

DIRECT PRIMARY CARE: A LEGAL AND REGULATORY REVIEW OF AN EMERGING PRACTICE MODEL

Abstract

Direct Primary Care (“DPC”) practices are a type of retainer practice where physicians directly charge patients a periodic fee and avoid any third party fee for service payments. These physicians have been small and overlooked group for many years, but the recent growth of the model demands attention. Previously tacit insurance commissioners have taken notice. Laws enacted by six state legislatures and the Affordable Care Act provides a background from which a legal framework can be developed. This article will articulate “business of insurance” concerns encountered by DPC physicians including recommended contractual provisions to minimize this risk, compare state laws written chiefly to address this concern, consider the DPC provisions of the Affordable Care Act, and briefly consider tax and scope of practice policy implications of 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.¹ For the practice to qualify as a direct primary care 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.² Billing third parties on a

¹ Eskew, P. *Direct Primary Care Membership Medicine*, W V Med J, 2014 Mar-Apr;110 (2):8-11.

² Interpretations of the Wash. Rev. Code § 48.150.010 (2007), Louisiana Senate Bill No. 516 (2014), available at: <http://www.legis.la.gov/legis/ViewDocument.aspx?d=880834> (last accessed on Sept 22, 2014), The Patient Protection and Affordable Care Act, Pub. L. No. 11-148, 124 Stat. 119, § 10104 (Mar. 23, 2010), Treatment of

fee for service basis in addition to the periodic fee is formally called the fee for “non-covered” services model, a practice commonly described as “double dipping,” commonly used by practices many describe as “concierge.” The fee for non-covered services model is used by groups such as MDVIP and SignatureMD.³ In a DPC practice third parties may pay the periodic fee on behalf of the patient, but traditional third party fee for service billing is strictly prohibited. If the per visit charge were larger than the monthly fee, the practice would be considered a cash pay urgent care facility. Figure 1 demonstrates terminology describing retainer practice subsets.

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 a decade ago as well, and these include John Muney, MD (of AMG Medical Group in New York City)⁷ and Robert Fields, MD (in Onley, Maryland).⁸ Each of these individuals was faced with inquiries from their respective state insurance commissioner regarding their practice models. Some physicians were threatened with criminal prosecution for the unlawful sale of insurance.

Direct Primary Care Medical Home, 76 Fed. Reg. 41900 (July 15, 2011) (amending section 1301(a)(3) of the Affordable Care Act), Treatment of Direct Primary Care Medical Home, 77 Fed. Reg. 18423 (Mar. 27, 2012), ORS § 735.500, 735.510 (2011). Available at: <http://www.oregonlaws.org/ors/735.500> (last accessed on July 6, 2014), W. Va. Code § 16-2J-1 (2013), Utah Code § 31A-4-106.5. Medical retainer agreements, available at: http://le.utah.gov/code/TITLE31A/htm/31A04_010605.htm (last accessed on July 6, 2014)

³ Portman, R., Romanow, K. *Concierge Medicine: Legal Issues, Ethical Dilemmas, and Policy Challenges*, J. Health & Life Sci L, April 2008, pp1-38.

⁴ Wu, WN., Bliss, G., Bliss, EB., Green, LA., *Practice Profile A Direct Primary Care Medical Home the Qliance Experience*, Health Affairs, 2010 May;29(5):959-62.,

⁵ Lowes, R. *Crisis in Healthcare Does Vic Wood Have the Answer?*, Med Econ 2006 Dec 15;83(24):68-73.

⁶ Forrest, BR., *Breaking Even on 4 Visits Per Day*, Fam Pract Manag. 2007 Jun;14(6):19-24. and Forrest, BR., *Access Healthcare: A Model to Provide Improved Access to High-Quality and Affordable Healthcare*, N C Med J. 2005 May-Jun;66(3):208-11.

⁷ Trapp, D. *Direct Primary Care Model: Cutting Out the Insurer*, Amed News, Aug 1, 2011. Available at: <http://www.amednews.com/article/20110801/government/308019949/4/> (last accessed on Sept 22, 2014).

