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Concierge Medicine: Complying With Medicare Regulations, State Laws and Anti-Kickback/Anti-Referral Law

THURSDAY, OCTOBER 8, 2015

1pm Eastern | 12pm Central | 11am Mountain | 10am Pacific

Today's faculty features:

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CONCIERGE MEDICINE: COMPLYING WITH MEDICARE REGULATIONS, STATE LAWS AND ANTI-KICKBACK/ANTI-REFERRAL LAWS

James J. Eischen, Jr., Esq.

October 2015
Strafford Publications

JAMES J. EISCHEN, JR., ESQ.

Jim Eischen is attorney with 28 years of experience practicing law, and is a partner with the San Diego law firm of Higgs, Fletcher & Mack, LLP. Over the last several years Jim has become a national expert in direct private medicine practice formation and compliance. He represents physicians, medical groups, and private medicine administration/support businesses throughout the US. He also assists both national and international software, IT, EHR, and health device solution/communication companies with monetization, data privacy and general compliance throughout the US. He is a regular presenter for the AAFP on DPC practice formation and compliance. He is the corporate secretary and board member of the American Academy of Private Physicians. As chairman of the AAPP's legal compliance committee he is responsible for organizing AAPP legal compliance presentations and published compliance guidelines. He provides private direct medicine compliance and healthcare policy presentations for several other organizations throughout the US, including the American College of Private Physicians and WordLink. He provides MCLE legal education credit presentations on various healthcare compliance issues for legal education providers throughout the US. He is a member of his law firm's healthcare, corporate and data privacy practice groups.

- WHAT IS PRIVATE DIRECT MEDICINE?

  - "DPC" or Direct Primary Care
  - Concierge
  - Retainer/Boutique/Membership
  - More variations coming?
  - Branding versus legal structuring

- WHAT IS THE FUTURE OF PRIVATE DIRECT/CONCIERGE MEDICINE

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The Future of Concierge Medicine

Presented by:
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The Future

- Mandatory health insurance coverage for 25+ million young and near poor Americans, coupled with physician shortage, exacerbates access problems for all patients
  - Geographic and socioeconomic disparities

Take-Away: More patients may become frustrated with not getting timely access to health care services, and more may prefer to pay for privilege of concierge care.

- Innovation and diversity of concierge models, including low cost, broad-based participation models (e.g., One Medical)

The Future

- Concierge practices may be excluded from:
  - ACOs
  - Clinically integrated networks
  - Integrated delivery systems
  - Limited/tiered insurance products
- Patients may have increased financial incentives not to seek out-of-network care

Take-Aways: May be more limited opportunities to obtain referrals from "in-network" physicians, and to authorize "in-network" referrals to "in-network" providers. Some patients may be deterred by insurance product design.

The Future

- Those concierge practices that can demonstrate improved quality (measured by PQRS, HEDIS, CHAPS, ACO and other recognized quality benchmarks), reduced ED admissions, reduced hospital admissions/readmissions, and appropriate utilization of ancillary and other services, may have the opportunity to remain "in-network"

Take-Aways: Need to manage care, and not just give patients what they want/demand. Requires data collection and reporting capability; and adherence to system-wide clinical protocols, pathways and standards. Meet medical home standards?

The Future

- Concierge practices are less likely to have value-based payment opportunities (e.g., participate in shared savings, managed care surpluses, health information technology support payments)

Take-Away: Concierge practices are less likely to be at risk for the cost and quality of care they provide—except as judged by the private marketplace.

- Increasing coverage by Medicare and payers of care/case management and navigators complicates concierge medicine value proposition

Take-Away: Concierge practices need to opt-out of care management programs (or from insurance participation) if they want to charge for covered patient navigation services.

The Future

- More payors may decide not to do business with concierge practices, as insurance products move toward value-based or risk-sharing arrangements

Take-Away: May somewhat impair marketability of concierge practices.

- More opportunities with private self-insured plans for executive health, particularly as "Cadillac" plans are taxed/phased out?

Take-Away: Concierge patients more likely to select open access plans. Potential "group purchase" opportunities with corporations (and maybe even some unions)?

The Future

- Challenge to develop models that provide access to a concierge "system of care", not just to a system component
  - Concierge care coordination/care management models are being developed (e.g., Private Health Management)
  - Some multi-specialty concierge medicine networks are being developed (e.g., Castle Connolly Private Health Partners/Top Doctors)
  - Concierge care continuum models have yet to be developed
  - Development of on-line concierge "spot-market"?

Take-Away: Opportunity for those who can successfully develop an affordable care continuum or robust spot-market model.

The Future

- Increased venture capital/private equity interest in multi-state, replicable concierge care arrangements (e.g., MDVIP/P&G; PartnerMD/Markell Ventures)

Take-Away: Structure your concierge business model upfront to accommodate VC/PE investment and an exit strategy.

The Future

- May be faced with more regulation, like Washington Insurance Commission registration requirement for direct providers and health services consultants
  - Growing toehold, but relatively small phenomenon (approx. 4,400 nationally)
  - Big health care issues with high priority currently distract from any anti-concierge effort
  - Movement by direct primary care to be excluded from insurance regulation (e.g., WA; legislation introduced in OR, UT, MD, IN)
  - Growth of retail medicine (e.g., CVS, Walgreens, CareMark, Optum) provides some allies and protection

Take-Away: Not likely to be legislated out of existence in foreseeable future in the absence of a public catastrophe.

The Future

- Evolution of European-type system with 5-10% who can afford to do so opting out of the "public" system for a private system of care?
- The greater the dissatisfaction with the "public" system of care, the greater the opportunity for the private system of care
- Will the "private" system of care become more coordinated across the care continuum?
- Will the private system be early adopters of new consumer-friendly technology tools and systems?
- Will the private system (continue to) be able to demonstrate better health outcomes?

Take-Away: If so, more patients may be able and willing to pay than today for timely access to the right care, at the right time and at the right location.

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Business Models for Concierge Practice

Business Models/Regulatory Considerations

- Ban on balance billing
- Medicare opt-out/private contracting
- Medicare care coordination and care management pilots
- Insurance regulation
- Unlawful discrimination
- Payer contract constraints/reimbursement policies
- Federal and state anti-kickback/fraud & abuse considerations
- Stark law
- Civil monetary penalty law/beneficiary inducements
- State corporate practice of medicine
- Fee-splitting
- Clinic/limited clinic license and certificate of need laws
- State registration requirements
- Scope of practice laws
- Patient abandonment
- HIPAA and state privacy, security and data breach laws

Business Models/ Ethical Considerations

Pros

- Consumer choice
- Personalized health care
- Preventive medicine
- Responsive
- Amenities
- Patient satisfaction
- Physician satisfaction
- More community activities
- Better economics
- Reduced hospital and ED admissions
- Better outcomes?
- Insurance “wrap-around”?

