Let's talk Legal:
Compliance Framework for New DPC Practices

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Participate in polling questions and submit your questions to: https://aafp4.cnf.io/

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Learning Objectives

At the end of this educational activity, participants should be better able to:

- Understand the development of DPC practices and the laws which govern it.
- Describe the fundamental legal requirements for a DPC practice.
- Identify the emerging issues in DPC practice and corresponding proactive responses to each.

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I am…

a) Interested in starting a DPC practice
b) Planning to start a DPC practice
c) Transitioning to DPC from traditional practice
d) Already operating a DPC or hybrid practice
e) Got stuck in here by accident, I was looking for pie

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Live Content Slide

When playing as a slideshow, this slide will display live content

Poll: I am…

I am presently (or was before starting DPC):

a) A resident or just out of residency

b) Employed by a health system, academic medicine or large group

c) Operating a traditional practice

d) Other

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Live Content Slide

When playing as a slideshow, this slide will display live content

Poll: I am presently (or was before starting DPC):

I am presently (or was before starting DPC):

a) Considering DPC

b) Planning to start a DPC practice

c) Planning to transition my existing practice to DPC

d) Already own, or am working in, a DPC practice

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Live Content Slide

When playing as a slideshow, this slide will display live content

Poll: I am presently (or was before starting DPC):

In The Beginning . . .

- 2003 in West Virginia Dr. Vic Wood offers direct pay primary care
- Advertises $83 per month per individual, $125 per family
- State insurance commissioner - itchin' for a fight
- Warns Wood that he's running an illegal insurance business- it's a felony worth up to 5 years in prison. – tells him to stop
- Instead Wood pushes for DPC pilot legislation

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2006 - Be Careful What You Wish For

Legislature Passes 3 yr. DPC pilot project. DPC is legal but-

- Insurance Commissioner and Health Care Authority have oversight
- Separate license for preventive Care Pilot
- HCA has to approve monthly charges
- Can only market to those without insurance or with HDP
- Excessive reporting requirements

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. . . Meanwhile up in Washington

- Dr. Garrison Bliss (Qliance) was having his own misery with his state insurance commissioner
- Dr. Bliss was told that he too was running an illegal operation and warned to stop
- Declining the invitation Bliss successfully cajoled the Washington Legislature to pass legislation clarifying that DPC is not insurance.
- The resulting statute not perfect but improvement over W.V.

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Washington Statute

- Gives insurance commissioner oversight
- Contains registration and reporting requirement
- But specifies that direct practices are not insurers
- States and fed will take cues from WA law in future legislation

Washington State Definition of DPC Practice

1) Written Agreement

2) Provides primary care services in exchange for a periodic fee

3) Does not accept payment from insurance for services provided under agreement

3) A per visit charge < the equivalent of 1 month periodic fee

From the Ridiculous . . .

Oregon

- Must be certified and recertified annually by the Department of Consumer and Business Services
- Must provide *only primary care*
- must limit the services or the number of patients to an amount that the practice can provide in a timely manner

Oregon

- Physician must be shown to be financially responsible and to have the necessary business experience or expertise to operate the practice
- May not engage in dishonest, fraudulent or illegal conduct in any business or profession
- Disclosures- **Any other disclosures** required by the department by rule.
- No Misdemeanors involving dishonesty

. . . To The Sublime

Wyoming

A direct primary care agreement means a written agreement that:

- (A) Is between a patient or their legal representative and a health care provider;
- (B) Allows either party to terminate the agreement in writing, without penalty or payment of a termination fee, at any time or after notice as specified in the agreement which notice shall not exceed sixty (60) days;
- (C) Describes the health care services to be provided in exchange for payment of a periodic fee;
- (D) Specifies the periodic fee required and any additional fees that may be charged;
- (E) May allow the periodic fee and any additional fees to be paid by a third party;
- (F) Prohibits the provider from charging or receiving additional compensation for health care services included in the periodic fee; and
- (G) Conspicuously and prominently states that the agreement is not health insurance and does not meet any individual health insurance mandate that may be required by federal law.