⁸ Fields, RP. *Further Perspectives on Concierge Medicine*, Ann Intern Med. 2010 Aug 17;153(4):274.

Six states have legislation designed to address this concern, but dispositive case law remains absent.

A History of the “Business of Insurance” Concern

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.⁹ Similar insurance commissioner inquiries in many states slowed wide adoption 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 the DPC practice model was not considered insurance. Similar motivations led to legislation in Utah and Arizona, where DPC physicians were threatened, only to successfully obtain legislative protection. Louisiana, through the efforts of Greg Waddel of the Louisiana State Medical Society¹⁰, and a persuasive white paper,¹¹ appears to be the only state that proactively passed DPC legislation without any individual physicians receiving insurance commissioner threats. While it is fortunate that state legislatures have been receptive to physician concerns, each individual DPC physician’s decision to avoid a courtroom battle with the insurance commissioner has led to a lack of dispositive legal precedent.

⁹ Eskew, P. *Direct Primary Care Membership Medicine*, W V Med J, 2014 Mar-Apr;110 (2):8-11.

¹⁰ Gonzalez, J. *New Law Lets Doctors Drop Insurance Model for Direct Pay*, Jefferson Parish Medical Society, Aug 28, 2014. Available at: http://www.jpms.org/index.php?option=com_content&view=article&id=144%3Ajindal-administration-doesnt-say-yes-or-no-to-arkansas-type-medicaid-deal-for-louisiana&catid=41%3A-top-headlines&Itemid=135 (last accessed on Sept 22, 2014).

¹¹ Flood, J. *Direct Primary Care in Louisiana A White Paper for Louisiana Lawmakers and Healthcare Stakeholders in Support of Senate Bill 516*, Flood International Consulting Agency, April 2014, Available at: http://www.floodconsulting.com/pdf/Direct%20Primary%20Care%20in%20La_Support%20for%20SB516.pdf (last accessed on Sept 22, 2014).

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 is able to define this term individually. 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."¹²

In a 1978 case reviewed by the Supreme Court of Iowa (*Huff v. St. Joseph's Mercy Hospital of Dubuque Corporation*) a hospital developed a prepaid obstetrical contract plan where the hospital would agree to furnish all necessary hospital services for seven days relative to childbirth for the mother 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. The hospital used portions of the \$400 to pay any physician service fees and lab fees, and discussions why the agreement did not amount to a health maintenance organization were included in the court opinion as well. 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."¹³

¹² *State v. Timmer*, 260 Iowa 993, 999, 151 N.W.2d 558, 561 (Iowa 1967).

¹³ *Huff v. St. Joseph's Mercy Hosp. of Dubuque Corp.*, 261 N.W.2d 695 (Iowa 1978).

Winning the Business of Insurance Argument

If the DPC practice contracts between physicians and patients are structured correctly, the DPC physician has an excellent legal argument 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.¹⁴ 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 physicians concerned about the possibility of an aggressive insurance commissioner: 1) limit the number of patients in your panel, 2) define your scope of practice (list services covered by the periodic fee and others at additional cost), 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, 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 continuity of care for all member patients. While the ability to rely on the DPC physician to minimize emergency department or urgent care usage is important, “being available” for these contingent events is not the central feature of the DPC

¹⁴ *Huff v. St. Joseph's Mercy Hosp. of Dubuque Corp.*, 261 N.W.2d 695 (Iowa 1978).

model. Do not speak in terms of patient “utilization” of your services. Do not advertise or name your practice “unlimited care,” which implies more than standard primary care services. 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.

Patient panel sizes vary widely across DPC practices. Many have publicly stated that they have around 600 patients in their panel, while others are known to have as many as 2,000 patients in a panel. No number is dispositive, but simply listing a panel cap is a helpful defense technique. A practice may select a higher cap to provide more flexibility. An individual physician is free to decide how much he would like to work, and panel size will likely vary based on the age and acuity of the patients in each panel.

State By State Comparisons – Beginning to Define Direct Primary Care

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 most states, DPC related legislation has been enacted in only six states: Washington¹⁵, West Virginia¹⁶, Oregon¹⁷, Utah¹⁸, Louisiana¹⁹, and Arizona²⁰. A summary of elements in each enactment is provided below in Table 2. Each of the six states that enacted DPC legislation wanted to encourage DPC practices to grow by reassuring them that

¹⁵ Wash. Rev. Code § 48.150.010 (2007).