Cons

- Impact on access
- Proliferation concern
- Abuse potential
- Voluntariness?
- Incentive to overutilize?
- Two levels of care?
- Reduction of patient panel
- Skills erosion?
- Loss of patient diversity?
- Adverse selection
- Impact on referral sources?
- Access to specialists?
- Lack of coordination with health system
- Payor risks
- Regulatory risks

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Overview of Current Regulatory Status

Current Regulatory Status

- AMA Ethical Standards – CJEA Report 3-A-03
- Medicare/CMS-- GAO Report, 05-929: no adverse impact to date on Medicare access; consistent with Medicare requirements as long as fee is not for any Medicare covered service
  - CMS no-action position; but OIG Alert about Added Charges for Covered Services (3/31/04); and enforcement actions against physicians who charged a membership fee for Medicare covered services (e.g., R. Douglas Thorsen, M.D., Minnesota ($53,400 CMP settlement, 07/28/2003); Lee R. Rocamora, M.D., North Carolina, ($106,600 CMP settlement, 5/15/07)); Heritage Medical Partners, South Carolina ($170,260 CMP settlement 1/9/13)

Current Regulatory Status (cont.)

- Divisions of Insurance–need to structure so that membership fee arrangement is a service contract, not a contract of insurance
  - No regulatory disapproval except NJ and NY (HMOs cannot do business with concierge practices)
  - Registration of "direct practices" and "health care services contractors" by Washington Insurance Commission (RSW 48.44); but exempt from insurance regulation (RSW 48.150)
    - Other states have introduced legislation exempting direct primary care practices (e.g., OR, UT, MD, IN)
  - Affirmatively permitted by MA Division of Insurance with disclosure in provider directory

Current Regulatory Status (cont.)

- Physician Licensing Boards – No regulatory disapproval, but in MA and Ohio cannot opt-out of Medicare and bill in excess of Medicare allowable
- Status with commercial payors – Where permitted, most payors will do business with concierge practices; some will not
  - Business v legal decision
  - Some national payors have anti-concierge policies, particularly for managed care products: (e.g., Aetna, CIGNA, United, certain Anthem/BCBS plans)
    - Left to regional enforcement and generally not enforced
  - Payor contract terms—some include anti-concierge language/anti-discrimination provisions

Current Regulatory Status (cont.)

- Status with legislatures
  - No current direct federal or state challenges

No current existential threat

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Concierge Medicine Business Models

Participation/Opt-Out Models

- Legitimate concierge medicine models
  - Opt-Out, direct care model
    - Can opt-out of Medicare and commercial insurance, and balance bill
    - Medicare opt-out to private contracting or subject to Medicare charge limits
    - Physicians who opt-out of Medicare in MA and OH cannot charge in excess of the Medicare allowable
  - Participate with payors and charge for non-covered amenities only (and not for any professional services)—e.g., personal health record, navigator
  - Participate and charge for non-covered amenities (including non-covered professional services)—e.g., non-covered telemedicine consultations

Participation v. Opt-Out Models

Membership Fee Pays for:	Covered Professional Services	Noncovered Professional Services	Noncovered Amenities/Enhancements
Examples of Service	E.g. ▪ Office visits ▪ 24/7 availability ▪ ER visits ▪ Annual health assessment?	E.g. ▪ Screening exams ▪ Telephone/email consults	E.g. ▪ Communication/Internet tools ▪ "Arranging for" function ▪ Nonmedical items (e.g., discounted health club membership, nutritious snacks, exercise physiology testing by personal trainer)
Charge/Payment	Accept health insurance as payment in full, subject to copays, deductibles	Generally no health insurance coverage Within membership fee (to extent not covered by insurance)	No health insurance coverage Within Membership Fee
Spending Account Reimbursement	Yes	Some	No
Legal Risk/Balance Billing	High/Illegal—unless Opt-Out	Moderate	Low

Participation Considerations

- Participation v. Opt-Out
  - Opt-Out generally frees practice to “balance bill”
  - Under Opt-Out model, membership fees may be reimbursable by health spending accounts to the extent payment is for “eligible medical expenses”
  - Under participation model, membership fees will generally not be reimbursable by health spending account (to the extent amenities paid for are not professional services)
  - But, Opt-Out may impair marketability of concierge practice
  - Payment by Medicare under care coordination and comprehensive care pilot programs makes opt-out decision more complicated

Participation Considerations (cont.)

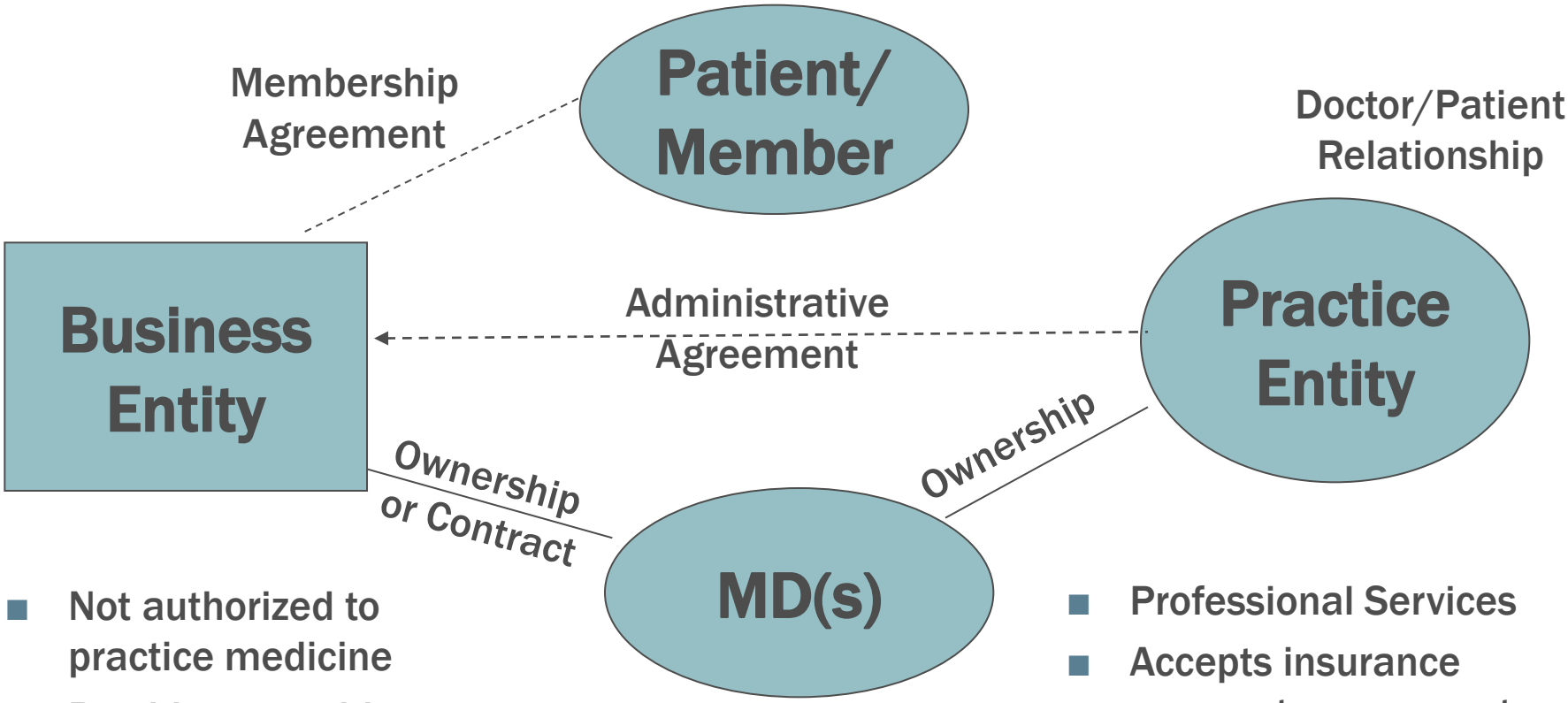
- Nonpar physician cannot serve as PCP gatekeeper (e.g., cannot authorize in-network referrals)
- Nonpar specialist may jeopardize consultation practice
- Nonpar physician will be treated as an out-of-network provider, whose services may be subject to higher copays
  - Increased risk with growth of limited, tiered and narrow networks
  - May be excluded from ACOs/integrated delivery systems
- Opt-Out generally jeopardizes ability to participate at other locations

