Direct Primary Care Business of Insurance and State Law Considerations Philip Eskew, DO, JD, MBA

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Introduction

Direct Primary Care ("DPC") practices have been small and overlooked group for many years. Recent growth may gain the attention of previously tacit insurance commissioners. Laws enacted by seventeen state legislatures and the Affordable Care Act provide a background from which a legal framework can be developed. This Article will articulate "business of insurance" concerns encountered by DPC physicians, recommend contractual drafting techniques to minimize this risk, and compare state legislation designed chiefly to address this concern. The Article will also consider the DPC provisions of the Affordable Care Act, and attempt to anticipate future regulatory debates about the scope of practice of physicians using the DPC model.

A Definition & Introduction

A retainer practice model involves a contract between the physician and patient whereby ongoing primary care services are provided in exchange for a periodic fee. For the practice to qualify as a DPC practice (a subset of the retainer category) the practice must 1) charge a periodic fee, 2) not bill any third parties on a fee for service basis, and 3) any per visit charge must be less than the monthly equivalent of the periodic fee. Billing third parties on a fee-for-service basis in addition to the periodic fee is more accurately described as a fee for non-covered services ("FFNCS") model, one many consider to be a form of "double dipping." This FFNCS model is used by concierge practices such as MDVIP and SignatureMD. In a DPC practice third parties may pay the periodic fee on behalf of the patient, but traditional third party fee for service billing on those same DPC patients are not submitted. If the per visit charge were larger than the monthly fee, the practice would be considered a cash pay urgent care facility, and thus would not gain undesired insurance commissioner attention.

The DPC model was originally used by only a handful of pioneers. Garrison Bliss, MD, (of Qliance in Seattle)⁴ Vic Wood, DO, (of Primary Care One in Wheeling, WV)⁵ and Brian Forrest, MD (of Access Healthcare in Apex, NC)⁶ are the three physicians credited most with growing the DPC model in its earliest stages. DPC pioneers were present in other locations over

¹ See generally Philip M. Eskew, Direct Primary Care Membership Medicine, 110 W.VA. MED, J. 8 (2014).

² See generally P. M. Eskew & K. Klink, *Direct Primary Care: Practice Distribution and Cost Across the Nation*, 28 J. Am. Bd. of Family Med. 793. (2015).

³ See generally R. M. Portman & K. Romanow, *Concierge Medicine: Legal Issues, Ethical Dilemmas, and Policy Challenges*, 1 J.OF HEALTH & LIFE SCI. L. 3 (2008).

⁴ See W. N. Wu et al., A Direct Primary Care Medical Home: The Qliance Experience, 29 HEALTH AFF.959 (2010).

⁵ See R. Lowes, Crisis in Healthcare Does Vic Wood Have the Answer, 83 MED. ECON. 68 (2006).

⁶ See Brian R Forrest, Breaking Even on 4 Visits Per Day, 14 FAM. PRAC. MGMT. 19-24, 19-24 (2007); Brian R Forrest, Access Healthcare: A Model to Provide Improved Access to High-Quality and Affordable Healthcare, 66 N.C. MED. J. 208 (2005).

a decade ago as well, including John Muney, MD (of AMG Medical Group in New York City)⁸ and Robert Fields, MD (in Onley, Maryland).⁹ Each of these individuals was faced with inquiries from a state insurance commissioner at some point during the growth of their practice. In New York, Dr. Muney agreed to increase the amount of his per visit fee to appease regulator concerns.¹⁰ In Maryland, an inquiry into a DPC practice resulted in harsh and now outdated guidance from a 2009 state insurance commissioner.¹¹

A History of the "Business of Insurance" Argument

When Vic Wood, DO and Garrison Bliss, MD established their practices, they received letters from their respective state insurance commissioners informing them that they would need to discontinue this model or face criminal prosecution for engaging in the unlawful sale of insurance. These insurance commissioner inquiries slowed the growth of the DPC model, but eventually Dr. Bliss and Dr. Wood were able to convince the Washington and West Virginia legislatures to pass legislation clarifying that their practice model was not an insurance arrangement. While it is fortunate that state legislatures have been receptive to physician concerns, the DPC physician's decision to avoid a courtroom battle with the insurance commissioner has led to a lack of dispositive legal precedent. This should not dissuade physicians from opening DPC practices in other states, but an understanding of the debate is certainly helpful and summaries are included in the tables at the end of this Article.