¹⁶ W. Va. Code § 16-2J-1 (2013).

¹⁷ ORS § 735.500, 735.510 (2011). Available at: <http://www.oregonlaws.org/ors/735.500> (last accessed on July 6, 2014).

¹⁸ Utah Code § 31A-4-106.5. Medical retainer agreements, available at: http://le.utah.gov/code/TITLE31A/htm/31A04_010605.htm (last accessed on July 6, 2014).

¹⁹ Louisiana Senate Bill No. 516 (2014), available at: <http://www.legis.la.gov/legis/ViewDocument.aspx?d=880834> (last accessed on Sept 22, 2014).

²⁰ Arizona Senate Bill 1404 (2014), available at: <http://www.azleg.gov/legtext/51leg/2r/bills/sb1404s.pdf> (last accessed on Sept 22, 2014).

they would not be regulated as insurers. 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. Providing a clear definition of the DPC model, an appropriate DPC scope of practice description, and alignment with federal ACA provisions are issues that have generally been unaddressed. Only three of the state acts attempt to define direct primary care, while the other three fail to reference the term at all. 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.²¹

The DPC model went by many names prior to the passage of Washington state legislation in 2007. Washington’s law 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.²² Louisiana’s legislation contains similar provisions without specifying a monthly basis as the specified payment period, and was clearly modeled after Washington’s law.²³ On its face, these provisions in the Washington and Louisiana laws appear to prohibit the usage of a third party insurer to pay the periodic fee on behalf of the patient, and this discrepancy will need to be addressed as large 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 pilots, activities that are already taking place in Washington.²⁴ Arizona defines a direct primary care provider plan as a “practice that collects on a prepaid basis fees to conduct primary health care for enrollees,” a generally vague and unhelpful definition that effectively forbids the physician from billing *after* the

²¹ The Patient Protection and Affordable Care Act, Pub. L. No. 11-148, 124 Stat. 119, § 10104 (Mar. 23, 2010).

²² Wash. Rev. Code § 48.150.010 (2007).

²³ Louisiana Senate Bill No. 516 (2014), available at: <http://www.legis.la.gov/legis/ViewDocument.aspx?d=880834> (last accessed on Sept 22, 2014).

²⁴ Bliss, G – Personal Communication, June 2014.

services have been provided (at the end of the month). Each of these three definitions is a poor attempt to define DPC, but represents a better effort than West Virginia, Oregon, or Utah which omitted the phrase DPC entirely from their laws addressing retainer practices.

Poor or absent definitions combined with decisions to lump various types of retainer practices together (namely DPC and concierge) have created confusion. Both Washington²⁵ and Oregon²⁶ provide a list of qualified practices, but their listing of retainer practices demonstrates that they have lumped together DPC and concierge practices. Separate laws should be authored for each of these different retainer models. Concierge groups are less likely to gain the attention of insurance commissioners because they charge a periodic fee *in addition* to traditional third party fee for services charges. Concierge practices face more traditional legal risks in the form of False Claims Act cases along with stark and anti-kickback laws.

Affordable Care Act Provision for DPC Participation in Insurance Exchanges

The Affordable Care Act contains a provision in Section 10104 stating that 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...”²⁷ In later announcements in the Federal Register, HHS defined a Direct primary care 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

²⁵ Washington State Office of the Insurance Commissioner, *Direct Health Care Providers*, Available at: <http://www.insurance.wa.gov/your-insurance/health-insurance/individuals-families/direct-health-care-practices/direct-health-care-practice-list.html> (last accessed on Sept 22, 2014).

²⁶ Oregon Department of Consumer and Business Services, Medical Retainer Practice Registrants, <http://www.oregon.gov/DCBS/insurance/insurers/regulation/Documents/retainermedicalpractice-registrants.pdf> (last accessed on Sept 22, 2014).