Take-Away: For these reasons, 76% of concierge practices currently participate with payors, including Medicare

Concierge Medicine Business Models

- Diversity and increase of business models
- Conversion of solo practice (e.g., Personal Physicians Health Care), small medical group, or component of a medical group (e.g., Bryn Mawr Medical Group)
  - Single entity conversions (principally in non-CPOM states)
  - Two entity (business entity to provide amenities/enhancements and practice entity to provide professional services) principally in CPOM states
- Low membership fee, large panel models v. high(er) membership fee, smaller panel models
  - "Voluntary" fee for specific technology/communications amenities (e.g., One Medical)

Self-Conversion: Two Entity/Participation Model



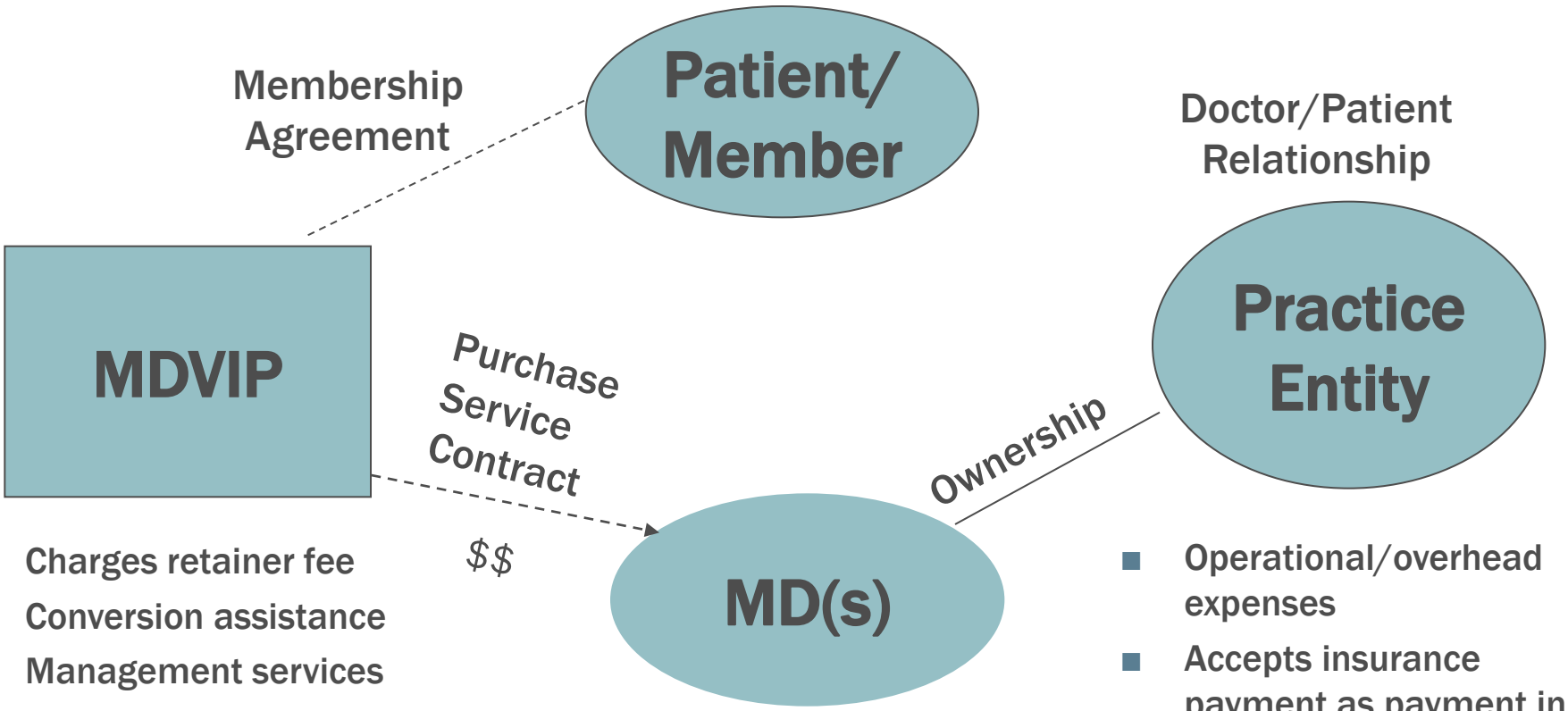
- Not authorized to practice medicine
- Provides amenities
- Charges retainer fee

- Professional Services
- Accepts insurance payment as payment in full, subject to copay, co-insurance, deductibles

Concierge Medicine Business Models

- Hybrid models: “membership” and traditional tier
  - Primary care v. Specialty care practices
  - May be required by certain payers to maintain participation
- Multiple tiers: different prices for different bundles of concierge services (e.g., AllCare)
- Practice management and network models
  - Membership fees paid to PPM/Network with purchased professional/amenities support services by PPM/Network (e.g., MDVIP in non-CPOM states)
  - Membership fees paid to Practice with management services purchased by Practice from PPM/Network (e.g., MDVIP in CPOM states)
  - Friendly PC model: financial consolidation (e.g., PartnerMD)

