333.290)
- Drug Saving Report (Section 333.240)

■ Surprise Billing Reforms

- Vetoed; Executive Order 2019-18D (Improving Price Transparency in Healthcare)

■ Transparency

- Vetoed; Executive Order 2019-18D (Improving Price Transparency in Healthcare)

FY 2020-2021 Budget (HB 166)



- Medicaid Program
 - Recoupment (ORC 5167.22, 5167.221)
 - Managed Care Fund (Section 333.225)
 - MyCare Form and Codes (Section 5164.91)
 - Employment connection incentive programs (Section 333.197)
 - Social Determinants (ORC 5167.72, 5162.01, 5162.1310)
 - Community Behavioral Health Rates (Section 333.180)
 - Reauthorizes – MyCare Incentive Payments (Section 333.60) and CICIP (Section 333.220)
- Nursing Home Quality Reforms - Quality and Licensure

FY 2020-2021 Budget (HB 166)



- Other Items of Interest
 - Telemedicine (ORC 3902.30)
 - Freestanding ERs (ORC 3727.49)
 - Direct Primary Care Agreements (ORC 3901.95)
 - Minimum Prices for Health Services (ORC 3902.31)
 - Solemn Covenant for Curing Diseases (ORC 3799.01)

Regulatory Developments



Regulatory Developments



- Ohio Department of Medicaid
 - Single PDL – January 1, 2020
 - Budget Implementation – “118 items”
- Ohio Department of Insurance
 - Mental Health Parity Engagement
 - Cybersecurity Compliance

Regulatory Developments



- Other areas of activity
 - RecoveryOhio – Initial Report March 2019
 - Initial Report included 70 recommendations in the areas of stigma, parity, workforce development, prevention, harm reduction, treatment and recovery supports, and data and outcomes measurement. Because of their unique needs - two specialty populations were highlighted because of their unique needs.
- Children’s Initiatives
 - Home Visitation Report – March 2019

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Questions ?
Comments?

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Legislative & Regulatory Landscape in Washington

David Stewart, Principal, Squire Patton Boggs

1:00 p.m. – 1:50 p.m.



Political Environment in Washington



- Divergent Policy Goals and Uncertainty
 - Deregulation agenda opposed by congressional Democrats
 - President Trump's policy proposals and tactics controversial to some
 - Decision making in the Trump Administration

- Divided Congress
 - Senate: 53 Republicans, 45 Democrats, and 2 Independents
 - House: 235 Democrats, 197 Republicans, 1 Independent

- Backdrop of 2020 Presidential Election
 - Health care issues part of the debate

Congressional Activity & Outlook



- ACA Taxes – HIT, Medical Device, Cadillac Tax
- Prescription Drug Pricing
- Surprise Billing
- Short-Term Limited Duration Insurance
- Appropriations: CR and Likely Omnibus

Affordable Care Act Taxes

- Health Insurance Tax
 - Fee on certain for-profit health insurers based on market share and value of business
 - Suspended in calendar year 2019, returns in 2020
- Medical Device Tax
 - Excise tax of 2.3 percent levied on the sale of medical devices at manufacturer or importer level
 - Delayed until December 31, 2019
- Cadillac Tax
 - Excise tax of 40 percent on certain health care plans if their value is above a certain threshold designed to capture high-end employer sponsored health plans
 - Delayed until January 1, 2022
- Congressional action on additional implementation delays for one or more of these taxes this year remains a possibility

Prescription Drug Pricing



- Senate HELP Committee Legislation
 - S. 1895, The Lower Health Care Costs Act
- Senate Finance Committee Legislation
 - Prescription Drug Pricing Reduction Act
- House Energy & Commerce Committee Legislation
 - H.R. 2296, More Efficient Tools to Realize Information for Consumers (METRIC) Act
- Senate Judiciary Committee Legislation
 - S. 1416, S. 440, S. 1227, and S. 1224
- Trump Administration Proposals & Positions
- Speaker Pelosi Draft Proposal

Surprise Billing, STLDI, & End of Year



- Surprise Billing
 - Senate Legislative Landscape
 - House Legislative Landscape
- Short-Term Limited Duration Insurance
 - Senate Legislative Landscape
 - House Legislative Landscape
- End of Year Appropriations Package
 - Possible inclusion of a variety of unrelated measures, including “Health Extenders”

Regulatory Developments



CMS Rulemaking Activity



- Proposed Rules on Interoperability
 - Proposes rules to require providers and insurers to implement open data-sharing technology to ensure data can move from one plan to another
 - Proposes insurers on Medicare Advantage, Medicaid, the Children's Health Insurance Program, and Affordable Care Act plans to provide enrollees with immediate access to medical claims and other information by 2020

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Questions ?
Comments?

