Concierge Medicine:
Complying With Medicare Regulations, Insurance Laws and the Anti-Kickback Statute

WEDNESDAY, MAY 28, 2014

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

Today’s faculty features:

James Eischen, Jr., Partner, Higgs Fletcher & Mack, San Diego
Joshua Kaye, Partner, DLA Piper, Miami

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Concierge Medicine

Presented By:
Joshua Kaye, Esq.
DLA Piper LLP (US)
305-423-8521
joshua.kaye@dlapiper.com

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The Value Agenda Proposition

- Providers are facing unprecedented reimbursement pressures, taking on risk vis-à-vis accountable care organizations and related vehicles and are being asked to do more for less and to migrate from a fee for service system to one that is driven by benchmarks (quality, patient satisfaction, cost efficiency, etc.).

  - “It’s time for a fundamentally new strategy. At its core is maximizing value for patients: that is, achieving the best outcomes at the lowest cost. We must move away from a supply-driven health care system organized around what physicians do and toward a patient-centered system organized around what patients need.
  - We must shift the focus from the volume and profitability of services provided—physician visits, hospitalizations, procedures, and tests—to the patient outcomes achieved. And we must replace today’s fragmented system, in which every local provider offers a full range of services, with a system in which services for particular medical conditions are concentrated in health-delivery organizations and in the right locations to deliver high-value care.”
Health care delivery in next five years

- Delivery system comprised of shared risk between payors, hospitals and providers
- Greater focus on wellness and preventative care
- Patient-centric bundled payments
- Tiered providers based on quality, efficiency, cost comparisons, and severity adjustments
- Seamless exchange of PHI vis-à-vis electronic health records
A Transformative Healthcare Landscape

- Universal coverage and Medicaid expansion expected to cover 30 million new insured
- Numerous strategic mergers, acquisition, and consolidation activity
- Private equity salivating for high return opportunities in a fragmented, inefficient health market with revenue enhancement growth through consolidation and innovative technology
- Payors are diversifying risk and investing in providers and provider-based technology driven by ACA’s Medical Loss Ratio rules
What is concierge medicine

- Distinguishing features of primary care concierge models
  - 300-800 patients per physician
  - Physician availability
  - Flexible appointment times
  - Minimized patient waiting room times
  - Personalized plan of care
  - Amenities/Enhancements
  - Retainer/Membership/Concierge/Service Fee
Indicators of Success

- Duration and strength of patient relationships
- Reputation/board certification
- Patient demographics
- Feasibility assessment and affordable price point
- Communications with patients (and payors/regulators)
- Staff training and customer service
- Managing the conversion process and transition plan for patients
Three Primary Concierge Models

- Non-participation -- Opt out of Medicare and out-of-network participation with commercial insurers

- Participation Option #1 -- Medicare and commercial insurance participation plus charge for non-covered amenities and non-covered professional health care services

- Participation Option #2 -- Medicare and commercial insurance participation plus charge for non-covered amenities only

- What all three models have in common – patient participation/membership fee

- Key distinction among concierge practices is size of fee and scope of services/amenities covered by the fee

- Non-participation model could jeopardize physician practice ability to participate in other office locations

- Substantial majority of concierge practices participate in Medicare and with commercial insurers around the country
Three Key Contractual Relationships

- Agreement with concierge network
- Agreement with patient member
- Agreement with payor
Concierge Networks

- Depending on state law and scope of concierge services, business entity will enter into membership agreement with patient/client and collect retainer fees (percentage of fee shared with physician may vary)

- Business entity will enter into contractual relationship with physician and physician practice to provide amenities and support services
  - Patient demographic analysis
  - Patient telephone survey
  - Initial and follow up mailings
  - Patient education seminars
  - Processing membership enrollments
  - Staff support
  - Billing & Collections of membership fees
  - Electronic medical records
  - After hours call center

- Similar to friendly physician practice management model with limited and narrowly defined scope of management services)
Concierge Network Management Model