MDVIP Model: Non-CPOM States

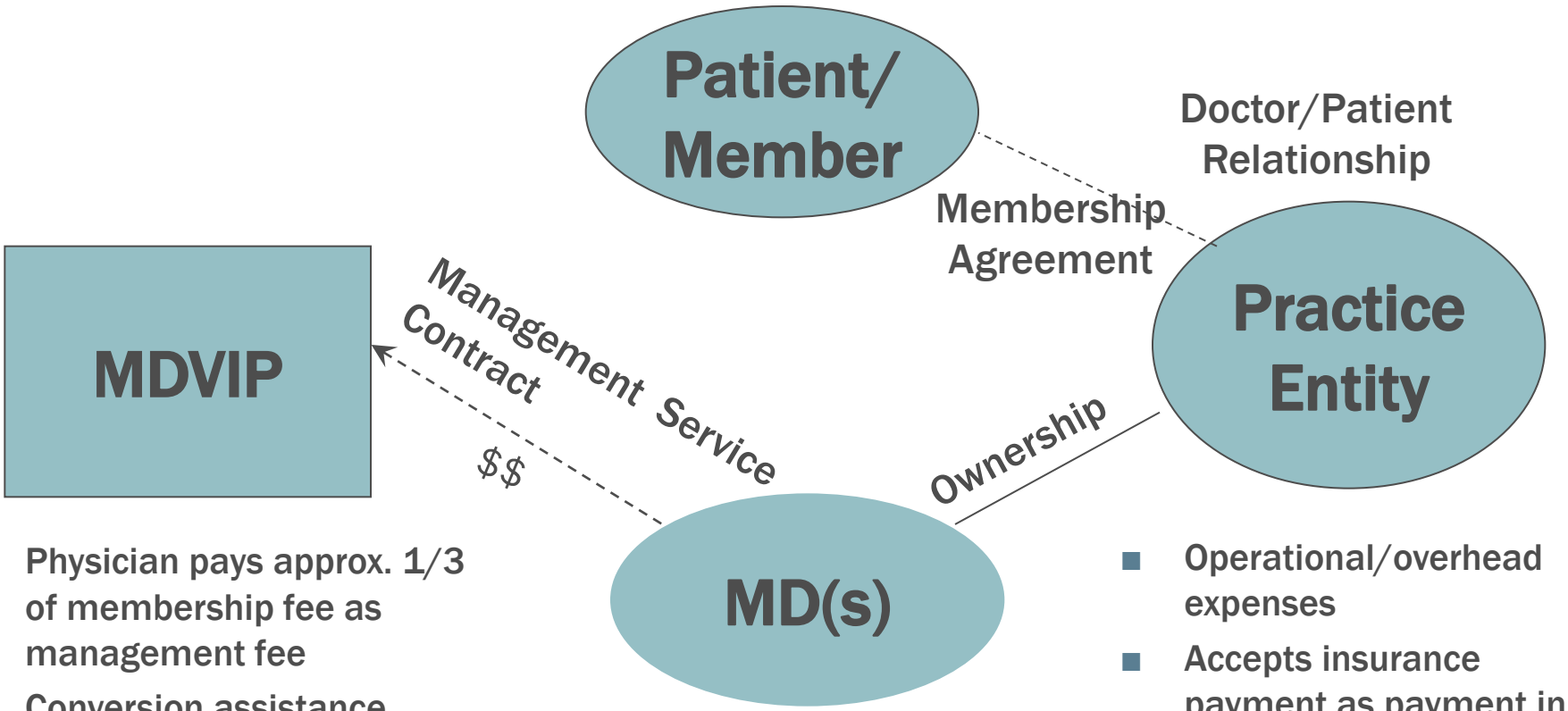


- Charges retainer fee
- Conversion assistance
- Management services
- IT platform
- Marketing
- Lobbying

- MDVIP pays physician approx. 1/3rd of membership fee
- 5-10 year commitment
- Post-termination non-compete
- Efforts to identify successor/purchaser

- Operational/overhead expenses
- Accepts insurance payment as payment in full, subject to copay, co-insurance, deductibles

MDVIP Model: CPOM States

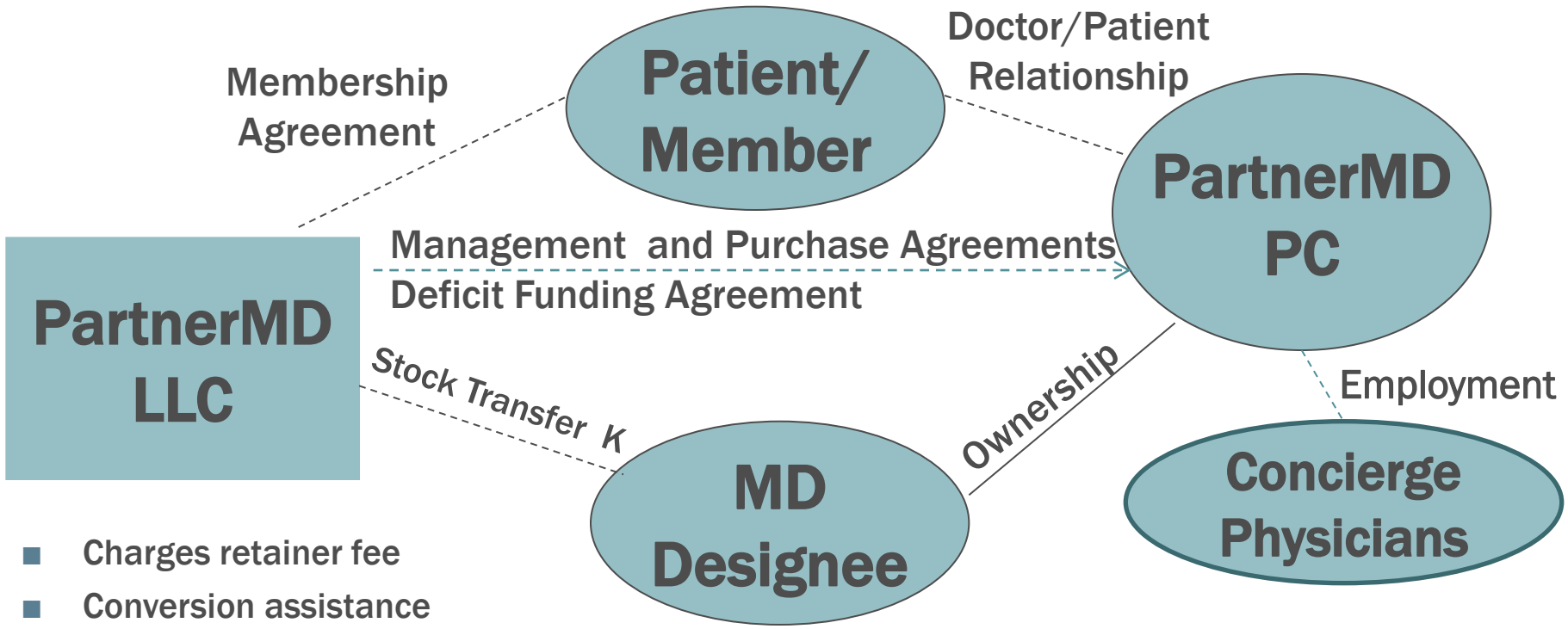


- Physician pays approx. 1/3 of membership fee as management fee
- Conversion assistance
- Management services
- IT platform
- Marketing
- Lobbying