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Privacy and Security in a World Filled with Innovation

Elliot Golding, Partner
2:10 p.m. – 3:00 p.m.



2019 Digital Health Trends: *Capturing the Upside of Healthcare Data*

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OHP
Ohio Association of Health Plans

- Consumer demand
- IoT / Wearables
- At-home testing services
- Federal interoperability and data blocking initiatives
- Telemedicine
- AI
- Blockchain
- New / enhanced data sources (patient-generated health data, social determinants)
- Population health tools



Behind these trends is one fundamental force driving healthcare transformation: the Power of Data.

Best Practice

- Move Beyond HIPAA
- Attack Privacy/Security Proactively
- Understand Your Risks
- Develop Program to Address



Approach to Privacy and Security

Proactive

- Take time to think through up front
- Reduce risk of legal issue or breach
- Take advantage of opportunities to use data
- No surprises from regulators
- Build trust of consumers
- Limited need to change operations when services evolve

Reactive

- Lower up front costs, but.....
- Greater risk of legal or reputational harm or need to redesign product or service
- May miss opportunities for data use that the law allows
- More expense later to re-develop approach
- Breach or violation of law could impact consumer trust
- Operational changes after products and services are established could be difficult

Legal Landscape for Data Sharing



■ Federal statutes / rules

- HIPAA (including HITECH and GINA)
- 42 CFR Part 2 (substance use)
- ONC and CMS Interoperability Regs
- Federal Trade Commission (FTC) Act Section 5 Authority
- Other (COPPA, FCRA, GLBA)
- Government program rules (Medicare, Medicaid, federal/state exchanges)
- Common Rule

■ State statutes

- Privacy, security, breach notification and data retention / destruction
- State laws governing medical information and sensitive services
- California Consumer Privacy Act

■ Guidance

- HHS Health App Use Scenarios
- HHS Cloud Computing Guidance
- SAMHSA Part 2 Guidance

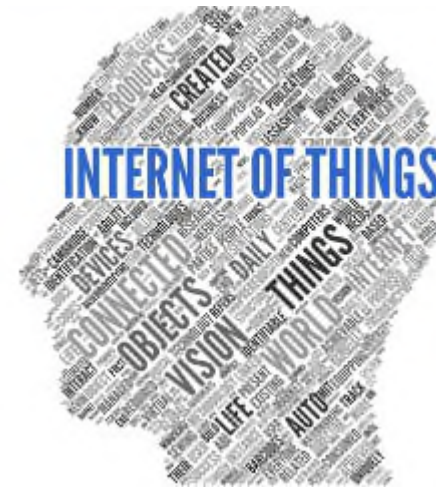
Population Health/Consumer Outreach



- Can improve quality/reduce costs, but ...
- Often requires integrating data from multiple sources that trigger additional responsibilities
 - Part 2
 - State laws (mental health, genetic testing, communicable diseases, substance abuse, etc.)
- Outreach methods raise risks
 - Telephone Consumer Protection Act (TCPA)
 - Is it marketing?
 - Is it secure?

IoT Issues

- Ubiquitous collection of data
- Difficult to anonymize data
- Unbeknownst to consumers
- Notice, consent, opt-outs are difficult
- Limited ability to disclose improper use of data
- IoT enforcement already occurring



Data Flow Decision Points

- Is the type of data flow regulated?
 - De-identified data
 - Limited Data Set
 - Patient Identifiable data (depending on source)?
- Patient authorization?
- Purpose (e.g., research)?
- Sensitive information (e.g., substance use disorder, HIV/AIDS/STD, mental health, genetic information)
- Source?
- What kind of agreement is required?
 - Data Use Agreement
 - Business Associate Agreement
 - Non-Disclosure Data Sharing Agreement
 - HIE Participant Agreement
- Operational/logistical issues?
 - Application Programming Interface (APIs)
 - Integration of multiple data sources
 - Possibility/feasibility of connecting to Health Information Exchange (HIE)

Use Case 1: Integrating Data Sources for TPO Activities



Scenario:

- *A health insurer wants to partner with a third party to develop an integrated mobile app to improve care coordination for members with a complex chronic disease. Data from EHR, pharmacy and members will be collected and collated, and secure communication between the plan, providers, and members will be supported.*
- Discussion Questions:
 - What type of agreements are required and between whom?
 - Is patient authorization required?
 - Is there a role for HIEs? What technical data integration challenges must be resolved?
 - Does the California Consumer Protection Act apply?
 - Are there fraud and abuse concerns that must be managed?

