2016 Georgia Concierge Medicine Assembly

Regulatory Update: Managing Legal Landscape Tension

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Atlanta Marriott Century Center
Atlanta, Georgia
"Preventive medicine and public health are harder to incentivize. Patchy access to insurance can leave emergency rooms clogged with chronic conditions. Obesity and mental illness often go entirely untreated. Though the system fosters excellence and innovation in places, the messy combination of underinsurance and over insurance has left the US with the highest healthcare costs in the developed world and some of the worst overall health outcomes."

[Source: https://www.theguardian.com/society/2016/feb/09/which-country-has-worlds-best-healthcare-system-this-is-the-nhs]

The push towards value-based reimbursement plans are evolving.
## Total Professionally Active Physicians As Of April 2016

<table>
<thead>
<tr>
<th>Location</th>
<th>Primary Care Physicians</th>
<th>Specialist Physicians</th>
<th>Total</th>
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<tr>
<td>United States</td>
<td>434,840</td>
<td>473,668</td>
<td>908,508</td>
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http://kff.org/other/state-indicator/total-active-physicians/

Doctors Are Burned Out By Busywork: Study

General Legal Considerations:

- Topic #1: Medicare Compliance Versus Opt-Out Requirements (Managing Medicare Assignment, Fee For Non-Covered Service Versus Opt-Out Models; OIG Analysis, Patient Agreement Guidance)
- Topic #2: Insurance/Consumer Protection (Marketing Promises, Capacity, Avoiding Unlimited Care Assurances)
- Topic #3: Data Protection (HIPAA & Related Federal/State Privacy Laws, 42 CFR Part 2 for Addiction Treatment)
- Topic #4: Business Practices (Stark/Referral, Incentivization)
A Very Short History of Private Direct Medicine

- Late 1990s In Washington/Florida: Qliance, MD2, MDVIP
- Low monthly fees for essential primary care versus higher monthly/annual fees for more high-touch "concierge" care
- Administrative "MSO" regional/national models (MDVIP, Concierge Choice, Signature MD, Cypress, Special Docs, etc.)
- Since late 1990s: i) Opt Out Of Medicare; or ii) Allocate Private Fees To Services Not Covered By Medicare
- Fee For Non-Covered Service Model: Medicare Compliant (If Done Correctly)
A Very Short History Continues . . .

- Private Direct Medicine: Fee For Service Is Broken, Undercompensating Primary Care, Delaying Intervention Until Proven Need = Expensively Delayed Healthcare
- Medicare & Private Plans:
  - Reforming Toward Disconnecting Care From Fee For Service
  - Trying To Better Compensate Primary Care
  - Enabling Care Coordination & Patient Connection
  - Struggling To Get It Right?
- Private Direct Medicine: Remains Relevant & Workable Now
Branding Categories: i) DPC; ii) Concierge; and iii) “Brand X”? (Technology/Health Coaching/Admin)

All 3 Brand Categories:
  - Collect Private Fees In Addition To Plan Dollars
  - If Medicare Participatory: Structured As Fee For Non-Covered Service

Examples: DPC: Nextera; Concierge: MDVIP; Other: OneMedical/Iora
Categories Of Private Direct Medicine Models: Plan Integration

- Plan Integration Categories:
  - Medicare Participatory (Nextera, MDVIP, Iora, OneMedical)
  - Medicare Opted-Out (Access Health, Qliance)
- Private Plans?
Medicare Participatory Practices: Frequently Private Plan Integrated (In-Network)
  - PPO
  - Not HMO (Unless Pure Tech/Patient Education Model)
  - Not Medicaid

But Some Medicare Participatory Practices Stay Private Plan Out Of Network
Private Direct Medical Practices: Two Versions

- Opted Out of Medicare/Outside of Plan Network
- Medicare Participatory (& Possibly In-Network)
Lower Admin/Overhead By Avoiding Plan Billing?
But: Participatory Practices % Of Gross Revenue From Plans: 10%–25% (Real Dollars, Net Of Billing Expenses & Profitable)
Virtually All Patients Are Plan Integrated Even When Physicians Elect Otherwise
Carefully Analyze Needs And Plan Integration . . .
So, you want out . . .?
During the opt-out period:

- Except for emergency services, services provided only through private contracts.
- Do not submit a claim to Medicare for any service furnished to a Medicare beneficiary.
- Do not receive direct or indirect Medicare payment for services to Medicare beneficiaries privately contracted.
- A patient who has not entered into a private contract and who requires emergency services may not be asked to enter into a private contract.
- Affidavit is binding.
No Billing Medicare When Opted-Out