Insurance commissioners argued that by offering full scope primary care to patients for a fixed monthly fee, too much risk was being transferred from the patient to the physician. What if too many patients required care on the same day and the care could not be delivered as promised? To analyze this argument one must begin by agreeing on a common definition of insurance. Each state may define the term "insurance" as they see fit. The Iowa Supreme Court's definition of insurance is a helpful example. Insurance "denotes a contract by which one party, for a compensation called the 'premium,' assumes particular risks of the other party and promises to pay to him or his nominee a certain ascertainable sum of money on a specified contingency."¹³

In Huff v. St. Joseph's Mercy Hospital of Dubuque Corp., ¹⁴ a 1978 case decided by the Supreme Court of Iowa a hospital developed a prepaid obstetrical contract plan where the hospital would agree to furnish all necessary maternal hospital services for seven days relative to childbirth for \$400 paid at least fifteen days prior to delivery. If the hospital stay exceeded seven days, the regular rate would be charged beginning with the eighth day. If the patient's charges were less than \$400, or she did not enter the hospital she would be given a partial or full refund.

⁸ D Trapp, *Direct Primary Care Model: Cutting Out the Insurer*, AM. MED. NEWS, August 1, 2011, http://www.amednews.com/article/20110801/government/308019949/4/ (last visited Sept. 7, 2016).

⁹ Robert P. Fields, *Further Perspectives on Concierge Medicine*, 153 Annals of Internal Medicine Ann Intern Med 274, 274 (2010).

¹⁰ J. Fermino, *State Slaps Dr. Do-Good*, NEW YORK POST, Mar. 4, 2009, *available at*http://nypost.com/2009/03/04/state-slaps-dr-do-good/ (last visited Sept. 7, 2016).

¹¹ Md. Ins. Admin., Report on "Retainer" or "Boutique" or "Concierge" Medical Practices and the Business of Insurance (2009), available at

http://insurance.maryland.gov/consumer/documents/agencyhearings/2009 retainermedicinereport-final.pdf (last visited Sept. 7, 2016).

¹² See Eskew, supra note 1.

¹³ State v. Timmer, 151 N.W.2d 558, 561 (Iowa 1967).

¹⁴ Huff v. St. Joseph's Mercy Hosp. of Dubuque Corp., 261 N.W.2d 695 (Iowa).

The hospital used portions of the \$400 to pay any physician service fees and lab fees. The Court held that these contracts were not subject to insurance because "they do cover the risks of assorted complications but the principal benefit or effect is the hospital care as opposed to a minimal indemnity feature. Additionally, the contracts in their operation are not insurance because there is [an] express provision for refund or additional charge depending on the actual hospital expense incurred."¹⁵

Winning the Business of Insurance Argument

If practice contracts are structured correctly, the DPC physician has an excellent legal defense against an aggressive insurance commissioner. An insurance commissioner will focus chiefly on risk in their analysis of whether a DPC practice is engaged in the unlawful sale of insurance. Steps can be taken to reduce risk transfer in the patient-physician DPC contract, easing the concerns of insurance commissioners. Here are ten reduce-your-risk suggestions for those that are concerned about an aggressive insurance commissioner. These are neither dispositive nor required to run a health DPC practice. These suggestions include: 1) limit the number of patients in your panel, 2) define your scope of practice, 3) include contractual and marketing disclosures that your DPC practice is NOT insurance, 4) recommend that patients purchase comprehensive insurance coverage, 5) permit patients to terminate the arrangement at any time with a pro-rated refund, 6) hold any funds paid more than one month in advance in a separate escrow account and do not accept payments until you have "accepted" the patient into your practice (usually at the first in-person visit), 7) require that all patients visit the practice at least annually, 8) require that each individual patient sign a contract with the practice (even if an employer is paying the periodic fee on behalf of the patient), 9) consider listing a contractual cap on the number of office visits and/or charging a per visit fee (in addition to the periodic fee), and 10) consider billing the patient at the end of the service period rather than the beginning.