FTC and State AG Mobile App Guidance

- Be truthful about what your app can do
- Be clear and conspicuous with disclosures
 - Make choices easy to find and use
 - Consider using icons and pop-up notifications
 - Call special attention to unexpected data practices
- Think about privacy from the start
 - Tailor privacy practices to data being collected
 - Limit data collection to only what you need
- Keep kids in mind
- Never collect sensitive information without consent
- Implement reasonable security to protect data

Use Case 2: Medical Research and Patient Recruitment



Scenarios:

1. *Third party (such as pharma / device study sponsor or CRO) offers to pay insurer to mine claims database to find candidates for a clinical study*
 2. *Pharma co. wants insurer to actually recruit / enroll patients*
 3. *Pharma company approaches insurer to do a retrospective study with claims data*
- Discussion questions:
 - Does it matter if the study is actively treating a person vs. retrospective?
 - What kind of data / access fees may the insurer charge?
 - Is Patient Authorization or DUA required? Is IRB approval required?
 - How do federal rules governing medical research apply?
 - Do the rules change based on the type of data (e.g., Part 2, HIV/AIDS, mental health, etc.)?

Components of a Privacy and Security Program



1. Identify and Classify Sensitive Data and Regulated Systems



- Identify types of data (PHI/PII/other), networks and systems
- Identify data locations and how the information is collected, used and shared
 - Marketing?
 - Internal Analytics?
 - Other?
- Understand regulations, standards, contracts and best practices that apply

2. Conduct a Risk Assessment

- Analyze Security Risks
 - Think About External Threats
 - Vendor/Supply chain
 - Organized crime
 - Nation states
 - Hactivists
 - Think About Internal Risks
 - Negligent employees
 - Disgruntled employees/insider threats
 - Network vulnerabilities
- Analyze Privacy Risks
 - Legally permissible to use or share data?
 - What will consumers think?



3. Manage Risk with Controls and Processes

High Priority Security Controls:

- Access control/authentication
- Stronger passwords/smart defaults
- Physical locks
- Automated timing systems to log out users
- Secure data transfer
- Automatic deletion of data
- Prevent automatic syncing of devices
- Encryption?
- Training

- Risk-based and role-based
- Upon hire and periodically thereafter
- Test training



3. Manage Risk with Controls and Processes

High Priority Privacy Controls:

- Limit Uses and Disclosures
- Data minimization (within reason)
- De-identify where possible
- Transparency
- Notice and Choice (where necessary)
- Training
 - Risk-based and role-based
 - Upon hire and periodically thereafter
 - Test training



3. Manage Risk with Controls and Processes

Manage Vendor Risks:

- Select capable providers and provide oversight
- Segregate networks and have access controls
- Review key contractual provisions
 - Privacy/security standards/requirements
 - Investigation
 - Indemnity
 - Incident response
 - Audit
- Ensure access-IT design documents, change/work orders
- Conduct compliance audits
- Provide/demand training



5. Review/Update/Develop Policies and Procedures

Internal:

- Incident response plan
- Privacy policy
- Security policy
- Document retention
- Other information governance

Public-facing:

- Web/mobile app privacy policy
- Terms of Use



Do Not Overpromise (Privacy or Security)

6. Prepare for an Incident

- Incidents don't need to be a crisis: response efforts often judged much more than the actual incident.
- Assess reporting and response requirements
- Develop an Incident Response Plan and Toolkit
 - Intake
 - Escalation
 - Investigation
 - Mitigation
 - Notification
- Retain service providers/vendors
- Conduct tabletop exercises



Key Incident Response Steps

- Follow the plan (and respond quickly)!
- Assemble Response Team (and involve counsel early)
- Investigate/Mitigate/Remediate Incident
- Prioritize Escalation and Repair
- Utilize Retained Forensic Vendors
- Identify Notification/Reporting Obligations
- Notify Insurance
- Evaluate Information Sharing Industry/Government
- Prepare Litigation Response

7. Consider Participation in Industry and Government Partnerships

- Info sharing can keep you up to date on important risks and helps demonstrate commitment to protecting your consumers



8. Export Risks

- Insurance
- Contract Liability
- Managed Services

9. Monitor and Repeat



- Audit
- Vendor Oversight
- Continuous Review and Improvement

Questions?