- Opt-Out Status Follows Physician, Not Tax ID/Entity
- Cannot Work For Medicare Reimbursed Services
- Be Very Cautious About Moonlighting/Locum/Part-Time: Safest To Presume Not Possible As Opt-Out (But, As More Practices Opt-Out, Opportunities To Work For Opted-Out Practices May Increase)
- Annual or Monthly Fees: May Not Be Submitted To Medicare/CMS
Affidavit in accordance with §40.9, 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
All private contracts are null and void.
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.
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.
Opted-Out Patient Agreements

- Must include specifically mandated terms for opted-out physicians.
- Must maintain opt-out compliant written agreements with all Medicare Eligibles.
- Recommendation: Use one version for all patients.
Ensure All Opt-Out Mandated Terms Are Included
Avoid Promising Emergent Care Services (*furnished within 12 hours in order to avoid the likely onset of an emergency medical condition*)
Assume All Patients Medicare Eligible (Carving Out Not Feasible)
Use Personalized Opt-Out Compliant Patient Agreements With All Patients
Avoid “One Size Fits All” Agreements & Marketing
MACRA & Other Opted–Out Time Frames

- Opt–Out Windows
- First Time vs. Ongoing
- Two Years Mandatory
- Cannot Rescind (Exception: First Time/90 Days)
- Automatic Renewal (For Another 2 Years – Calendar Your Possible Medicare 30–Day Return Window!)
Opted-Out & Mixed Models

- Possible To Combine Opted-Out Physicians With Participatory Physicians?
- Consult Competent Healthcare Counsel To Structure Properly!
Medicare Participatory Models: Must Private Direct Physicians Opt Out? No!

- Not All Opt–Out!
- Roughly 80% Of All Private Direct Practices (DPC & Concierge & Tech Solution) Remain Medicare Participatory
- Orthodoxy Versus Practicality--Weighing Pros & Cons
- Significant Numbers Of Physicians Cannot Easily Opt–Out
- Since Late 1990s: Fee For Non–Covered Service Generally Lawful, Low Prosecution Rate & Compliant With Proper Guidance
- Beware Of Simplistic Legal Guidance On This Issue!
So What Exactly Is “Fee For Non-Covered Service”?  

- Charging Private Fees For Services Not Covered By Medicare: Lawful  
- Q: Can You Give Me a List of All Non-Covered Services?  
- Q: Can’t You Just Give Me a National Form Patient Agreement For This?  
- The Real Question: What Do You Want To Do For Patients Regardless Of Plan Reimbursement Requirements? You Design The Care System!
HHS/CMS Describes Lawful “Concierge Care”

https://www.medicare.gov/coverage/concierge-care.html

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As of November 2015: “Medicare law excludes from coverage routine foot care, routine physical checkups, and services that are not reasonable and necessary for the diagnosis or treatment of an illness or injury or to improve the functioning of a malformed body member.”

Routine physical and services not medically “necessary” remain outside Medicare coverage.

Basically: Pre–Condition Care & Check–ups.

Fee For Non-Covered Service: The “Safe Harbor”?

- No official or formal “safe harbor” but . . .
- The routine regardless-of-condition exam = an ongoing compliant FFNCS solution
Other Non-Covered Services?

- Communication Directly Related To Non-Covered Services
- Integrative/Complimentary/Functional Medicine (Watch "Integrating" Integrative With Science-Based Medicine)
- Services/Exams In Excess Of Plan Frequency/Restrictions
- Patient Education
- Technology Subscription
Why Should I Create A Fee For Non-Covered Service Practice?

- Cannot Feasibly Opt Out
- Willing To Integrate With Plans (Plan Revenues)
- Safe/Compliant Since Late 1990s (If Structured And Marketed Properly)
How Do I Create A Fee For Non-Covered Service Practice?

- First: Identify Medical & Other Services You Believe In & Want To Deliver To Your Patients
- Second: Identify Aspects Outside of Medicare Coverage
- Third: ALLOCATE Private Fees To Strictly Non-Covered Services & Bill Plan(s) For Covered Services
How Do I NOT Create A Fee For Non-Covered Service Practice?