- Physician charges retainer fee
- 5-10 year commitment
- Post-termination non-compete
- Efforts to identify successor/purchaser

- Operational/overhead expenses
- Accepts insurance payment as payment in full, subject to copay, co-insurance, deductibles

PartnerMD Friendly PC Model



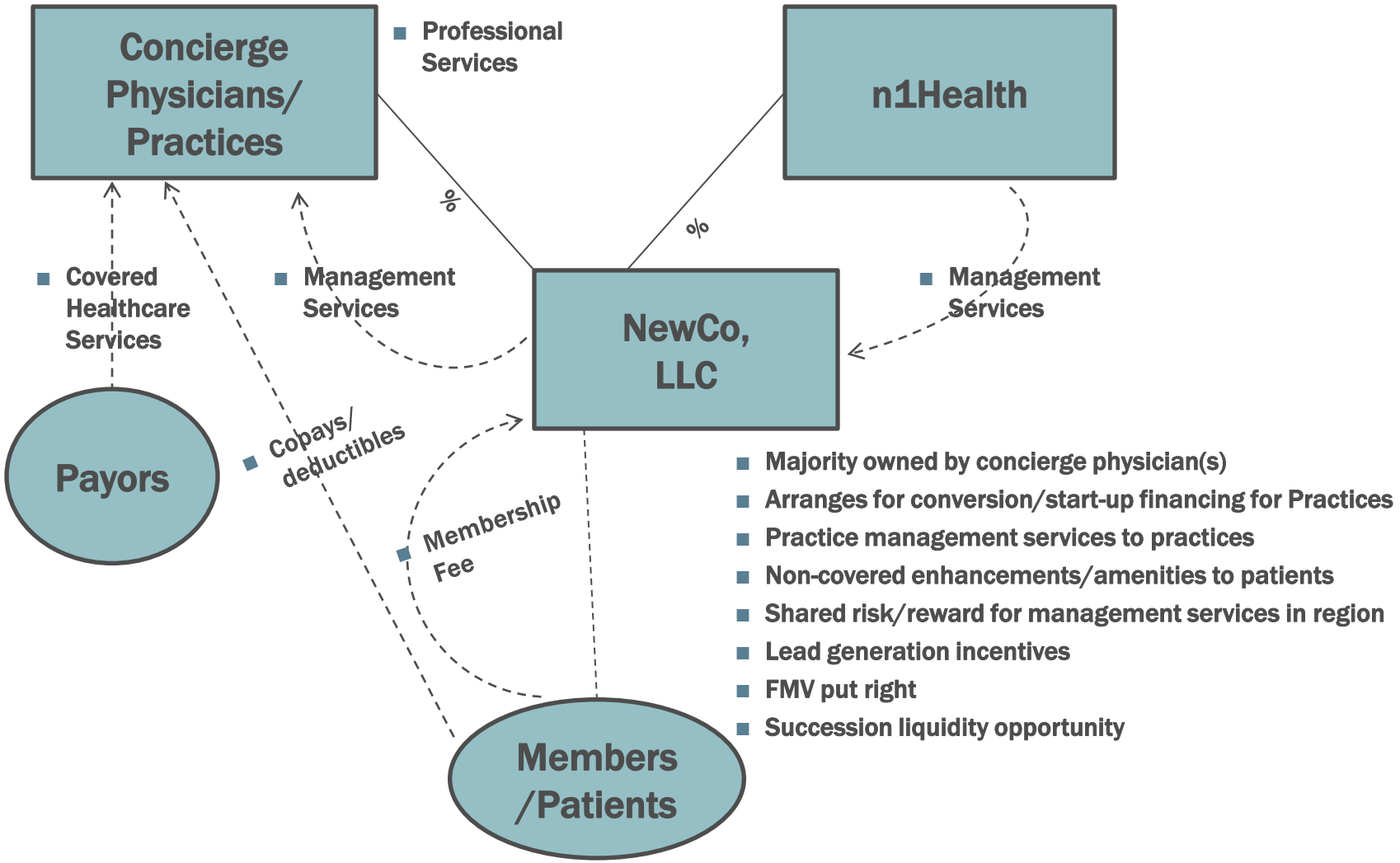
- Charges retainer fee
- Conversion assistance
- Management services
- IT platform
- Marketing

- Salaried employee/comp based on # of members
- No financial risk of operations for employed MDs
- PC accepts insurance payment as payment in full, subject to copay, co-insurance, deductibles

Concierge Medicine Business Models

- Joint venture models
  - Membership fees paid to Practice with management services purchased by Practice from JV ManageCo (e.g., n1Health)
  - Membership fees paid to JV ManageCo with payment to Practice for professional/amenities support services
  - Membership fees paid to JV ManageCo with distributions only-- no management fee or purchased services (e.g., Castle Connolly)
- Practice acquisition models (e.g. WellcomeMD)
  - Can be combined with any of the above models

n1Health Regional Joint Venture Model



Concierge Medicine Business Models

- No current model with single membership fee for multi-specialty or continuum of care services that does not involve "insurance" risk?
  - Concierge care continuum models have yet to be developed
  - Development of on-line concierge "spot-market"?
  - Concierge care insurance?

Take-Away: Opportunity for those who can successfully develop an affordable care continuum or robust spot-market model.

PRIVATE/CONCIERGE MEDICAL PRACTICES CAN

- Engage in electronic communications
- Utilize EMR/EHR platforms to enable communications & scheduling
- Utilize health devices/apps storing data
- May involve health entrepreneurs/physicians creating varied business units
- Include amenities that can appear to sell “access” or “care coordination”
- Involve healthcare products sales and vendor business relations

WE WILL EXPLORE

- Data compliance (HIPAA and more) requirements
- Avoiding “access” and “care coordination” Medicare assignment violations
- Avoiding Stark/Anti-Referral exposure

Private Medicine & Electronic Communications

BECKER'S Hospital CIO

93% of Adult Patients Want E-mail Communication With Physicians

Written by Akanksha Jayanthi (Twitter | Google+) | May 13, 2014

According to Catalyst Healthcare Research:

- 93% of patients likely to select a physician who offers communication via e-mail
- 25% of that said they would still choose that physician if there was a $25 fee per episode
- Quick and convenient for patients

"As healthcare changes, it's crucial that providers stay relevant."

http://www.beckershospitalreview.com/healthcare-information-technology/93-of-adult-patients-want-e-mail-communication-with-physicians.html

PRIVATE/CONCIERGE PRACTICES TYPICALLY INCLUDE ELECTRONIC COMMUNICATION AMENITIES

- Website patient portal
- Email
- Texting
- Videoconferencing
  - Skype
  - WebEx

HIPAA: Quick Summary & Update

HIPAA

- The Health Insurance Portability and Accountability Act of 1996 (HIPAA)
- **HIPAA Privacy Rule** and the **HIPAA Security Rule**.
  - **Privacy Rule** (*Standards for Privacy of Individually Identifiable Health Information)* establishes national standards for the **protection of certain health information**.
  - **Security Rule** (*Security Standards for the Protection of Electronic Protected Health Information*) establishes a national set of security standards for **protecting certain health information that is held or transferred in electronic form**.
- Within HHS, the **Office for Civil Rights (OCR)** has responsibility for enforcing the Privacy and Security Rules with voluntary compliance activities and civil money penalties.