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Problems

- Failure to distinguish DPC from Concierge
- Conflicting provisions
- Providing an exclusive list of reasons that a physician can terminate a patient
- Limiting the type of specialties allowable
- Limiting the scope of services

Preliminary Legal Issues and Considerations In Starting a DPC Practice

Restrictive Covenants

- Prohibited in California, Delaware, Massachusetts, Montana, North Dakota, and South Dakota.
- But gaining more traction in other states as health systems and physician employers consolidate
- Often possible to negotiate out of restriction with health systems looking to preserve downstream referrals
- Some success arguing that DPC is not competition for traditional mode

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Review Your Contract

Restrictions *While* Employed

- Employee shall not be permitted to be employed or perform services, including those requiring a license to practice medicine or surgery, for any employer or organization or individual unless approved by the Hospital in writing. This applies to speaking, honoraria, expert witness services, and consulting activities whether or not involving the treatment of a patient. All fees or income which Employee earns in connection with any professional services or activities, including those administrative in nature, during the term of this Agreement, other than compensation paid under this Agreement, shall belong to the Hospital and immediately upon receipt by Employee be delivered to the Hospital.

The Dreaded TRO

Physician agrees that if Physician breaches [the restrictive covenants]that Employer shall suffer irreparable harm for which monetary damages may be inadequate. Therefore, in the event of a breach or threatened breach by Physician, in addition to any other rights, remedies, or damages available , Employer shall be entitled, without having to post a bond, prove irreparable harm, or lack of adequate legal remedy, to a temporary restraining order, preliminary injunction, and permanent injunction in order to prevent or restrain any such breach by Physician or by any and all persons directly or indirectly acting for or with Physician.

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Entity Formation

PA? PLLC ? LLC? S Corp?

- Requirements vary by state
- some require professional entity
- Some allow only physicians to be members/shareholders (CPOM)
- Some require a certificate of good standing from the state medical board
- Bylaws/operating agreement- vital when more than one member/shareholder.
- It's a prenuptial agreement

Pure DPC or Hybrid?

Hybrid can work for physicians transitioning out of traditional practice and health plan panels but can be a clerical nightmare

To new start ups:
“If you give up your freedom for safety, you won’t get either one.”

– Ben Franklin

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DPC Lite

- Many physicians successful at combination DPC and cash pay
- Cash pay patients help with cash flow
- Good way to introduce new patients to the practice
- After a few visits at FFS, patients often see the value of membership
- Patients pay at time of service so no billing

Terminating Health Plan Agreements

- Most hospital systems and groups are signed at the corporate level
- Must terminate If signed on individual level
- Requirements vary by plan so review documents carefully
- Typical notice period – 60-120 days

What can the insurance company do if you don't want to wait?

Please Don’t Throw Me in That Briar Patch!!

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Opting Out of Medicare

Legal Effects

- Mandatory two years before physician can opt back in
- Cannot bill Medicare for any services personally provided by physician
- Neither physician, nor any entity to which physician reassigns billing rights may receive payment physician's services.
- All in or all out

So . . .

NEVER

NEVER

NEVER

Allow another entity to bill Medicare for your services

Opt Out Properly

Failure to properly opt-out can result in nullification of all private contracts, a return of all funds for covered services, potential sanctions and civil monetary penalties.

