DIRECT PRIMARY CARE Summit

AMERICAN ACADEMY OF FAMILY PHYSICIANS

FAMILY MEDICINE EDUCATION CONSORTIUM, INC

acofp American College of Osteopathic Family Physicians

DPC Practices: Formation Options & Compliance Solutions

James “Jim” Eischen, Jr., Esq.

Learning Objectives

- Analyze alternatives/options that private direct practices have regarding plan integration versus out-of-network/opted out of Medicare, and provide guidance how on best to weigh those alternatives.
- Overview the federal (and typically also state) laws that generally protect privacy, and specifically apply to health information privacy, and explain why engaging in solid HIPAA compliance remains both responsible and necessary.
- Describe the current shifts in US healthcare regulation, and provide insight into anticipated future regulatory changes based on the current political climate and how those changes may impact/help DPC practices.

Activity Disclaimer

The material presented here is being made available by the DPC Summit Co-Organizers for educational purposes only. This material is not intended to represent the only, nor necessarily best, methods or processes appropriate for the practice models discussed. Rather, it is intended to present statements and opinions of the faculty that may be helpful to others in similar situations.

Any performance data from any direct primary care practices cited herein is intended for purposes of illustration only and should not be viewed as a recommendation of how to conduct your practice.

The DPC Summit Co-Organizers disclaim liability for damages or claims that might arise out of the use of the materials presented herein, whether asserted by a physician or any other person. While the DPC Summit Co-Organizers have attempted to ensure the accuracy of the data presented here, these materials may contain information and/or opinions developed by others, and their inclusion here does not necessarily imply endorsement by any of the DPC Summit Co-Organizers.

The DPC Summit Co-Organizers are not making any recommendation of how you should conduct your practice or any guarantee regarding the financial viability of DPC conversion or practice.

Faculty Disclosure

It is the policy of the DPC Summit Co-Organizers that all individuals in a position to control content disclose any relationships with commercial interests upon nomination/invitation of participation. Disclosure documents are reviewed for potential conflict of interest (COI), and if identified, conflicts are resolved prior to confirmation of participation. Only those participants who had no conflict of interest or who agreed to an identified resolution process prior to their participation were involved in this CME activity.

All faculty in a position to control content for this session have indicated they have no relevant financial relationships to disclose.

The content of this material/presentation in this CME activity will not include discussion of unapproved or investigational uses of products or devices.

Integrating Business & Law Into 21st Century US Private Direct Practice Models

James J. Eischen, Jr., Esq.

- Jim Eischen is a California attorney with nearly 30 years of experience representing commercial interests locally, nationally, and internationally. His clients have included life science companies, national healthcare enterprises, medical groups/physicians, software/IT companies, health plans, industrial enterprises, financial institutions, real estate developers/managers, and telecommunications conglomerates. He has extensive experience managing all facets of business representation, from formation to contractual relations and managing disputes and transitions.

- Since 2009, Jim has worked with clients in matters involving health care and privacy licensing and regulatory issues, including Medicare compliance and physician compensation and private direct fee business modeling and compliance. Jim has experience structuring physician practice purchase and employment structures, and assisting companies delivering wellness products or programs, to ensure reimbursement and privacy compliance.

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

- Professional Memberships: Professional Memberships: Chair, ABA Tort Trial & Insurance Practice Section Medicine and Law Committee, Vice-Chair, TIPS Health and Disability Insurance Law Committee, Dispute Resolution Committee, San Diego County Bar Association Law & Medicine Section, Attorney-Client Relations Committee, American Academy of Family Physicians healthcare compliance educator, American Academy of Private Physicians corporate secretary and chair of the Legal Compliance Committee.

Topics We Will Cover Today

- Private Direct Medicine Models: What's Out There?
- Private Direct Medicine Model Formation: Quick Primer & Options
- The "Fork" In The Road: Plan Integration (or Disintegration)
- Practice Amenity Pricing (Please, Not Fee For Service Again!)
- Data Privacy 101: Compliance Solutions
- Business Dealings: Identifying Compliance Issues

Private Direct Medicine Models
What's Out There?

- Private Direct Medicine Models

What's Out There?

Model 1: Fee For Non-Covered Service (Medicare Participatory)

- “Concierge” Branded
- “Direct Primary Care/DPC” Branded
- “Functional Medicine” or “Integrative” (or “Cash”) Branded
- Connected Care (or “none of the above….”)

Fee For Non-Covered Service Models
If Medicare Participatory:

- Allocate private patients fees to only those services NOT covered by Medicare
- Bill Medicare for what Medicare covers
- If private plan in-network: may bill private plans for what those plans cover (and may bill plans as out of network)
- Examples: MDVIP, Cypress, Concierge Choice, Special Docs, Nextera (and many integrative/FM practices….)