When describing and defending the practice model, remember to articulate that the greatest value of a DPC practice is ongoing primary care for all member patients. While the ability to rely on the DPC physician to avoid some emergency room visits is important, "being available" for these contingent events is not the central feature of the DPC model. The physician should not speak in terms of patient "utilization" of services and should not advertise "unlimited care," which implies more than standard primary care services and more visits than the practice could reasonably deliver. Require that all patients have a physical visit at least once per year. This allows the practice to demonstrate that the periodic fee is for ongoing care. Opinions differ about whether billing the patient after the services have been provided (at the end of the month) reduces risk, this is often a helpful strategy to avoid unwanted escrow obligations and "health maintenance organization" debates as well. Delaying the acceptance of payments from the patient until you have accepted the patient into the practice is a wise move to avoid both patient abandonment concerns (in case the patient is requesting narcotics that you would not routinely prescribe) and escrow account obligations.

Patient panel sizes vary widely across practices. Many have publicly stated that they have around 600 patients in their panel, while others are known have as many as 1,200 or more patients in a panel. Simply listing a number (whether high or low) is likely reassuring to the insurance commissioner that the practice has contemplated volume concerns. A practice may select a higher patient cap to provide more flexibility. It is the physician's decision how much

Id. at 700-01.

the physician would like to work, and numbers will vary based on the age and acuity of the patients in each panel. There are no states where DPC practices are prohibited, but there are a few where barriers are more burdensome.

State By State Comparisons

Most state insurance commissioners have not documented official stances on the limited number of DPC practices in operation and continue to take a watchful waiting approach. While DPC practices have been located in forty-seven states, DPC related legislation has been enacted in only seventeen states (in the following order): West Virginia (2006)¹⁶, Washington (2007)¹⁷, Oregon (2011)¹⁸, Utah (2012)¹⁹, Arizona (2014)²⁰, Louisiana (2014)²¹, Michigan (2015)²², Arkansas (2015)²³, Mississippi (2015)²⁴, Idaho (2015)²⁵, Oklahoma (2015)²⁶, Kansas (2015)²⁷, Texas (2015)²⁸, Missouri (2015)²⁹, Wyoming (2016)³⁰, Nebraska (2016)³¹, and Tennessee (2016)³². A summary of elements in each enactment is provided below in Table 1. States that have passed DPC legislation were generally motivated by a desire to provide reassurance to cautious physicians and lower legal barriers to DPC entry. Some states achieved this aim more effectively than others, but the goal of any state legislation should be more than merely addressing "business of insurance" concerns (see Table 5). Providing a clear definition of the DPC model, an appropriately broad DPC scope of practice description, and alignment with federal ACA provisions are issues that have been overlooked by some states. The majority of the state laws offer a helpful DPC definition, while others fail to reference the term at all (see Table 1). Fortunately a definition can be found in the Affordable Care Act which contains a provision to permit direct primary care medical homes to participate in insurance exchanges with wrap around health plans.³³

Washington Lineage

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¹⁶ W. VA. CODE § 16-2J-1 (2013).

¹⁷ Wash. Rev. Code § 48.150.010 (2007).

¹⁸ OR. REV. STAT. § 735.500, 735.510 (2011).

¹⁹ UTAH CODE § 31A-4-106.5.

²⁰ Ariz. Rev. Stat. § 20-123.

²¹ La. Stat. Ann. §§ 37:1360.81 - 1360.91.

²² MICH. COMP. LAWS § 500.129.

²³ ARK. CODE §§ 23-60-104,23-76-103(c).