OMNIBUS/FINAL RULE

- **All covered entities must review documentation including business associate agreements, notice of privacy practices, and their policies and procedures to ensure compliance with the Final Rule**
- **BAA and NPP MUST BE UPDATED**

FEE CHARGES FOR ELECTRONIC RECORDS?

- Actual costs only
  - Retrieval costs or capital costs not allowed to be charged
- Supplies upon request can be charged

✓ **Best practice is to list fees on authorization/consent form itself**

✓ **Avoid EMR access as private fee amenity**

HIPAA ACCOUNTING RULE

- Individual can restrict ePHI to health plan when paying out of pocket in full for a service (Accounting Rule)
- Must track and segregate upon request

BASIC HIPAA DOCUMENTATION

- Notice of Privacy Practices (NPP)
- Business Associate Agreement (BAA)
- Internal risk analysis memo
  - Practice's written office procedures and processes must be examined thoroughly
  - Evaluate risks and decide how to address those risks

SHOULD PHYSICIAN-PATIENT AGREEMENTS INCORPORATE ELECTRONIC COMMUNICATIONS?

- Recommend separate agreement
  - Need separate ePHI agreement for risk management/HIPAA compliance
  - HIPAA Final Rule: Requires non-compound ePHI consent

DATA COMPLIANCE VIGILANCE REQUIRED

- Check marketing/practice communication platforms for data compliance
  - Website
  - Calendar/Scheduling
  - FAQs
  - Patient letters
  - Staff training

MEDICARE COMPLIANCE

Access?

Care Coordination?

OIG ON MEDICARE COMPLIANCE FOR PRIVATE MEDICINE

MEDICARE COMPLIANCE: OIG ALERT #1

In 2004, a physician from Minneapolis, Minnesota paid $53,400 under the Civil Monetary Penalties Law. The physician charged a yearly contract for services characterized as "not covered" by Medicare: (1) coordination of care with other providers; (2) a comprehensive assessment and plan for optimum health; and (3) extra time. Some services deemed covered by Medicare.

https://oig.hhs.gov/fraud/enforcement/cmp/overcharging.asp

MEDICARE COMPLIANCE: OIG ALERT #2

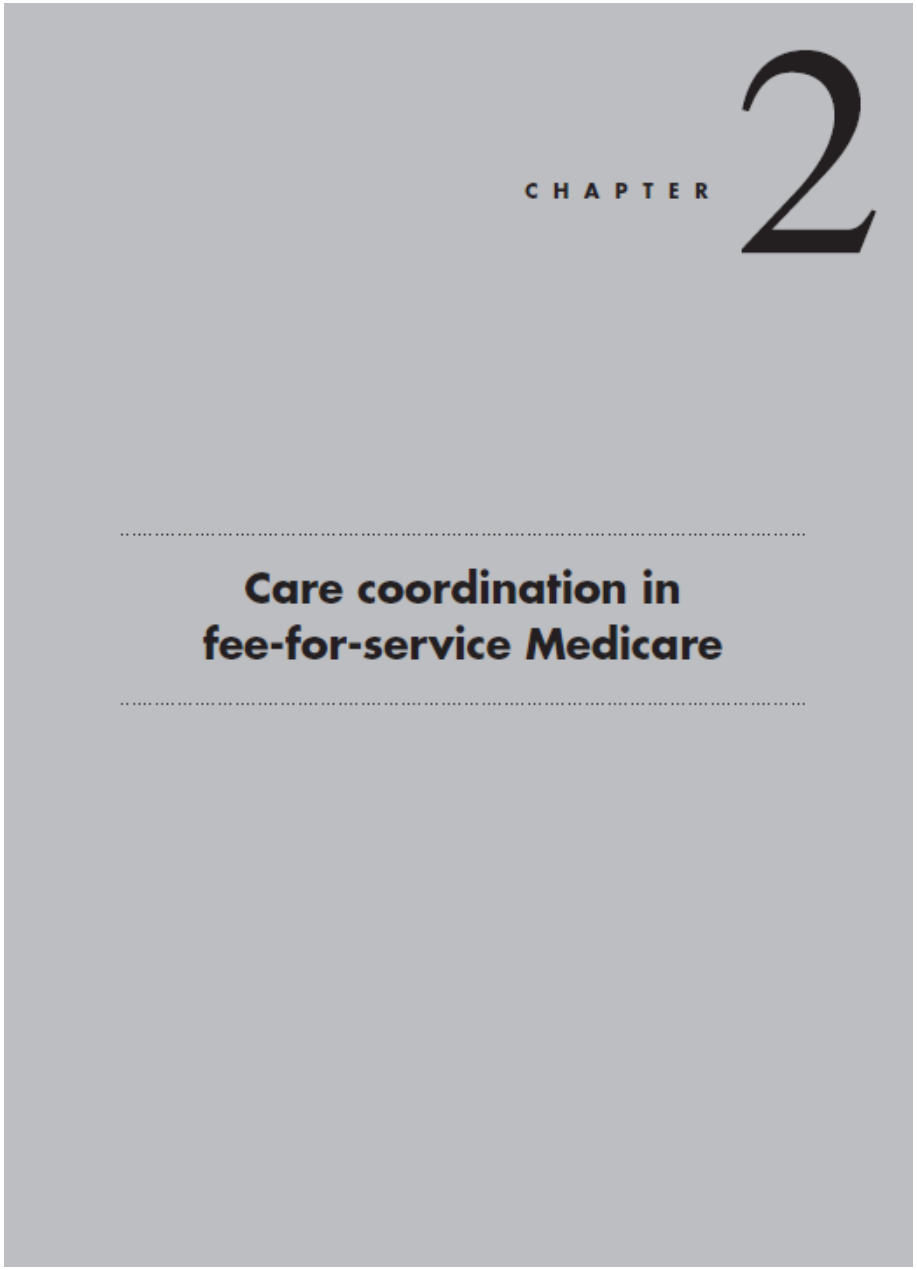
In 2007, North Carolina physician paid $106,600 to resolve Civil Monetary Penalties Law liability. The practitioner and patients entered into a membership agreement for a patient care program for an annual fee, providing: (1) annual comprehensive physical examination; (2) same day or next day appointments; (3) support personnel dedicated exclusively to members; (4) 24 hours a day and 7 days a week physician availability; (5) prescription facilitation; (6) coordination of referrals and expedited referrals, if medically necessary; and (7) other service amenities as determined by the practitioner. Some services deemed covered by Medicare.