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Litigation Watch: Trends Affecting Commercial, Medicare, Medicaid and Medicare Part D Plans

Ben Beaton and Kimberly Donovan
3:00 p.m. – 3:50 p.m.



Pharmacy Benefit Managers (PBMs)



Ongoing War on PBMs

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Termination of Pharmacy Agreements



CareZone v. Anthem Insurance Co, Inc. et al, Case No. 3:19-cv-04453 (N.D. Cal.)

- CareZone is a venture-backed online pharmacy that interacts with patients primarily through an app.
- PBM terminated its contract with CareZone for shipping prescription drugs in violation of the contract.
- CareZone alleged that Express Scripts violated the Tennessee any willing provider law.
- Express Scripts said that the Tennessee AWP law does not apply to PBMs.
- CareZone sued the insurance plans that contracted with Express Scripts alleging that the plans violated California's unfair competition law, Tennessee AWP law, and the Medicare any willing pharmacy law when the PBM terminated the contract.

Why CareZone is a Case to Watch



- Will the insurance plans be held liable for the decisions of its PBMs under state law?
- Does the Tennessee Any Willing Provider law apply to out of state pharmacies?
- Are the state laws (and state cause of action) preempted by the express preemption provision in the Medicare Act?
- Will the California unfair competition laws be applied to a termination of a pharmacy?
- Will the court challenge a PBM/plans right to prohibit shipping prescription drugs?
- How will the unique business model of CareZone impact the decisions?

Affordable Care Act



ACA Challenge: SCOTUS Round 4



- *NFIB v. Sebelius* (2012) – constitutionality of individual mandate under Congress’ interstate-commerce and taxing powers
- *Burwell v. Hobby Lobby* (2014) – religious exemption to contraceptive mandate under Religious Freedom Restoration Act
- *King v. Burwell* (2015) – availability of tax subsidies for an “Exchange established by the State”
- ***Maine Community Health Options v. United States*** (2019) – Congress’ authority to restrict “risk corridor” payments to insurers based on ACA-related losses already incurred
 - Consolidated with *Moda Health Plan v. United States* and *Land of Lincoln Mutual Health Insurance Co. v. United States*

ACA Challenge: SCOTUS Round 4?



Maine Community Health Options v. United States, No. 18-1023 (consolidated) (oral arg. Dec. 10, 2019)

- 3-year program intended to offset early losses and keep premiums low on ACA exchanges
- Insurers seeking more than \$12 billion in losses from “massive government bait-and-switch” based on appropriations riders restricting payments
- Opening briefs plus 9 amicus briefs (including AHIP, US Chamber, BCBS, NAIC, and 24 states) filed this month; USA response next month
- Big legal question: contractors’ immediate reliance on government’s future promises
 - Implied repeal, breach of contract, or power of the purse?

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Usual & Customary Price


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U&C Pricing

United States v. SuperValu, Inc. 2019 U.S. Dist. LEXIS 130016 (C.D. Ill. Aug. 5, 2019)

- Pharmacies had an advertised price-matching program where it would match the price of competitors for customers who presented documentation of a lower price than cash price for original prescription.
- Refills generally honored at lower price without additional documentation.
- Pharmacies price matched only about 2% of all Defendants' transactions, but grew from around 8% - 39% of cash transactions.
- On a single day for the same drug, pharmacies could match different prices charged by Rite Aid, Walmart, CVS and any other competitor, or no competitor at all.

U&C Pricing - Medicaid

United States v. SuperValu, Inc. 2019 U.S. Dist. LEXIS 130016 (Aug. 5, 2019)

- The Court concluded that Pharmacies' price match program was an offer to the general public that determined the Defendants' usual and customary price.
- In absence of regulatory definition, the applicable definition of usual and customary price for Medicaid reimbursement is the "cash price offered to the general public." *United States ex rel. Garbe v. Kmart*, 824 F.3d 632, 643 (7th Cir. 2016)
- "Because the Defendants offered their price match program to the general public and made those lower cash prices widely and consistently available, the California, Illinois, Utah and Washington Medicaid programs should have received the benefit of those prices."

U&C Pricing - Medicare



- *SuperValu* found that Medicare Part D was also entitled to those actual usual and customary prices.
- “Usual and customary (U&C) price means the price that an out-of-network pharmacy or a physician’s office charges a customer who does not have any form of prescription drug coverage for a covered Part D drug.” 42 C.F.R. § 423.100.