²⁴ MISS. CODE ANN. § 83-1-101.

²⁵ IDAHO CODE ANN. §§ 39-9201 to 39-9208.

²⁶ OKLA. STAT. tit. 36, § 4604.

²⁷ KAN. STAT. ANN. § 65-4978.

²⁸ Tex. Bus. & Com. Code § 162.001.

²⁹ Mo. Rev. Stat. § 376.1800-1.

³⁰ WYO. STAT. ANN. §§ 26-1-104(a)(vi),§ 26-22-301(c).

³¹ NEB. REV. STAT. §§ 71-9501 through 71-9511.

³² TENN. CODE ANN. §§ 63-1-501 - 63-1-504.

³³ The Patient Protection and Affordable Care Act, Pub. L. No. 11-148, § 10104, 124 Stat. 119, (2010) [hereinafter *Affordable Care Act*]; Treatment of Direct Primary Care Medical Home, 76 Fed. Reg. 41900 (July 15, 2011) (interpreting section 1301(a)(3) of the Affordable Care Act), Treatment of Direct Primary Care Medical Home, 77 Fed. Reg. 18423 (Mar. 27, 2012).

The DPC model went by many names prior to the passage of Washington state legislation in 2007. Washington's statute states that "a direct practice must charge a direct fee on a monthly basis" and does "not accept payment for healthcare services provided to direct patients from any entity" subject to the state's insurance code. Louisiana's statutory language contains similar provisions without specifying a monthly basis as the specified payment period, and was clearly modeled after Washington's law. Mississippi and Nebraska borrowed much of this statutory language as well. Washington and Louisiana statutes facially appear to prohibit the usage of a third party insurer to pay the periodic fee on behalf of the patient, and this could become a problem if cohorts of patients seek to enter a DPC relationship in a bundled payment fashion through healthcare exchange purchases (per the ACA – to be discussed below) or in Medicaid managed care relationships, activities that are already taking place in Washington.

Utah Lineage

Utah, Michigan, Kansas, and Missouri all passed DPC laws with similar "medical retainer agreement" language (see Table 2). Utah chose to define a medical retainer agreement as one "in which a person agrees to provide routine health care services to the individual patient for an agreed upon fee and period of time and either party may terminate the agreement upon written notice to the other party." Each state that followed this format made small changes to the definitions of "routine health care services" as well, often with confusing scope of practice language.

Red Flag States (West Virginia, Oregon, Arkansas, and Arizona)

Each of these states made the critical mistake of failing to appropriately define DPC. West Virginia was the first state to pass a DPC law in 2006, and thus was at a disadvantage, but the others failed to understand DPC prior to passing legislation. The requirements to participate as a DPC practice within West Virginia's "Preventive Care Pilot Program" include severe marketing, pricing, and scope of practice restriction along with strict reporting requirements. Most traditional DPC practices would likely opt for the freedom (and legal risk) of operating outside the Preventive Care Pilot program.

Oregon's DPC statute states that a "[r]etainer medical fee means any fee paid to a retainer medical practice pursuant to a medical retainer agreement" and that a "retainer medical practice must be certified by the Department of Consumer and Business Services" which is free to investigate and subpoena the practice, and to adopt new retainer practice rules. ⁴⁰ The law fails to explicitly state that these retainer practices are not a form of insurance and lumps DPC and FFNCS practices into one category. ⁴¹

Arkansas passed a "concierge" law that never mentions the phrase "direct primary care" and fails to narrowly define the group of physicians that fit within the "concierge" definition to

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³⁴ Wash. Rev. Code § 48.150.010 (2007).

³⁵ La. Stat. Ann. §§37:1360.81 - 1360.91.

³⁶ MISS. CODE ANN. § 83-1-101.

³⁷ Neb. Rev. Stat. §§ 71-9501 - 71-9511.

³⁸ Interview with G. Bliss (June 2014).

³⁹ UTAH CODE § 31A-4-106.5.

⁴⁰ OR. REV. STAT. §§ 735.500, 735.510 (2011).