https://oig.hhs.gov/fraud/enforcement/cmp/overcharging.asp

MEDICARE COMPLIANCE: OIG ALERT #3

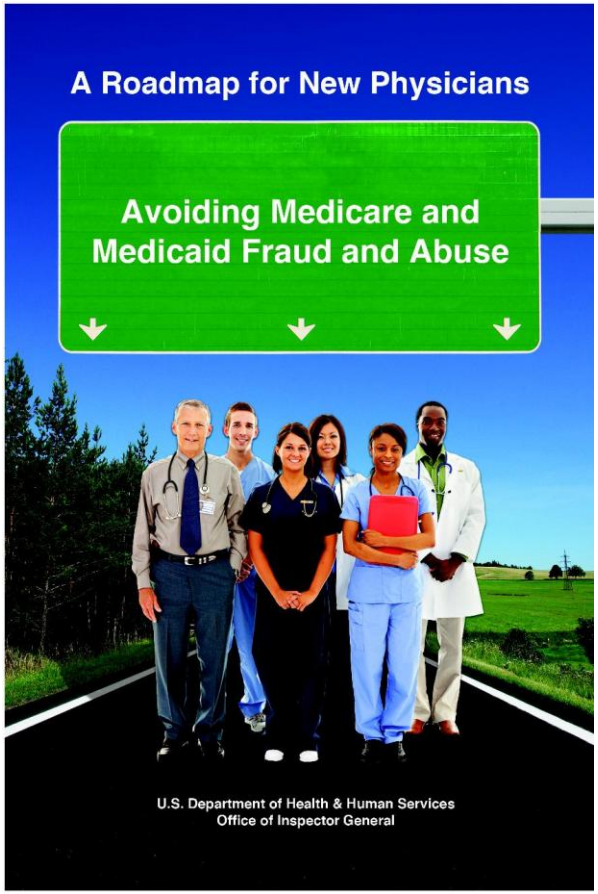
In 2013, a South Carolina practice paid $170,260 for charging mandatory “administrative ” or “forms” fee to all patients to cover certain unspecified administrative services, with explanation that the charge was necessary due to poor plan reimbursement. (i.e. “access” charge).

https://oig.hhs.gov/fraud/enforcement/cmp/overcharging.asp



http://www.medpac.gov/chapters/Jun12_Ch02.pdf

BE CAREFUL



- *A Roadmap for New Physicians: Avoiding Medicare and Medicaid Fraud and Abuse,* U.S. Department of Health & Human Services and Office of Inspector General
- http://oig.hhs.gov/compliance/physician-education/index.asp
- Private reimbursement compliance issues

Civil Monetary Penalties Law

Penalties range from $10,000 to $50,000 per violation

5. Civil Monetary Penalties Law

You should also be aware that OIG may seek civil monetary penalties for a wide variety of abusive conduct, including presenting a claim that is false or fraudulent because it is for a medically unnecessary procedure.

OIG also may impose civil monetary penalties for violating the Medicare assignment agreement by overcharging or double billing Medicare beneficiaries.

- For example, a physician paid $107,000 to settle charges that he violated the Medicare assignment agreement by charging Medicare beneficiaries an annual fee when some of the services he promised in exchange for that annual fee were already covered by Medicare.

Your booklet contains additional examples of Civil Monetary Penalties Law violations.

Penalties range from $10,000 to $50,000 per violation.

Some physicians also require patients to pay additional fees to receive care from the practice. These fees go by many names, including "annual fees" and "concierge fees."

Whether you are a participating or non-participating physician, if you decide to seek extra payment from your Medicare patients, make sure that you are providing additional service beyond what is already covered by Medicare.

OIG has pursued enforcement actions against physicians for charging improper and excessive fees.

For example, a physician paid $107,000 to resolve potential liability for charging patients an annual fee for services that were already covered by Medicare.

OPT-OUT: COMPLIANCE REQUIREMENTS

MLN Matters Number: MM6081 | Related Change Request (CR) #: 6081

Related CR Release Date: June 27, 2008 | Effective Date: September 29, 2008

Related CR Transmittal #: R92BP | Implementation Date: September 29, 2008

Private Contracting/Opting out of Medicare

- The physician/practitioner has filed an affidavit in accordance with §40.9 and has signed private contracts in accordance with §40.8
- The physician/practitioner complies with the provisions of §40.28 regarding billing for emergency care services or urgent care services
- **The physician/practitioner retains a copy of each private contract that the physician/practitioner has entered into for the duration of the opt-out period for which the contracts are applicable or permits CMS to inspect them upon request**

OPT-OUT: NONCOMPLIANCE CONSEQUENCES

MLN Matters Number: MM6081 | Related Change Request (CR) #: 6081

Related CR Release Date: June 27, 2008 | Effective Date: September 29, 2008

Related CR Transmittal #: R92BP | Implementation Date: September 29, 2008

Private Contracting/Opting out of Medicare

- All private contracts are deemed null and void.
- The opt-out of Medicare is nullified.
- The physician or practitioner must submit claims to Medicare for all Medicare covered items and services furnished to Medicare beneficiaries.
- The physician or practitioner or beneficiary will not receive Medicare payment on Medicare claims for the remainder of the opt-out period, except as stated above.
- The physician or practitioner subject to limiting charge provisions.
- The practitioner may not reassign any claim except as provided in the Medicare Claims Processing Manual, Chapter 1, "General Billing Requirements," §30.2.13. (For more information about the General Billing Requirements refer to ***http://www.cms.hhs.gov/manuals/downloads/clm104c01.pdf*** on the CMS website).
- The practitioner may neither bill nor collect any amount from the beneficiary except for applicable deductible and coinsurance amounts.
- The physician or practitioner may not attempt to once more meet the criteria for properly opting out until the 2-year opt-out period expires.

IMPROPER REMUNERATIONS

Anti-Kickback Statue and Stark

OIG MATERIALS ON ANTI-KICKBACK

Private Medical Practices Doing Vendor Business

WHAT IS A KICKBACK?

- Anything of value presented to a practitioner or supplier that may induce that entity to refer health services back to the source of remuneration. Adherence to business relationships based on fair market value transactions will usually negate accusations of the acceptance of kickbacks.
- http://www.asha.org/practice/reimbursement/medicare/QAs/#sthash.oex2lJFz.dpuf

Anti-Kickback Statute

Prohibits asking for or receiving anything of value in exchange for referrals of Federal health care program business

2. Anti-Kickback Statute

In some industries, it is acceptable to reward those who refer business to you.

However, asking for or receiving any remuneration in exchange for your referrals of Federal health care program business is a crime under the Anti-Kickback Statute.

The Anti-Kickback Statute applies to both payers and recipients of kickbacks. Just asking for or offering a kickback could violate the law.

Anti-Kickback Statute

Prohibited kickbacks include:

- Cash for referrals
- Free rent for medical offices
- Excessive compensation for medical directorships

"Remuneration" is basically anything of value.