Two necessary documents:

- Opt Out Affidavit
- Private Contract for Beneficiaries

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Opt Out Process

- Must file a valid opt out affidavit with all relevant MAC's
- In order to order, refer, and prescribe, SSN and NPI *must* be on the Opt Out Affidavit (they won't necessarily warn you)
- Must keep a Private Contract with all beneficiaries on file and available for each two year period.
- Non-Par – anytime Non-Par- must be filed by the first day of the month before quarter you want the opt out to be effective

Moonlighting For Opted Out Physicians

- Employer- onsite primary care- employer financed
- OC Med – WC Paid somehow or another by employers
- Correctional Facilities- paid for by the county, state or federal govt.
- VA- may bill supplemental insurance but do *not* bill Medicare
- ER
- Urgent care

ER and Urgent Care

- “If the services are emergency or urgent care services furnished by an opt-out physician . . . to a beneficiary with whom he/she has not previously entered into a private contract.”
- No participating physician available
- Claims reimbursed at Medicare non-par rate
- Use CPT modifier - GJ

Definition of Emergency and Urgent Care

15 §40.29 - Congress intended that the term “emergency or urgent care services” not be limited to emergency services since they also included “urgent care services.”

Beneficiary needs care in a relatively short period of time (12 hours) to avoid adverse consequences and may not be able to find timely alternative care

Example: Ear infection with significant pain – requires treatment to avoid the adverse consequences of continued pain and possible perforation

Physician Dispensing

Significant value component of DPC

Significant benefit to patients

Dispensing controlled drugs not recommended

Barriers to physician dispensing in some states

States Unfriendly to Physician Dispensing

Texas- Limited to dispensing drugs to meet the patient's immediate needs or in rural areas.

Massachusetts -Physicians may only dispense samples

Montana- Only when a pharmacy is not available or not in usual course of business

New Jersey- Limited to 7 days

New York- Limited to 72 hours

New Mexico – for new prescriptions only, limited to 10 days

Oregon- limited to 10 days

Maryland

Only to patients under direct care who have informed the physician that a pharmacy is not conveniently available.

Physician must maintain a form in each patient's chart which at minimum shall:

(1) Indicate the reason, given by the patient that a pharmacy is not conveniently available;

(2) Include a statement signed by the patient stating that the determination that a pharmacy is not conveniently available is made solely by the patient; and

(3) Be signed and dated by the patient before dispensing prescription drugs to the patient for the first time. See COMAR 10.13.01.04."

Utah

Allowed to dispense a cosmetic drug, a cancer drug treatment regimen, injectable weight loss or a prepackaged drug at an employer-sponsored clinic (not open to the public).

Labs and Pathology

- Physician pass through billing to patients is common in DPC practices and most states allow it. Practices are able to secure substantial discounts from the labs and physicians are billed directly in bulk for the testing.
- Pathology presents more of a problem as more states put prohibitions on pass through billing

Anatomic Pathology Services

- **Direct Billing** Arizona, California, Colorado, Connecticut, Kansas (except for DPC!) Massachusetts, Nevada, New Jersey, New York, Rhode Island, Louisiana, Ohio, South Carolina, Tennessee, Indiana, Iowa, Maryland, Montana, and Washington
- **Anti-Markup** California, Florida, Illinois, Michigan, Oregon, Pennsylvania, Utah, Virginia, and Washington
- **Disclosure** Arizona, Connecticut, Delaware, Florida, Louisiana, Maine, Maryland, Nebraska, North Carolina, Ohio, Pennsylvania, Texas, Vermont, New Jersey, Tennessee, and Utah

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Kansas Exception For DPC

HB 2027

- Nothing in this subsection shall be construed to prohibit billing for anatomic pathology services by: a physician providing services to a patient pursuant to a medical retainer agreement in compliance with K.S.A. 65-4978, when the bill : (i) Identifies the laboratory that performed the services; (ii) discloses in writing the actual amount charged by laboratory that performed the service; and (iii) is consistent with Board rules and regulations for appropriate billing standards.