Physician Investors

Owners

Concierge Network

Concierge Practice

Payors

Members

Patients

Concierge Participation Fee

Administrative/Management Services

FMV Fee (fixed or contingent)

Claims

$
Contracts with Concierge Network

- Consider state corporate practice of medicine and fee splitting laws
- Scope of services to be provided by concierge network
  - Transitional services
  - On-going management services
  - Lobbying/legal support/payor assistance
- Economics
- Practice size limitations (400 patients, 600 patients, 1,000 patients)
- Applicability to entire practice and all locations or subset of physicians or locations
- Term/Duration
- Ease of Termination
- Effect of Termination
- Indemnification
- Non-Competition and other restrictive covenants
- HIPAA Business Associate Agreement
Patient/Client Membership Agreements

- Clearly specify the scope of services covered by the fee.
- Specify whether the concierge practice will accept Medicare and/or other insurance.
- State that the fee is paid in addition to and not in exchange for any co-payments, deductibles or co-insurance.
- Specify the duration of membership, when the fee must be paid, whether all or any portion is refundable or non-refundable.
- Specify terms of renewal (i.e., automatic renewal versus term of one year and patient must notify practice of renewal).
- Allow the patient to terminate the relationship without financial penalties or undue burden.
- Marketing materials should not be misleading nor promote better diagnostic or therapeutic services.
- Agreement should be easy for patient to understand and patient should execute contract acknowledging that they understand the terms of the agreement.
- Practice staff should walk patient through key terms of agreement.
Physician-Patient Relationship Termination

- Check state laws regarding patient abandonment issues
- Give written notice to patients
- Agree to and continue providing services for a reasonable period of time (30 days)
- Provide support or recommendations to assist patients in locating another physician
- Offer to transfer records to the newly-designated physician
PRIVATE/CONCIERGE MEDICINE DATA COMPLIANCE

James J. Eischen, Jr., Esq.

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JAMES J. EISCHEN, JR., ESQ.

Partner at Higgs, Fletcher & Mack, LLP

26+ years of experience as an attorney in California with planning and compliance with emphasis on private medicine, healthcare, start-ups and reimbursement planning.

Several years of experience in the healthcare field.

Graduated from the University of California at Davis School of Law in 1987.

Professional Memberships: San Diego County Bar Association Law & Medicine Section, Attorney-Client Relations Committee, American Academy of Private Physicians corporate secretary and chair of the legal compliance and advocacy committee.
PRIVATE/CONCIERGE MEDICAL PRACTICES CAN

• Engage in electronic communications
• Utilize EMR/EHR platforms to enable communications & scheduling
• Utilize health devices/apps storing data
• 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
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.”

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
OIG ALERT – MARCH 31, 2004

Alert from Office of Inspector General, March 31, 2004


OIG ALERTS PHYSICIANS
ABOUT ADDED CHARGES FOR COVERED SERVICES

Extra Contractual Charges Beyond Medicare’s
Deductible, Coinsurance: A Potential Assignment Violation

Acting Principal Deputy IG Dara Corrigan today reminds Medicare participating physicians of the potential liabilities posed by billing Medicare patients for services that are already covered by Medicare.

Medicare participating providers can charge Medicare beneficiaries extra for items and services that are not covered by Medicare.

Participating providers may also, of course, charge beneficiaries for any Medicare deductibles and coinsurance without violating the terms of their assignment agreements. But when participating providers request any other payment for covered services from Medicare patients they are liable for substantial penalties and exclusion from Medicare and other Federal health care programs.

“We are hearing reports about physicians asking patients to pay additional fees, and we believe this is an ideal time to remind physicians and Medicare patients about this potential liability. Charging extra fees for already covered services abuses the trust of Medicare patients by making them pay again for services already paid for by Medicare,” Corrigan said.

—MORE—
OIG ALERT 03-31-04

• While the physician characterized the services to be provided under the contract as “not covered” by Medicare, the OIG alleged that at least some of these contracted services were already covered and reimbursable by Medicare.