²⁷ The Patient Protection and Affordable Care Act, Pub. L. No. 11-148, 124 Stat. 119, § 10104 (Mar. 23, 2010).

Washington.”²⁸ 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.”²⁹ 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 could start here when considering potential legislation.³⁰

Finally, federal IRS treatment of DPC practices remains unsettled. In spite of the ACA language defining DPC practices as independent of “health plans,” current IRS interpretation is that DPC practices are another “health plans,” a decision that means that periodic fees are currently not deductible as a health expense or available for health savings account usage.³¹ Efforts are underway 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.³² A change from the IRS health plan designation will likely result in DPC scope of practice guidance designed to restrict the types of DPC services eligible for favorable tax treatment.

Summary

²⁸ Treatment of Direct Primary Care Medical Home, 76 Fed. Reg. 41900 (July 15, 2011) (amending section 1301(a)(3) of the Affordable Care Act).

²⁹ Treatment of Direct Primary Care Medical Home, 77 Fed. Reg. 18423 (Mar. 27, 2012).

³⁰ Direct Primary Care Coalition, www.dpcare.org, (last accessed on Sept 22, 2014).

³¹ Direct Primary Care Coalition, *Letter to IRS Commissioner*, June 17, 2014, Available at <http://www.dpcare.org/#!blank/c1op5> (last accessed on Sept 22, 2014).

³² Direct Primary Care Coalition, *Letter to IRS Commissioner*, June 17, 2014, Available at <http://www.dpcare.org/#!blank/c1op5> (last accessed on Sept 22, 2014).

Family physicians electing to operate a DPC practice should be aware that legal, policy, and regulatory issues are continually evolving. Risk averse physicians should follow the ten recommendations listed above to minimize the risk that their practice will face unlawful “business of insurance” accusations. The lack of legislation the majority of states should not dissuade informed physicians from considering the DPC model. 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. Physicians wishing to educate policy makers about the DPC option should look to the three part definition above and model legislation. Monitor the anticipated debates about the tax treatment of DPC periodic fees, and anticipate the scope of practice discussions that are likely to follow.

Listing of Figures, Tables, and Appendices:

Figure 1 Membership Medicine Hierarchy	Page 13
Table 1 State by State Direct Primary Care Legislative Comparison	Page 14
Appendix A Model Legislation Checklist	Page 15
Appendix B Additional State Issues Worth Considering	Page 16