⁴¹ *Id*.

FFNCS practices. The law states that a "[c]oncierge service arrangement means a contractual agreement between a licensed healthcare provider and an individual to provide select medical services as specified under a medical arrangement for an established fee."

Arizona defines a DPC provider plan as a "practice that collects on a prepaid basis fees to conduct primary health care for enrollees," a definition that effectively forbids the physician from billing *after* the services have been provided (or at the end of the month).⁴² Arizona's statute also states that a DPC plan "does not constitute the transaction of insurance... if the plan does not assume financial risk or agree to indemnify for services provided by a third party."⁴³ This hedge on the part of the legislators keeps the "not insurance" question alive and thus fails to provide a safe harbor for DPC physicians.

Affordable Care Act Provision for DPC Participation in Insurance Exchanges

The Affordable Care Act contains a provision in Section 10104 stating that the U.S. Department of Health and Human Services ("HHS") "shall permit a qualified health plan to provide coverage through a qualified direct primary care medical home plan that meets criteria established by the Secretary..." In subsequent Federal Register announcements, HHS defined a DPC medical home plan as "an arrangement where a fee is paid by an individual, or on behalf of an individual, directly to a medical home for primary care services, consistent with the program established in Washington." HHS applied an appropriately broad definition of primary care services as "routine health care services, including screening, assessment, diagnosis, and treatment for the purpose of promotion of health, and detection and management of disease or injury." Each state considering passing DPC legislation should take note of this broad definition and scope of practice description. States should ensure that their legislation does not enact any barriers for DPC practices that wish to obtain patients via the insurance exchanges. Model legislation has been discussed by many leaders in the DPC field, and states should start here when considering potential legislation.

Finally, those interested in operating DPC practices should be aware of pending issues at the federal level, most importantly any change in the Internal Revenue Service's ("IRS") treatment of DPC practices, which are currently deemed to be "health plans" by IRS⁴⁸ a decision that means that periodic fees are currently not deductible as a qualified health expense for health savings accounts. Attempts to educate the IRS have been unsuccessful,⁴⁹ and efforts are underway with Congress to change the IRS treatment of DPC practices (no longer treating them as "health plans") so that expenditures in this area may be appropriately treated as health expenses.⁵⁰ A change from the IRS health plan designation would likely result in DPC scope of

⁴² Ariz. Rev. Stat. § 20-123.

⁴³ Id.

⁴⁴ Affordable Care Act, § 10104.

⁴⁵ Supra note 33.

⁴⁶ Treatment of Direct Primary Care Medical Home, 77 Fed. Reg. 18423 (Mar. 27, 2012).

⁴⁷ See generally Direct Primary Care Coalition, www.dpcare.org, (last visited Sept. 7, 2016).

⁴⁸ IRS Comm. John A Koskinen, Letter to Sen. Murray (2014), available at

http://media.wix.com/ugd/677d54_a5749b970c184035a3bcf5c4a2064526.pdf (last visited Sept. 7, 2016).

⁴⁹ Maria Cantwell, Patty Murray & Jim McDermott, Letter to IRS Comm. Koskinen (2014), *available at* http://media.wix.com/ugd/677d54_d6cf9ad6556a4e99b73123d735f7aa25.pdf (last visited Sep 7, 2016).

⁵⁰ Take Action, DIRECT PRIMARY CARE COALITION (Sept. 21, 2015), http://www.dpcare.org/#!2015-capg-coalition/czy1 (last visited Sept. 7, 2016).

practice guidance designed to restrict the types of DPC services eligible for favorable tax treatment.

Summary

Physicians electing to operate a DPC practice should be aware that legal, policy, and regulatory issues are continually evolving. If you are especially risk averse, follow the ten recommendations listed above to minimize the risk that your practice will face unlawful "business of insurance" accusations, and avoid establishing a DPC practice in Vermont, West Virginia, or Oregon. The lack of legislation the majority of states should not be a concern at this stage. Only three out of six states with legislation aimed at encouraging DPC practices made any attempt to define DPC or similar terms, and the three that attempted a definition largely missed the mark. Look to the three part definition above and model legislation when speaking to your state legislators. Monitor the anticipated debates about the tax treatment of DPC periodic fees, and anticipate the scope of practice discussions that are likely to follow. Physicians are also advised to consult competent legal counsel who are familiar with DPC.