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Imaging

- Best to negotiate cash prices with independent center if available
- Recommend no pass through billing
- Patient pays cash to imaging center at time of service

Essential Ingredients of a Patient Agreement

1) In writing
2) Between a patient and a health care provider
3) For ongoing primary care services in exchange for a periodic fee
4) Allows either party to terminate the agreement in writing
5) Specifically describes the primary care services included under the agreement
6) Specifies the amount of the periodic fee and any additional fees
7) Prohibits the provider from billing health insurance or any other third parties for services included in the periodic fee
8) Conspicuously states that the agreement is not health insurance and does not meet any individual health insurance mandate that may be required by law

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Addressing Important Issues in Patient Agreements and Avoiding Potential Landmines

Early Termination

i. If this Agreement is cancelled by either party before the Agreement ends, We will review and settle your account as follows:

ii. We will refund to You the unused portion of your fees on a per diem basis; or

iii. If the fair market value of the Services you received over the term of the Agreement exceeds the amount You paid in membership fees, You shall reimburse the Practice in an amount equal to the difference between the fair market value of the services received and the amount You paid in membership fees over the term of the Agreement. The Parties agree that the fair market value of the services is equal to the practice's usual and customary fee-for-service charges. A copy of these fees is available on request.

Non-Participation in Insurance

You acknowledge by placing your initials at the end of this paragraph 7 of the Agreement that you understand and agree that neither the PRACTICE, nor its Physician, participate in any health insurance or HMO plans or panels and have opted out of Medicare. Further, the Practice makes no representation that the fees paid under this Agreement are reimbursable by Your health insurance—and it is the Patient's responsibility to determine whether reimbursement is available from a *private*, *non-governmental* insurance or payment plan and to submit any required billing. _____ (Initial)

Medicare

You acknowledge by placing Your initials at the end of this paragraph 8 of the Agreement that you understand and agree that **the Physician has opted out of Medicare, and as a result, Medicare cannot be billed for any services performed for the Patient by the Physician. The Patient agrees not to submit a bill to Medicare or attempt to obtain Medicare reimbursement for any such services. If the Patient is eligible for Medicare, or becomes eligible during the term of this Agreement, then s/he will sign the Medicare Opt Out and Waiver Agreement attached as Appendix 4 and incorporated by reference. The Patient shall sign and renew the Medicare Opt Out and Waiver Agreement every two years, as required by law. _____ (Initial)**

This is Not Insurance

Your initials on this paragraph 9 of the Agreement acknowledges Your understanding that **this Agreement is not an insurance plan or a substitute for health insurance. You understand that this Agreement does not replace any existing or future health insurance or health plan coverage that You may carry. The Agreement does not include hospital services, or any services not personally provided by the Practice or its staff. You acknowledge that We have advised You to obtain or keep in full force, health insurance that will cover You for and for hospitalizations, catastrophic events, and all other healthcare not personally provided by the Practice, _____ (Initial)**

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Communications

Use of e-mail, facsimile, video chat, cell phone, texting, and other forms of electronic communication can never be absolutely guaranteed to be secure or confidential methods of communications. **If you consent to the above means of communication by participating, You expressly waive the Physician's obligation to guarantee confidentiality with respect to same.** Patient further acknowledges that all such communications may become a part of the medical record.

By providing an e-mail address and cell phone number on the attached Appendix B, You authorize Us to communicate with You by e-mail or text message regarding Your "protected health information" (PHI).

Explain Extra or Optional Charges

"Patient is responsible for the costs associated with any laboratory or specimen analysis, and will be informed of the price in advance."

Although You are always free to use any pharmacy of choice, You have the option of obtaining most generic medications from the Clinic at considerably discounted prices. These are subject to an additional charge, for which You are responsible. You shall be informed of the cost in advance .

Don’t Overpromise

Physician Absence. From time to time, due to vacations, illness, conflicting obligations, or personal emergency, the Physician may be temporarily unavailable to provide the services referred to above in this paragraph one. In order to assist Patients in scheduling non-urgent visits, CLINIC will notify Patients of any planned Physician absences as soon as the dates are confirmed. In the event of the Physician’s unplanned absences, Patients will be given the name and telephone number of an appropriate provider for the Patient to contact. Any treatment rendered by the substitute provider is not included under this Agreement, but the charges may submitted to Patient’s health plan.

Temper Expectations

After Hours Access. Clinic will make all reasonable efforts to provide telephone and text access to the Physician after hours for urgent needs. Patient shall be given a phone number where patient may reach the Physician directly for guidance regarding concerns that arise unexpectedly after office hours.