- Figure out all possible non-covered services, insert into that into patient agreements, then market and do whatever you want.....
- Find a colleague who created a similar practice, and copy verbatim their agreement and marketing (gee, I saved $, or did I?)
- Focus on how to make more money rather than what is superior patient care
- White-knuckle it (I hear this is a low prosecution priority....)
- Purport to carve-out Medicare eligibles (No one over 64? Kicked out on their 66th birthday?)
- DON'T DO THESE! (You'll make an attorney too much money . . . )
What Does OIG/HHS Think Violates Medicare Assignment?

- "Access" Fee For Privilege Of Seeing Medicare Participatory Physician (That Is What Their Taxes Covered)
- "Care Coordination" (Becoming More Covered)
- "Home Visits" (Covered When Medically Necessary)
- "More Time" (Covered When Medically Necessary)
- Communication Without Allocation (Electronic Communication To Schedule Or Follow-Up A Covered Visit/Services = Covered)
- Combining Covered & Non-Covered Services Without Careful Allocation
Compliance Lessons: Three OIG Alerts
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.
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.
In 2013, a practice in South Carolina agreed to pay $170,260 for allegedly violating the Civil Monetary Penalties Law. The practice implemented a mandatory non-allocated “admin fee” for forms, other services not reimbursed by plans. OIG alleged that the medical practice knowingly presented or caused to be presented to Medicare beneficiaries requests for payment that were in violation of Medicare assignment.
Lack of precision with covered versus not covered services

Potential disconnect between patient agreements/marketing and actual practice functions

Poor message control

Potential lack of competent legal guidance

But the good news: compare three prosecutions since late 1990s versus virtually any other healthcare regulatory issue.... (HIPAA, Medicare fraud, plan over billing, improper business practices, etc.)
Watch Out For These Marketing Messages . . .

- “24/7 Access” (Needs Better Clarification).
- “Annual Wellness Visit/Exam” (Sounds Like AWV = Covered).
- “You Can Use Your HSA/FSA” (Don’t Give Tax Advice Or Promises).
- “Coordination With Your Specialists And Hospitalization” (Bundled/Covered?).
- “Avoid Co-Pays & Deductibles!” (Incentive).
Patient Agreements: The Basics

- Assume All Patients Medicare Eligible (Carving Out = Not Feasible And Not Recommended)
- Implement Personalized And Compliant Patient Agreements With All Patients
- Then, Ensure All Marketing, Staff Messaging and Patient Agreement Are All Consistent & Compliant
How to Structure Medicare-Participating Private Direct Medicine Models

Drafting Recommendations: Patient-Physician Contract

- Duration/termination, fair refund policy.
- Renewal (automatic renewal vs. termination?).
- Disclaim insurance/Medicare reimbursement for private fees.
- Confirm: Will bill Medicare for covered services (if Medicare participatory).
- Accurate and compliant marketing materials.
- **AVOID PROMISES YOU CAN’T KEEP.**
How To Structure Medicare-Participating Private Direct Medicine Models

- Easy-to-read contract
- Clarity on key issues
- Navigate state insurance/consumer issues
- FAQs and brochures for amenity details, contract for compliance clarity -- be consistent!
Covered Services Will Continue To Evolve

Private Fees For Routine Regardless Of Condition Exams/Checkups/Physicals; Patient Education; Extra-Plan Interaction & Enhanced Communication Connected To Non-Covered Services = Continue To Be Lawful Non-Covered Services

BUT: Watch Plan Reforms
Medicare Reforms

- What’s Coming?
- How Will Reforms Impact Fee for Non-Covered Service Brands/Models?
Good news: Medical practices may avoid substantial MIPS burdens while remaining Medicare participatory.

Summary of Merit-Based Incentive Payment System (MIPS)


American Medical Association
Expect Medicare to soon announce that it will start paying physicians for having advanced-care planning conversations with patients.

Last year, the American Medical Association developed billing codes for these consultations to nudge CMS toward reimbursement.

CCM 99490

48 Hours After Hospitalization

Expect Further Expansion Of Care Coordination Coverage

Don’t Depend On Care Coordination As Key Private Fee Amenity!
MACRA Timeline?


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Assume All Patients Are Medicare Eligible & Comply With Federal Requirements

Patient Agreements & Marketing: Stylize & Know Your Personalized Offering

Medicare & Plan Reforms: Evolving! Check Annually With Experienced Counsel to Ensure Private Fees Outside Coverage

The Future: Can Public Plans Create An Effective Value-Based Reimbursement Marketplace?