Table 1 State by State Direct Primary Care Legislative Comparison

Freedoms	WV	WA	OR	UT	ΑZ	LA	MI	AR	MS	ID	ОК	KS	TX	МО	WY	NE	TN
"Not Insurance" Protection		Yes	Yes	Yes	No	Yes											
"Not Insurance" Mandatory Disclosures		Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
"Double Dipping" Insurance FFS Prohibition		Yes	Yes	Yes	No	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes
Restrictions																	
Ins Commish Policing Auth	Yes	Yes	Yes	No													
Data Reporting Obligations		Yes	Yes	No													
Marketing Restrictions	Yes	No	Yes	No													
Separate License Required		No	Yes	No													
Additional Considerations																	
Limited to Primary Care	Yes	Yes	Yes	No	Yes	Yes	No	No	Yes	No	Yes	No	Yes	No	No	Yes	Yes
"DPC" Phrase Used		0	R	R	Yes	Yes	R	С	Yes	0	Yes	R	Yes	R	Yes	Yes	Yes
Modeled After	NA	NA	NA	NA	NA	WA	UT	NA	WA	UT	NA	UT	NA	UT	NA	WA	ОК

O = Other

R = Retainer

C = Concierge

Table 2 State DPC Law Lineage

WV (2006)	WA (2007)	OR (2011)	UT (2012)	AZ (2014)	AR (2015)	ID (2015)	OK (2015)	TX (2015)	WY (2016)
	LA (2014)		MI (2015)				TN (2016)		
	MS (2015)		KS (2015)						
	NE (2016)		MO (2015)						

Table 3 Mandatory Disclosure Compilation

The practice is not insurance

The practice provides only the limited scope of primary care services specified

The patient must pay (separately) for all services not specified

Describe the specific services that are included in the contract

State prominently in writing that the agreement is not health insurance

Prohibit the provider, but not the patient, from billing an insurer for the services provided under the contract

Inform the patient of his financial rights & responsibilities to the direct practice

Encourage the patient to obtain & maintain insurance for services not provided by the direct practice

The practice will not bill a health insurance issuer for services covered under the agreement

List contact information for the state medical board

Providers must disclose the text of the enrollee hold harmless clause if insurance denies coverage

Exact quotation requirements (typically "not insurance" language)

Prominently state in writing that the individual patient must pay the provider for all services not specified in the agreement

Table 4 Common Written Agreement Requirements

Be in writing

Signed by provider and patient

Allow either party to terminate upon written notice

Describe the services covered by the periodic fee

Specify the periodic fee

Specify the duration of the agreement

Specify any automatic renewal periods

Prohibit the prepayment of the agreement

Patient not liable for continued payment after agreement termination

State the agreement is not health insurance

State that the agreement alone does not satisfy the health benefit requirements of the ACA

State that without adequate insurance coverage in addition to this agreement the patient may be subject to ACA fines/penalties Prohibit the health care provider and the patient from billing an insurer or other third party payer for the DPC services Prominently state in writing that the individual patient must pay the provider for all services not specified in the agreement

Require inclusion of quoted language that this is not health insurance

Table 5 Model Legislation Checklist

Define "Direct Primary Care" using three part definition above

Specifically and explicitly state that DPC is NOT insurance, and reference the state insurance code

Discourage any formal registration with the state or oversight from the insurance commissioner

Require an individual contract with each patient, which must contain:

Mandatory disclosures

A phrase specifically stating that "this is NOT insurance"

Discontinuation of care provisions

Minimize any attempts to limit the scope of practice (broadly define "Primary Care")

Include a provision promoting the formation of "Wrap around" health insurance