U&C Pricing – PBM Contracts

- *HM Compounding Services, Inc. v. Express Scripts, Inc.*, Case No. 4:14-CV-01858-JAR (E.D. Miss. Nov. 8, 2018).
- Undisputed evidence established that pharmacy breached the agreement “by submitting manipulated U&C cash prices for reimbursement. Because HM breached the Agreement, ESI had a contractual right to immediately terminate HM and did not breach the Agreement.”
 - Reimbursement was lesser than: contract methodology and U&C.
 - Claims had to be submitted accurately and completely
 - Pharmacies were prohibited from submitting compound claims with an inflated AWP and from manipulating U&C retail price.

Co-payments

HM Compounding Services, Inc. v. Express Scripts, Inc., Case No. 4:14-CV-01858-JAR (E.D. Miss. Nov. 8, 2018):

- Court also found that pharmacy breached the agreement by failing to collect co-payments.
 - Materiality of breach is ordinarily a question of fact.
 - “whether HM’s collection rate is 2.7 percent, as asserted by ESI, or 8-9 percent, as asserted by HM, the number is so woefully inadequate that no reasonable jury could find HM substantially complied with its contractual obligation to collect copayments”
- See also *Alternative Medicine and Pharmacy, Inc. v. Express Scripts, Inc.*, Case No. 4:14 CV 1469- CDP (E.D. Miss. Feb. 8, 2016) (“Because the contract does not specify any particular efforts that must be undertaken or set any particular percentage threshold of collections that are required, the court cannot say as a matter of law that Omniplus breached the contract. This is a fact question.”)

Affordable Care Act



ACA Challenge: SCOTUS Round...5?



Texas v. United States, 5th Cir. (oral arg. June 9, 2019)

- Challenge to constitutionality of individual mandate in light of 2017 penalty repeal in tax-cut bill
- 18 states (AGs and 2 governors) sued in 2018
- Federal district court in Texas held law unconstitutional
- US House of Representatives and 21 other state AGs defending the law
- USA position?
 - Initially, urged invalidation of some ACA provisions related to the penalty
 - On appeal, supported the district court's wholesale invalidation
 - Just before argument, suggested invalidity in plaintiff states only
 - Plaintiffs' worry: another bait and switch?

ACA Challenge: SCOTUS Round...5?



Texas v. United States, 5th Cir. (oral arg. June 9, 2019)

- Oral argument: 2 judges skeptical of defenders' position; 1 judge silent
- Threshold legal question:
 - “standing” of state AGs and House to defend the law
- Big legal question:
 - constitutionality of mandate-related provisions
- Bigger legal question:
 - “severability” of the rest of ACA
- Massive legal/political/business question:
 - Will ACA return to the Supreme Court before the 2020 election?

Surprise Billing



PARE

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PATHOLOGISTS

ANESTHESIOLOGISTS

RADIOLOGISTS

EMERGENCY ROOM PHYSICIANS

PARE Reimbursement is Attracting Attention

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Trends with PARE

- Consolidation of PARE providers
- Non-Par PARE provider groups are suing plans (no Arbitration provisions)
 - Continuing Offer
 - Unjust Enrichment
 - RICO – *Emergency Care Services of Pennsylvania, P.C. v. UnitedHealthGroup, Inc.*, CASE 1:19-cv-01195-SHR (M.D. Pa) (filed July 11, 2019)
 - Statutory or regulatory provisions setting reimbursement
 - Third-party beneficiary of member’s plans
- Hospitals Starting to Put Pressure on PARE to Negotiate with Payors
- Patients suing PARE providers
- State legislation prohibiting balance billing and setting reimbursement methodology – Florida, California

“Continuing Offer” Theory



“Sheridan continually offers, despite any successive rejections or counteroffers of that continuing offer, to provide non-emergent Affected Health Services to all of Aetna's Commercial Members at the Locations at (100%) of Sheridan's applicable billed charges
Aetna alone has the responsibility, and the ability, to authorize or refuse to authorize its members to receive Sheridan's services . . .

If Aetna refuses to authorize or otherwise permit the services on the terms and conditions of the Continuing offer, Aetna must take all steps necessary in managing its Members' care to ensure that the Affected Health Services are provided to its members in the numerous alternative facilities available for such services.