Private Direct Medicine: An Accountable Physician Incentivized By Outcome To Track Patients & Care Coordinate With Patient Investment Into A Truly Transparent Health Marketplace: That Sounds Pretty Good!
Topic #2: Consumer Protection/Insurance
STATE LAW INSURANCE ISSUES (REGardless OF OPT–OUT STATUS)

- **Avoid** appearance (or reality) of insurance
- **Why?**
  - Lack of adequate capitalization
  - Lack of registration
  - State law violation of insurance regulations
- **Accurate marketing & supportable patient promises**
- **Look for potential state regulations that may apply**

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Watch Out For . . .

- Promises of Unlimited Care For Flat Fees: Indemnity/Insurance?
- Promises of Care Availability Beyond Actual Resources – Avoid!
- Private Fees Allocated To Electronic Records Access (Federal & State Law Mandates/Charge Limits)
Can I Charge For Patient Access To Electronic Health Records?

- Patients entitled to a copy of their electronic medical record in an electronic form.
- When individuals pay by cash they can instruct their provider not to share information about their treatment with their health plan.
- New limits on how information is used and disclosed for marketing and fundraising purposes.
- Prohibits the sale of an individuals’ health information without explicit permission.
- **MUST ONLY CHARGE ACTUAL COSTS**

HHS.gov
U.S. Department of Health & Human Services

Topic #3: Data Protection: IT Matters
HHS Reports Huge Increase In Hack Data Breach Incidents

Note: *a non-hacking/IT incident includes all other types of reported health information breaches: theft, loss, improper disposal, unauthorized access/disclosure, other, or unknown (not reported or data missing). See notes below for types of IT and devices involved in these incidents.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA)
Electronic personalized health information
HIPAA Privacy Rule and the HIPAA Security Rule
Office for Civil Rights (OCR) enforcement
HIPAA: Did I Escape?

- No: All Private Direct Care May Intersect With Plan Reimbursement
- Federal & State Laws Generally Mandate Privacy Protection Anyway (Ex: States Laws, FTC)
- Therefore: Please Comply With HIPAA!
Basic HIPAA Compliance Documents

- Notice of Privacy Practices (NPP)
- Business Associate Agreement (BAA)
- Internal Risk Analysis Memo
  - Written internal procedures and processes for ePHI
  - Evaluate risks, adopt reasonable standards
  - Update!

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HIPAA Requires Safeguards When Texting or Emailing PHI

- Privacy Rule requires covered entities to implement appropriate safeguards when emailing or texting e- PHI to patients
- Security Rule requires covered entities and business associates to encrypt e- PHI when transmitting it is “reasonable and appropriate” or document why not
- Warn the patient of unsecure communication if patient wants to use unencrypted emails (78 FR 5634)
- RULES DO NOT APPLY TO EMAILS OR TEXTS FROM THE PATIENT

http://www.hhs.gov/ocr/privacy/hipaa/faq/health_information_technology/570.html
http://www.lexology.com/library/detail.aspx?g=ec4f9322-649d-4357-bab4-c80b2ce7ebc8
In addition to HIPAA – 42 CFR Part 2
Watch Privacy Rights For Addiction Treatment Patients: Variations With HIPAA
○ Consent Terms
○ Records Retention
○ Authorizations Needed for Disclosures
Private Direct Practices Frequently Involve Enhanced Electronic Communication

- Be sure to enact privacy protocols (password encryption)
- Use a separate electronic communications agreement to manage & mitigate risks & achieve meaningful consent
Topic #4: Business Practices
Can I Escape Federal & State Laws Barring Incentive & Referral?

- Probably Not: All Private Direct Care Can Intersect With Public Plan Care
- Referral & Incentive Law: Intended To Protect Medical Judgment From Financial Distortions
- Business & Compensation Deals: Get Competent Healthcare Counsel To Properly Structure
May not “incentivize” healthcare:
  - No free toaster oven
  - Do not market “avoiding co-pays and deductibles”
  - Can I discount? Ad hoc, based on situations vs. marketed policies?

Do not financially induce utilization
Private Direct Medicine: Future Trends

- Expanding Medicare Plan Care Coordination: CMS Could Make You An Offer You Can’t Refuse! Combining Care Coordination With Private Market Amenities: Possible!
- Integration Of Rapid Communication/Tech/Genomic Advancements Into Primary Care: Plan Or Private Fee?
- **Both!** Plans Alone Cannot Implement Care Innovation.
- Private Health Market And Plans: Seek Integration.
- U.S. Healthcare: Unique Mixture of Public & Free Market Features, We Need Both!
Questions?

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