The law prohibits obvious kickbacks, like cash for referrals, as well as more subtle kickbacks, like free rent, below fair market value rent, free clerical staff, or excessive compensation for medical directorships.

Numerous physicians have been sanctioned for selling their product loyalty to drug or device companies or other vendors.

- For example, an orthopedic surgeon accused of accepting kickbacks from device manufacturers in exchange for preferentially using their artificial hip and knee joints recently paid $650,000 to settle the case against him.

Kickbacks can lead to:

- Overutilization
- Increased costs
- Corruption of medical decisionmaking
- Patient steering
- Unfair competition

Kickbacks are illegal because they harm the Federal health care programs and program beneficiaries. They can lead to:

- overutilization of items or services,
- increased program costs,
- corruption of medical decisionmaking,
- patient steering, and
- unfair competition.

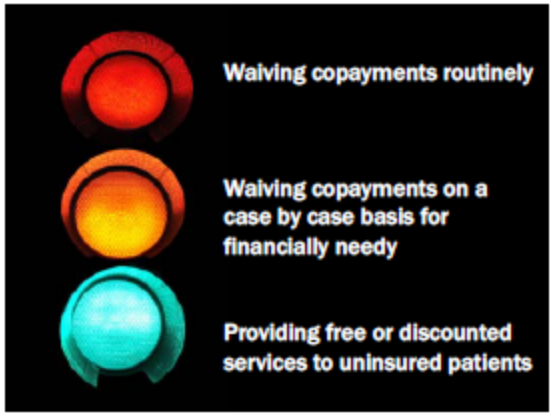
As physicians, you owe your patients the benefit of your best clinical judgment.

Violating the Anti-Kickback Statute carries stiff penalties. Violators can be found liable under the False Claims Act as well.

Violations can result in prison sentences and fines and penalties of up to $50,000 per kickback plus three times the amount of the remuneration.

Additionally, physicians can be excluded from participation in the Federal health care programs for violating the Anti-Kickback Statute.

Some refer to exclusions as a “financial death sentence” because excluded physicians may not receive payment for treating any Medicare and Medicaid beneficiaries.



The Anti-Kickback Statute also is implicated when physicians give patients financial incentives to use their services.

- *[Red Light]* Federal law does not prohibit you from offering free care to Medicare and Medicaid patients.

  However, if you choose to waive copayments from patients but bill Medicare or Medicaid, you are not providing free care. In some circumstances, you could be in violation of the Anti-Kickback Statute.

- *[Yellow Light]* You are free to waive a copayment if you determine that the individual patient cannot afford to pay or if reasonable collection efforts fail.

  However, you may never advertise that your practice has a policy of forgiving copayments.

- *[Green Light]* This rule prohibiting routine waivers of copayments does **not** apply to uninsured patients.

  You may treat uninsured patients for free or offer them discounted fees.

OIG MATERIALS ON SELF-REFERRAL

WHAT IS SELF-REFERRAL?

- Referral by a physician to an entity with which the physician or a member of the physician's family has a financial relationship. The relationship is such that the physician would earn a financial return based on the success of, for example, a speech and hearing clinic in which the physician invested. The Stark II law (introduced by Rep. Pete Stark, D-CA) designates ten categories of Medicare and Medicaid health services for which self-referral is prohibited. Speech-language pathology services, durable medical equipment, orthotics and prosthetics are included in the designated health services.
- http://www.asha.org/practice/reimbursement/medicare/QAs/#sthash.oex2lJFz.dpuf
- https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/index.html?redirect=/physicianselfreferral/

Physician Self-Referral Statute

Limits physician referrals when you have a financial relationship with the entity

3. Physician Self-Referral Statute

The Physician Self-Referral Statute, or Stark law as it is sometimes called, prohibits you from referring Medicare or Medicaid patients for designated health services to entities with which you have a financial relationship, unless an exception applies.

- Financial relationships covered by this law include ownership/investment interests, as well as compensation relationships.

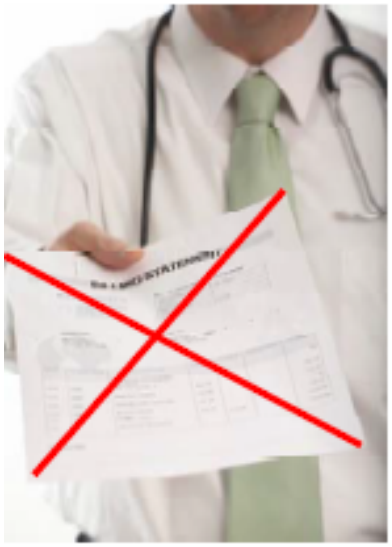
  This law applies to your financial relationships and those of your immediate family members.

- Designated health services include clinical laboratory services, physical therapy, and home health services, among others.

  A complete list is found in the booklet.

For example, unless an exception applies, you may not refer patients to an imaging center for designated health services if you have a financial investment in that center.

A physician was charged with violating the Stark law for routinely referring Medicare beneficiaries to an oxygen supply company he owned. He paid $203,000 to settle the case.



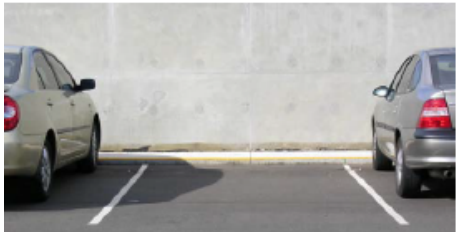
Consequences of violating the Physician Self-Referral Statute:

- **Payment denial**
- **Monetary penalties**
- **Exclusion**

The Physician Self-Referral Statute is a strict liability law, which means proof of specific intent to violate the law is not required.

The entity submitting improper claims is subject to repayment of all amounts received from Medicare and Medicaid that are connected with the improper relationship and may be subject to additional penalties.

Physicians who violate the law may be subject to monetary penalties as well as exclusion from participation in the Federal health care programs.



Avoid violating the Anti-Kickback Statute and Physician Self-Referral Statute by fitting into a "safe harbor" or exception

Many arrangements can be structured to avoid the risk of fraud.

Additionally, the law provides for "safe harbors" and exceptions to the Anti-Kickback and Stark laws.

To fit into an Anti-Kickback safe harbor or Stark law exception, you must fit squarely within the requirements. If the safe harbor or exception contains multiple elements or conditions, you must satisfy each element or condition.

For example, a full-time lease agreement between a physician and a provider to whom the physician refers patients can meet the space rental safe harbor if the agreement:

- is set out in writing and signed by the parties;
- covers all of the premises rented by the parties;
- is for a term not less than 1 year;
- has an aggregate rental charge set in advance, is consistent with fair market value in arm's length transactions, and does not take into account the volume or value of Federal health care program referrals; and
- the aggregate space rented may not exceed the space that is reasonably necessary to accomplish the commercially reasonable business purpose of the rental.

You may want to consult with a health care attorney for assistance in structuring your arrangements properly.

QUESTIONS?

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