The specific, unambiguous terms and conditions of this Continuing Offer require acceptance or rejection only by performance. By providing Aetna with the information in this Continuing Offer, including the information contained on Schedules 1 and 2, Sheridan has provided Aetna with the means to accept or reject Sheridan's Continuing Offer. Sheridan will not treat or provide services to Aetna's Commercial Members as a non-participating provider . . .”

Sheridan Healthcorp, Inc. v. Aetna Health, Inc., CACE 15-009394 (07) (Fla. 17th Jud. Cir. Jan. 31, 2019).

“Continuing Offer” Theory



“We previously made it clear to you that we reject unequivocally your novel, fictitious continuing offer. It is not accepted; nor will it ever be accepted.”

Sheridan Healthcorp, Inc. v. Aetna Health, Inc., CACE 15-009394 (07) (Fla. 17th Jud. Cir. Jan. 31, 2019).

“Continuing Offer” Theory

“Upon review of the record, the Court finds that genuine issues of material fact exist as to:

- whether Defendants manifested the intent to be bound by the terms of the Continuing Offers notwithstanding their express rejections of the same; and
- whether Defendants' pre-authorizations operated as an acceptance of the terms set forth in the Continuing Offers.

These issues directly implicate the words and conduct of the parties during the relevant time period and are central to the issue of contract formation. As such, summary judgment is inappropriate at this juncture.”

Sheridan Healthcorp, Inc. v. Aetna Health, Inc., CACE 15-009394 (07) (Fla. 17th Jud. Cir. Jan. 31, 2019).



Exhaustion of Administrative Remedies



Exhaustion of Administrative Remedies



Beneficiaries

- A Medicaid beneficiary lacked constitutional standing to file a petition for judicial review over the denial of services.
 - Provider sought appeals of denial of payment through the MCOs' internal appeals process as an "authorized representative" of beneficiary. Provider sought state fair hearings with the Cabinet to challenge the denial of payments for services.
 - No injury - Beneficiary had no financial interest in the dispute. She was not liable for the cost of those services.
 - Beneficiary had not alleged a lack of needed and proper care.
 - Any purported interest in maintaining the Medicaid system's integrity was insufficient to satisfy standing.

Commonwealth of Kentucky, Cabinet for Health and Family Servs., Dep't of Medicaid Servs. v. Sexton, 566 S.W.3d 185 (Ky. 2018); see also *Appalachian Reg'l Healthcare v. Commonwealth*, 2019 Ky. App. Unpub. LEXIS 629 (Ky. App. August 30, 2019) (holding that the individual beneficiaries lacked standing to pursue a state fair hearing).

Exhaustion of Administrative Remedies



Providers

- Hospital alleged Medicaid managed care plan failed to pay it for services pursuant to contract and Kentucky law.
- Court held that “it was necessary for the Hospital to exhaust its administrative remedies prior to filing an action in circuit court. Consequently, the trial court properly granted the motion to dismiss the complaint.”
- General allegation that all conditions precedent have been satisfied was insufficient to survive a motion to dismiss.
- Kentucky Supreme Court denied cert. Several lower courts have dismissed complaints based on *Wayne County*.

Wayne County Hospital, Inc. v. WellCare Health Insurance Company of Kentucky, Case No. 2017-CA-001273-MR (Ky. Ct. Appeals Nov. 16, 2018).

Questions?



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Legal and Industry Trends Impacting Hospitals, Health Systems and Providers

Adam Colvin

3:50 p.m. – 4:30 p.m.





- Current Trends for Provider Structure
- Concerns of Providers Related to Value-Based and other Payor Contracting

Hospitals

- Physician Employment
- Clinically Integrated Networks
- ACOs
- Bundled Payments/Gainsharing/Co-Management

Physician Employment

- Hospitals lose estimated \$100K - \$200K per employed physician
 - Compensation plus practice expenses and overhead > collections
- Biggest Factor – Compensation Models
 - Compensation Models – Productivity-Based
 - Misaligned → Reward Physicians' work effort regardless of reimbursement
- Compensation Plans in Place up to 5 years