Some Red Flags

- Bundling purchased goods/ services (labs, drugs) into membership fee
- Bundling cost of services from outside providers into membership fee
- Offering unlimited services (always, “when appropriate, in sole discretion of Physician”)

Avoid “Insurance” words

Don’t say this:

- Plan
- Benefit
- Covered

Say this:

- Membership
- Services
- Included

Formal Limitation on panel size?

- Maybe. Some insurance commissioners get “all unnecessary” about it – some statutes imply you need to do so
- Something to worry about? Not so clear.
- What about the HMO practices with 2,000 patient panels?
- But don’t want to be that test case

Brokers, Networks, Consultants

- Can be helpful under the right circumstances
- Be mindful of how they are paid
- Never pay a broker- state anti-kickback- CPOM- fee splitting – they already get paid
- Networks and Consultants – due diligence. Will the network control your fees, scope of services, practice policies? Restrictive covenants? Add administrative duties? Any fee splitting or CPOM issues? Do you need them?

HSA Problem

No fix yet for the long standing Health Savings Account (HSA) problems:

- The “gap plan” problem — the IRS has determined that DPC is a health plan under section 223(c)(1) of the code, making DPC members ineligible to establish or contribute to an HSA.
- The “qualifying expense” problem — assuming the Gap plan problem goes away, the question remains (and the IRS declined to decide) whether DPC periodic fees are reimbursable as qualified medical expense under 213(d).

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What to Tell Patients

- Get Guidance from your accountant or benefits manager
- Do not give definitive advice
- This is not a physician issue

Emerging Issues

- Increased Employer interest
- Medicaid and state employee pilots
- Medicare pilot

So, what's to worry about?

Medicaid and State Employee Pilot Programs

- Indiana- For any pharmacy service not covered under the direct primary care services agreement between the direct primary care services provider and the participant, **authorize the use of a drug covered only under the formulary of the respective office or managed care organization**.

  (3) **Comply with any prior authorization requirement** set by the respective office or managed care organization.

  (4) Allow the **office to have access to the participant's medical records** for the sole purpose

- Minnesota-“Under the program, patients may choose a primary care provider to act as the enrollee's case manager. Primary care physicians, nurses, and other qualified medical professionals may provide primary care case management.

Considerations

The increased interest from employers and government is great but . . .

- The danger is filling your practice with too many patient from one source
- Wants become requests, which become demands
- Data requests have *always* grown more - not less intrusive
- Too many patients from one source means you can't say no
- Deja' vu

Possible Responses

- Charge more to those who demand data and extra work
- Limit the number of patients from those sources your
- Limit the number of patients from any one source
- Question every additional task they request no matter how small
- Push back unless it makes sense to you and your practice
- Don’t be afraid to walk away

Outlook For The Future

Growth

- 26 states have DPC statutes
- 1086 known DPC practices across 48 states(https://mapper.dpcfrontier.com/
- CMS interested in DPC as an option for Medicare and CHIP
- Pilot programs established or being established in several states for Medicaid and state employees

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Rate of Growth is Steady

- 2014 125
- 2015 290
- 2016 445
- 2017 620
- 2018 840
- 2019 1086

https://mapper.dpcfrontier.com/

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Direct Employer Contracting

Employers are increasingly recognizing the value of DPC

Direct employer/physician contracting is seen by HR professionals as one of the top employee benefits trends to watch in 2019.

https://www.businessmanagementdaily.com/52353/4-key-employee-benefit-trends-to-watch

Important Take-Aways

- There has never been a better time to join the DPC movement
- Certain essential legal requirements to understand
- Compared to CMS and insurance compliance is a walk in the park
- You can do this
- Look around you at the happy smiling faces - no burn out here
- When was the last time you were in a crowd of happy docs?

Questions?

Submit your questions to:
aafp4.cnf.io

Don’t forget to evaluate this session!

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