Figure 1 Membership Medicine Hierarchy

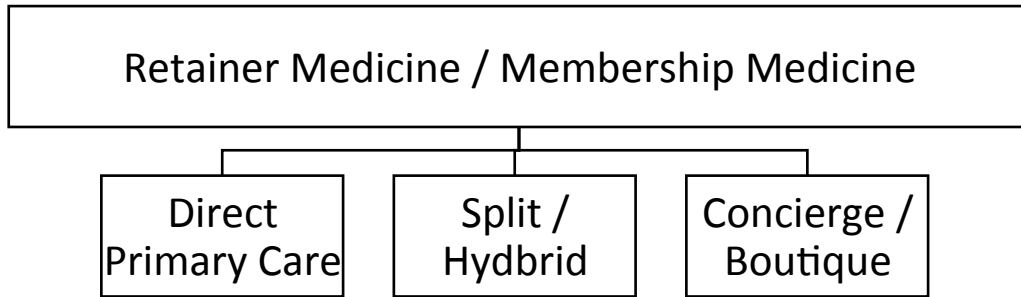


Table 1 State by State Direct Primary Care Legislative Comparison

State	Washington	West Virginia	Oregon	Utah	Arizona	Louisiana
Date Passed	2007	2006	2011	2012	2014	2014
Title	Direct Patient-Provider Primary Health Care	Preventive Care Pilot Program	Requirements for Certification as Retainer Medical Practice	Medical Retainer Agreements	Direct Primary Care Provider	Direct Primary Care Practice
Phrases Defined	Requires that a "direct fee" be charged on a monthly basis, no definition or use of term periodic fee	"primary care" poorly defined using terms basic and simple	"primary care" = outpatient, nonspecialist, "retainer medical fee" poorly defined	"Routine" health care services	Poor definition of "DPC Provider Plan", Poor definition of "Primary Care Provider"	failed to define periodic fee, vague definition of "direct fee"
"Not Insurance"	Yes (& HMO)	Yes	Unclear - the only time the phrase "not insurance" is used is in the mandatory disclosures section	Yes	Yes	Yes
Reporting Obligations	Yes	Yes - Severe	Yes	None	No	No
Mandatory Disclosure	Yes	No	Yes (in both contracts and marketing materials)	Brief "not insurance"	No	Yes
Discontinue Care Provision	Yes	No	No	None	No	Yes
"Double Dipping" Prohibition	No	No	No	Yes	No	No
Marketing Restrictions	No	Severe	No, only via disclosure requirements	No	No	No
Inadvertent Pilot/Exchange Ban	Potentially	No	Likely	Potentially	No	Potentially
Mention DPC as option in exchange	No	No	No	No	No	No
Scope	Mild restrict, primary care is broadly defined	Narrow	Narrow	Broadly defined	Broad	Mild restrict, primary care is broadly defined
Policing Authority	Must submit annual statements to	WV state "Health Care	Dept of Ins - may investigate and subpoena,	None	None	LA State Medical Board

	the insurance commissioner	Authority” & Insurance Commish	broad authority to adopt new rules			
Separate License needed for DPC	No	Yes	Yes	No	No	No

Appendix A: Model Legislation Checklist

Define “Direct Primary Care”

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

Discourage any formal registration with the state

Oversight from the medical board rather than 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

Avoid an overly narrow primary care scope of practice interpretation

Include a provision promoting the formation of “Wrap around” health insurance in the state exchange

Appendix B: Additional State Issues Worth Considering

Vermont – Passed Act 48 in May of 2011. This law is designed to implement a single payer health system in the state as of 2017. The Green Mountain Care Board will have the authority to set all health care prices, and thus may effectively ban all private medicine through price setting measures. DPC practices might be forced to change their prices or leave the state entirely.³³

West Virginia – The requirements to participate as a DPC practice within their “Preventive Care Pilot Program” are rigid. Any DPC practice would likely prefer to market itself freely to potential patients, avoid certificate of need-like applications for operational decisions and pricing approvals, and avoid strict reporting requirements. This means that a DPC practice would likely operate outside the Preventive Care Pilot program, without the guaranteed protections from the insurance commissioner’s office.

Oregon – Legislation related to DPC is especially poor, containing onerous reporting requirements and technically failing to provide any assured protection from the insurance commissioner. Physicians planning to operate a DPC practice in Oregon should not register in the state program, and instead defend the DPC practice on its merits in the event of a business of insurance argument from the insurance commissioner.

Arizona – This state passed DPC legislation defining DPC as “not insurance,” but due to poor language and the failure to include multiple provisions related to patient (consumer) protections, it is unlikely to survive any judicial scrutiny. DPC physicians in the state of Arizona should continue to practice as if they were in a state with no DPC “business of insurance” protection laws.

Maryland – A former Maryland Insurance Commissioner issued harsh guidance in 2009.³⁴ Fortunately numerous practices are persisting in Maryland in spite of this aggressive guidance, and the current commissioner is using the all too common “wait and see” approach.

New York – AMG Medical Group was threatened by an insurance commissioner using state HMO laws, and the group agreed to increase the amount of their per visit fee to appease regulator concerns.³⁵

³³ Act No. 48 An Act Relating to a Universal and Unified Health System, available at: <http://www.leg.state.vt.us/docs/2012/Acts/ACT048.pdf> last accessed on Sept 22, 2014.

³⁴ Maryland Insurance Administration, Report on “Retainer” or “Boutique” or “Concierge” Medical Practices and the Business of Insurance (Jan. 2009), available at [https://www.msba.org/sec_comm/sections/health/docs/homepage/concierge/2009RetainerMedicineReportfinal\(00022566\).pdf](https://www.msba.org/sec_comm/sections/health/docs/homepage/concierge/2009RetainerMedicineReportfinal(00022566).pdf) (last accessed on Sept 22, 2014).

³⁵ Fermino, J. *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 accessed on Sept 22, 2014).