How are Hospitals Responding – Renewal Negotiations

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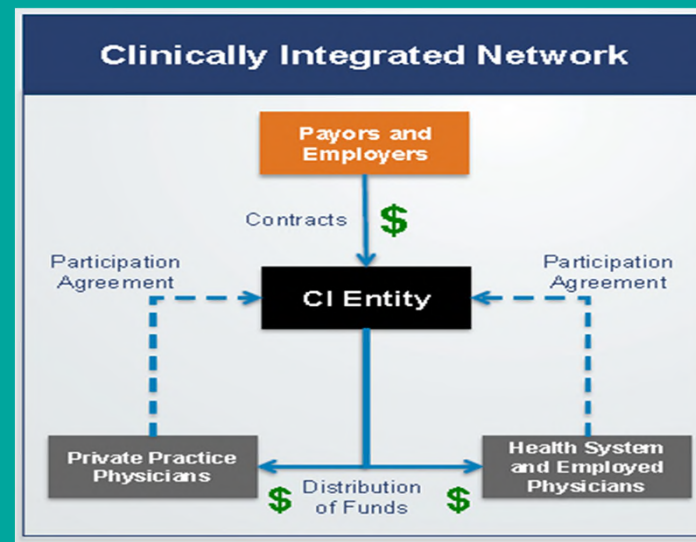
- Attempt to increase quality incentives as percentage of compensation
- Service Line/Management Compensation
- Population Health Models
- Reducing Terms to year-to-year
- Focus on Reduced Costs

- RESULT:
 - Incredibly long, intense, combative negotiations furthering tensions between Hospital and Physicians
 - Failure to renew/break-up

Hospital Relationships – Independent and Employed Physicians

- Clinically Integrated Networks and ACOs
- A health network of providers working together using proven protocols and measures to improve patient care, decrease cost and demonstrate value to the market

GOAL:



- How does the CIN align interests of Hospital and Physicians?
 - If properly established and operated, CIN is able to engage in joint contracting with payors on behalf of its participating physicians and hospitals
 - Through joint contracting, hospital and physician goals and interests are aligned because both need to meet requirements of the CIN and payor contract in order to achieve better reimbursement alternatives (potential higher reimbursement, potential for shared savings)
 - In order to gain the benefits of joint contracting, must meet the FTC requirements of a CIN

CIN Structure

■ Legal Entity

- CINs are separately organized entities, but form may vary
- Often the case, formed as a wholly-owned subsidiary of Hospital or affiliate
- A membership organization, typically an LLC or non-profit corporation
 - Allows for multiple classes of members depending on participating providers
- Role of Hospital
 - Typically the “sponsor” of the CIN
 - Hospital brings capital, HIT and administrative support
 - In exchange, Hospital will retain certain reserve powers (especially if tax exempt) – but CIN will still be dominated by practicing physicians
- Reserve Powers include:
 - Approval of major transactions (mergers, asset sales, etc.)
 - Decisions related to actions which could affect tax-exempt status of Hospital
 - Many decisions will require Hospital approval after Governing Board approval – payor contracts, amendments to governing documents, budgets, strategic plans
 - Hospital must make sure CIN acts in accordance with mission of Hospital to provide quality care and meet community needs

CIN Structure

■ Distribution Mechanisms

- In early stages, CIN typically allows providers to maintain fee-for-service contracts directly with payors – goal is to eventually negotiate the fee-for-service as well
- CIN's performance-based contracts with payors typically involve payment directly to CIN, with distribution by CIN to providers
- Distribution:
 - % distributed to Hospital as a return on initial and ongoing investment in CIN
 - % retained by CIN for ongoing administrative expenses
 - Remainder distributed to providers – CIN must determine distribution methodology – equal share, performance-based; CIN may also agree with payor on provider distribution methodology to further align incentives

Considerations for Network Development

CHALLENGES OF DEVELOPMENT

- **Timeframe can be 18-36 months for development**
- **Physician urgency / patience with network development**
- **Alignment of win-win criteria**
- **Defining the right payor partnership model**
- **Sufficient payor and employer willingness to contract**
- **Significant investment in time and resources**

Hospital – Other Mechanisms to Align Interests

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- Bundled Payments
- Gainsharing Arrangements
- Service Line Co-Management

Independent Physician Groups

- Obstacles in preparation for Value-Based Contracting:
 - Lack of capital and management expertise
 - Fee-for-service medicine acts as a disincentive to improving quality and cost-efficiency
 - Costs of public reporting and accountability
 - Decreasing reimbursement – hurting not only practicing physicians but their ability to recruit physicians
 - For many groups (particularly in certain regions), Hospital employment has been the solution
 - However, many groups still desire independence and the ability to run their own business
 - Becoming more difficult in certain regions

Independent Physician Groups



- Options:
 - Sale of Practice and Employment
 - Hospital (the “known”)
 - Private Equity (the “unknown”)
 - Align with Hospital and/or Private Networks