• Among other services offered under this contract were the “coordination of care with other providers,” “a comprehensive assessment and plan for optimum health,” and “extra time” spent on patient care. OIG alleged some of these contracted services were already covered and reimbursable by Medicare.

➢ **Result:** Settlement paid to OIG and physician stopped offering the contract
Care coordination in fee-for-service Medicare

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

BE CAREFUL
OIG: NO “DOUBLE BILLING”

• Participating or non-participating physicians may not ask Medicare patients to pay a second time for services for which Medicare has already paid
  • Charging an “access fee” or “administrative fee” that allows patients to obtain Medicare-covered services from medical practice may constitute double billing
  • It is legal to charge patients for services that are not covered by Medicare

• Physicians who have opted-out of Medicare
  • May charge for “access” and “care coordination”
  • But, must comply with opt-out contract rules
Case Example of a Physician Violating an Assignment Agreement by Charging Beneficiaries Extra Fees

- A physician paid $107,000 to resolve potential liability for charging patients, including Medicare beneficiaries, an annual fee. In exchange for the fee, the physician offered: (1) an annual physical; (2) same- or next-day appointments; (3) dedicated support personnel; (4) around-the-clock physician availability; (5) prescription facilitation; (6) expedited and coordinated referrals; and (7) other amenities at the physician’s discretion. The physician’s activities allegedly violated the assignment agreement because some of the services outlined in the annual fee were already covered by Medicare.
- Private reimbursement compliance issues
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

- 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

- 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 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.

Private Contracting/Opting out of Medicare

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

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IMPROPER REMUNERATION

Anti-Kickback Statue and Stark
OIG MATERIALS ON ANTI-KICKBACK

Private Medical Practices Doing Vendor 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
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.
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.
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?

James J. Eischen, Jr., Esq.
Office: (619) 819-9655
Email: eischenj@higgslaw.com
Skype: jeischenjr
http://www.higgslaw.com
DIRECT CONCIERGE PRACTICES:
STATE LAW INSURANCE ISSUES

Jack Marquis
Warner Norcross & Judd LLP

May 28, 2014

jrm@wnj.com
616.396.3054

85 East 8th Street
Holland, MI 49423
Two Kinds of Concierge Practices

Fee for Non-covered Services (MDVIP style)

“Direct” Practices (Fee for Care)
Fee for Non-covered Services (MDVIP style)

Not charging flat sum for “fortuitous” medical care
Direct Practices

Charge flat sum for all medical care physician can provide
Elements

1. Payments by patient directly to Dr.
2. Dr. opts out of Medicare
3. Dr. does not bill insurance (or patients for visits)
History

$MD^2$ 1996 - $18,000

Qliance - $60 +/- @ month
Advantages of Direct Practices

Predictable cash flow
Few billing problems
Fewer employees
Fewer patients
Legal Issue

Insurance Question

A State Law Issue
What is the Legal Issue?

New York Case – Dr. Muney
Insurance = transfer and spreading of risk
Political Dimension

**Washington**
Wash. Rev. Code Sec. 48.44.010 (2007)

**West Virginia**

**Oregon**
Senate Bill 86, 2011. ORS 731.036

**New York**

**Maryland**

**Utah**
31A-4-106.5, Utah Insurance Code
Important “Insurance” Elements of Patient Agreement
Define extent of medical care
Payment in arrears
Termination at any time
Specify it’s not insurance
Limit number of visits [?]
What to do?
Internet search of AG and Ins. Com.
Don’t ask, don’t tell, just inquire
Explain risk to client
“Walk-like-a-duck” Phenomenon

Use of Terms
- “covered”
- “benefits”

Where do direct patients come from?
- Employers?

Offer as part of insurance package?
Conclusion

Jack Marquis
Warner Norcross & Judd LLP
jrm@wnj.com
616.396.3054