So, What Is Not Covered By Medicare?

- Annual routine regardless of condition physicals (or “checkups”) not delivered based on medical necessity
- Integrative or “Complimentary” services—remain outside Medicare (if not bundled with allopathic covered care)
- Exams or tests or services in excess of Medicare frequency or requirements
- “Health coaching” or “health data support” or software/platform subscriptions—basically services that do not constitute healthcare
- Communication services/amenities directly connected to non-covered services

What Does Medicare Cover That Might Surprise Me?

- Expanded Care Coordination (includes electronic communication)
- CCM/Chronic Care Management—separate written patient agreement no longer required (includes electronic communication)
- 24/7 electronic communication that may include communications to schedule or follow-up covered services
- “Access” to Medicare participatory physicians: can’t charge an “access” fee

Anticipated Medicare Coverage Expansions

- CCM/9940: only 1% US adoption despite favorable reimbursement per GAO
  - anticipate further expansion with easing regulations
  - worth evaluating & may be compatible with private direct models
- MIPS/MACRA: anticipate further delays with roll-out
- Telehealth: unlikely to significantly expand in 2017/2018, still focusing on rural health
- Fee For Service: rapid evolution to bundled reimbursement may slow with US healthcare regulatory confusion and new HHS leadership

Can't I Just Charge Medicare Eligibles One Price, And Non-Eligibles Whatever I Want?

- No
- Carve-Outs: OIG disfavors
- Happy 65th Birthday/Happy 62nd Birthday (early Social Security elector)/Sorry About Your Disability/Sorry About Your End Stage Renal Failure: You're Kicked Out Of My Cash Practice?

Model 2: Medicare Opt-Out/Cash
(Free At Last??)

- Must formally Opt Out
- Often “DPC” or “Direct Primary Care” (And some integrative/FM and “concierge” branded practices)
- Sometimes branded “Cash”
- Examples: Access Health, MedLion, MD2 (concierge), most DPC-branded practices

Medicare Opt-Out/Cash Models

- Allocate private fees to virtually all healthcare, no allocation needed to avoid Medicare assignment violation
- But: must take care to avoid allocating private fees to emergent or urgent healthcare (still covered)
- Watch opt-out requirements (quarterly windows to opt out)
- Watch opt-back requirements (window every two years)
- May not provide services billed to Medicare

What about Medicaid and HMO?

- Cannot opt out of Medicaid
- State laws generally prohibit added patient fees for healthcare provided to HMO/Medicaid eligibles
- “Connected Care” may work…….

Do Your Patient's Want Electronic Communication?

- YES!
- They can't live without their mobile devices

"I already diagnosed myself on the Internet. I'm only here for a second opinion."

Connected Care: Not Branded “Concierge” or “DPC” But Charging Added Fees

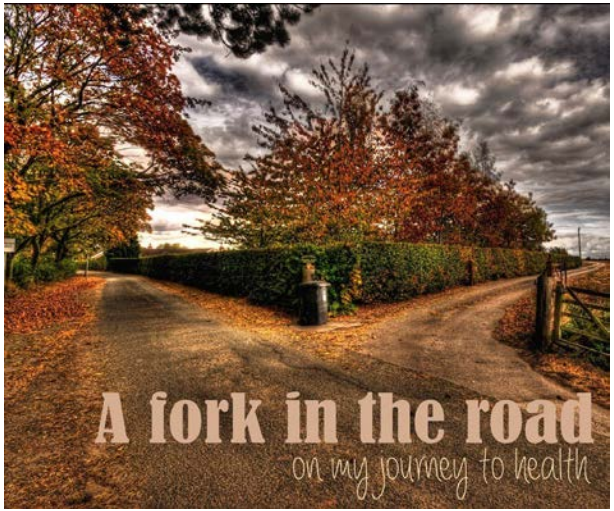
- Medicare/plan participatory
- Not “concierge” or “DPC” branded
- Allocate private fees to “not healthcare” such as health coaching, technology services, online platform/communication system subscription
- Examples: IORA, OneMedical, Arivale (not practicing medicine, pure genomic testing plus health coaching)
- Medicaid & HMO eligibles may participate

The Future: All Of The Above

- Concierge and DPC growth should remain steady & upward
- Connected Care: poised for strong growth (healthcare tech investment, scale, broader solutions)
- Employer-funded solution: expected to grow

To Sell Healthcare or Something Else?

- Another fork in the road
- Employer Funding
- HSA/FSA/HRA?