Private Equity



- **Building the Platform:**

- lower overhead/improved efficiency through scale
- increase profitability and sell
- Invest 3-7 years → anticipated returns of 20% annually

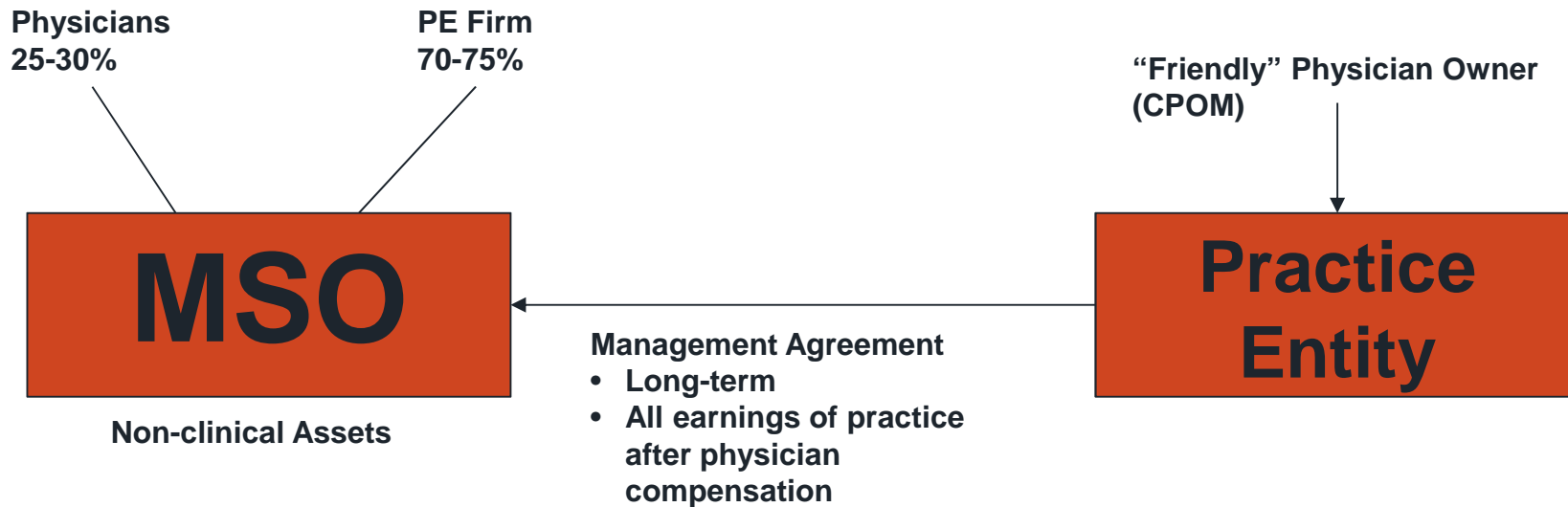
- **Targets:**

- **Initial:** Ophthalmology, pain management, dermatology
- **Now:** OB/GYN, orthopedics, urology, gastroenterology

Big Money

- Investment Bankers doing roadshows
- Hospitals typically constrained → pay for FMV of assets, not going concern
- Private Equity:
 - 8-12X EBITDA
 - Single Physician with \$1.0M EBITDA → \$8-12M
 - Large Practice with \$15M EBITDA → approx. \$150M
 - 25-30% as rollover equity
 - Monetization of portion of on-going income

Typical Structure



***Doctors have ownership in business side.**

Employment Provisions

- 3 to 5 year initial term
- Loss of rollover equity if terminate
- Loss of management autonomy → key in decision
- Lower compensation (based on Quality of Earnings Components)
 - Income Replacement is forecast by Buyer → higher reimbursement
- 1 to 2 year noncompete (a longer noncompete may also be imposed due to sale)

Population Health Management Contracting



■ Lack of Forms

- PHM company often asked to draft the Agreement
- Huge Advantage in “taking the pen”
- Payors with well-established forms are in a great position

■ Key Provisions

- Indemnification
- Limitation of Liability
- Required Insurance
- Business Associate Agreement
- Division of Financial Responsibility
- Intellectual Property

Provider Frustrations

- Internal Plan Policy Changes and Opportunity to Provide Input
- Criteria for Authorization Unclear/Vague
- Peer to Peer Review/Discussions



CLE Seminar for Ohio Health Insurer In-House and General Counsel

Wednesday, September 18, 2019

11:00 a.m. – 6:00 p.m.