HSA/FSA/HRA & Employer Funding

- I.R.C. § 167(d) & Pub. 502
- Physicals
- Diagnostic Services
- Health Data Plan?
- NOT: Concierge or DPC branded models
- ERISA? IRC/ACA?

HSA/FSA/HRA: What's Possible?

- Tracks IRC Section 167(d) and IRS Publication 502
- Watch out for "wellness" versus "diagnostic" health services
- Take care with marketing messaging: you can unintentionally frustrate HSA/FSA/HRA eligibility
- Strongly consider helping patients utilize these fund sources

Private Direct Practice Formation: Compliance Primer

- How do I form a compliant private direct medical practice?
- How NOT to do it:
  - Use the internet and copy what others do….(there are a lot of non-compliant models out there….)
  - Purchase or borrow forms from another practice or colleague (significant risk of error/non-compliance….)
  - Carve-out the Medicare eligible ☹
  - Go dark and hidden without billing Medicare: same as opting out, right? (No!)
  - Promise unlimited care for flat fees (insurance and consumer protection issues triggered)

OK, What's The Right Way?

- Ignoring all plans: What is Your Personal Vision Of The Healthcare YOU Want To Deliver?
- Forget $ or plan requirements: think science, medicine, personal healthcare theories: what is your dream scenario?
- Determine if your vision of healthcare can be packaged as outside Medicare coverage (the fork in the road)
  - If yes, proceed to form a proper fee for non-covered service model
  - If no, opt out of Medicare if otherwise feasible
- In either scenario: ensure the patient agreement and marketing carefully personalized and packaged
- Consider Consultants/Expert Guidance on:
  - Marketing
  - Finance/Management

Why The Medicare Fuss?

- Medicare Assignment
- CMP
- Three OIG Alerts

Can’t I Just Opt Out And Do What I Want?

- Watch state law issues!
- State insurance laws (does DPC practice fit state statute definition of DPC?)
- State consumer protection
- Medicaid/HMO
- Medical records access fees: watch out

Plan Alert!

Plan Integration Versus Disintegration: Navigating That Fork In The Road

- Medicare opt-out feasibility: good for some, good for everyone?
- Medicare and private plan revenue: does your business plan reflect you don’t need any plan reimbursement?
- Medicare and private plan requirements: balancing act, not for everyone

Amenity Pricing & Marketing

- Pricing as a behavior modifying factor
- Pricing as identifying you and your product
- Is your pricing replicating “fee for service?” (hope not)
- Marketing content: view from patient/consumer perspective
- Amenity descriptions: does it make sense to the patient/consumer?

Pricing & Marketing

- What patient/consumer behavior am I trying to encourage or discourage with my pricing model?
- What does my pricing tell my community, peers, and consumers regarding the value of what I offer?
- How does my marketing express concepts that I could substantiate with evidence, versus claims intended to drive sales without support?
- Does my marketing educate the consumer about better options, hidden values, potential significant benefits?
- Does my marketing tell my story, or, does my marketing invite the consumer into a better version of their story?

Data Privacy: Great Expectations (& Significant Risks)

- Consumers want privacy protection, particularly with health records
- Many federal and state agencies focusing on data privacy regulation/enforcement
- HIPAA: can we just say it does not apply to me? NO! ☹

Why Can't I Forget About HIPAA?

- Your care may interconnect with federally paid healthcare
- State and federal agencies generally expect healthcare providers to comply with HIPAA
- State and federal laws generally imitate HIPAA

Business Regulatory Compliance: Watch Out For…..

- Referral compensation
- Sending patients/consumers to business that you/family own
- Excessive marketing on “discounting” or providing items of value in exchange for joining your practice/model
- Corporate practice of medicine/CPOM

Gazing Into The Crystal Ball-The Future?

- US healthcare plan confusion and political discord (but....possibility new US consensus shifts the debate?)
- The plans: trying to plan ahead with little certainty, but meanwhile focus on population management
- CPOM weakness, need for business enterprise funds to promote health tech solutions
- Defining what is "healthcare" or "medicine" challenged by AI, treatment guidance, patient data empowerment--a more diverse array of "providers" with more tech/ehealth probable
- Continued demand for ehealth/tech solutions: DPC can be tip of that spear!
- With US healthcare and plan uncertainty: consumer/patient/employer private fee funding must drive innovation

Questions?

Contact Info:

JAMES "JIM' EISCHEN, ESQ.

MCGLINCHEY STAFFORD

18201 Von Karman Avenue, Suite 350

Irvine California 92612

D: 949-381-5925

F: 949-271-4040

E: jeischen@mcglinchey.com

Twitter @JimEischenEsq

Submit your questions to: aafp.cnf.io