Direct Primary Care Business of Insurance and State Law Considerations
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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.[1] 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.[2] 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.[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 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.[12] 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.

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[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/2009retainermedicinereport-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

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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

[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.[34] 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.[35] Mississippi[36] and Nebraska[37] 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.[38]

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."[39] 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

[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…"[44] 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."[45] 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."[46] 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.[47]

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 IRS[48] 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

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[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	AZ	LA	MI	AR	MS	ID	OK	KS	TX	MO	WY	NE	TN
"Not Insurance" Protection	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
"Not Insurance" Mandatory Disclosures	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes	Yes
"Double Dipping" Insurance FFS Prohibition	No	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	No	No	No	No	No	No	No	No	No	No	No	No	No
Data Reporting Obligations	No	Yes	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No
Marketing Restrictions	Yes	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	No
Separate License Required	Yes	No	Yes	No	No	No	No	No	No	No	No	No	No	No	No	No	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	O	O	R	R	Yes	Yes	R	C	Yes	O	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	OK

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

SPECIAL COMMUNICATION

Direct Primary Care: Practice Distribution and Cost Across the Nation

Philip M. Eskew, DO, JD, MBA, and Kathleen Klink, MD

Direct primary care (DPC) is an emerging practice alternative that (1) eliminates traditional third-party fee-for-service billing and (2) charges patients a periodic fee for primary care services. We describe the DPC model by identifying DPC practices across the United States; distinguish it from other practice arrangements, such as the "concierge" practice; and describe the model's pricing using data compiled from existing DPC practices across the United States. Lower price points and a broad distribution of DPC practices were confirmed, but data about quality are lacking. (J Am Board Fam Med 2015;28:793–801.)

Keywords: **Fees and Charges, Primary Health Care, Health Care Costs, Health Services Accessibility, Patient-Centered Care**

Direct primary care (DPC) is a growing model used by family physicians and other primary care specialties aimed at delivering quality care at an affordable price. The model emphasizes ongoing and preventive care services, and third-party fee-for-service payments are abandoned. Instead, a periodic (usually monthly) fee is paid to the DPC physician to better reflect the ongoing patient relationship. The affordability of the monthly fee and the high patient and physician satisfaction have garnered national media attention from many news sources including *Time*,[1] *Forbes*,[2] the *New York Times*,[3] and *The Hill*.[4] This article clarifies terminology in part by analyzing practice self-descriptions, describes Medicare "opt out" and "split" practice data, provides an overview of the periodic fees practices have made publicly available on their websites, and presents other raw practice data in an effort to offer a national snapshot of the growing DPC movement.

DPC Terminology and Background

For the purposes of inclusion in our study, a DPC practice must be a primary care practice that (1) charges a periodic fee for services, (2) does not bill any third parties on a fee-for-service basis, and (3) any per-visit charges are less than the monthly equivalent of the periodic fee.[5] This definition represents a comprehensive legal interpretation of 14 state laws passed to clarify DPC "business of insurance" regulatory questions and language from the Affordable Care Act describing mechanisms for DPC practices to participate in the insurance exchanges with "wraparound" insurance products. DPC practices often are compared with other models that charge a periodic fee, most commonly the concierge model. Price differences between the models are usually acknowledged, but price is absent from any legislative or regulatory definition of DPC.

Practices' periodic fees have been described using many terms, including *retainer*, *membership*, *concierge*, *hybrid*, *split*, *direct pay*, and *direct primary care*. Any group that charges patients on a periodic basis might be described using 1 or more of these adjectives. The terminology continues to evolve, but *direct primary care* and *concierge* are the terms that have taken on the greatest meaning. The most well-known concierge practices, such as MDVIP or MD,[2] continue to bill third parties in the traditional fee-for-service fashion *in addition* to the periodic fee, a method many describe as "double dipping."[6] By contrast, DPC practices rely on the periodic fee to finance the practice without any third-party fee-for-service payments. Some prac-

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tices treat one cohort of patients in the DPC model and another cohort in the traditional third-party fee-for-service model; we refer to these as "split practices." Medicare regulations prohibit physicians from charging DPC patients for covered primary care services via the DPC model, so many DPC physicians who would like to make their services available to the Medicare population decide to "opt out" of Medicare so that they may privately contract with Medicare patients.

DPC practices claim to reduce overhead by more than 40% by eliminating administrative staff resources associated with third-party billing, resulting in lower price points for patients.[7] DPC physicians cite 3 key practice improvements: (1) increased availability and, therefore, access; (2) more time for each patient encounter, leading to improved quality; and (3) lower overhead costs.[8] Patients may usually join without regard to their insurance or socioeconomic status since practices often "opt out" of Medicare and do not sign traditional contracts with private insurance companies or Medicaid. For non–primary care services, DPC patients rely on a variety of options, ranging from the usage of high-deductible health insurance plans or "wraparound" insurance plans designed to cover everything except primary care (as specifically authorized by the ACA; discussed below) to traditional employer-sponsored insurance, Medicare, Medicaid, or ACA-exempted "health-sharing" ministries.[9] Uninsured patients who need traditionally expensive nonemergent procedures such as a colonoscopy or magnetic resonance imaging often benefit from the DPC physicians' efforts to negotiate lower "cash pay" prices on their behalf, and depending on the DPC practice, some radiologic testing might be included at no additional cost.[10]

Methods

A thorough literature search demonstrated a paucity of data available to describe the DPC practice model. Studies related to DPC were located using the following search terms in PubMed and Google: *direct primary care*, *retainer medicine*, *membership medicine*, *concierge medicine*, and *boutique medicine*. The phrase "direct primary care" yielded only 3 relevant results in PubMed. We conducted a review of information publicly available on DPC practices' websites that met our 3-part definition in an effort to describe the number of practices adopting the model, the terminology advertised (self-description), and their distribution. We gathered information about the size of practices, the providers involved, and costs to provide a broad overview of the current state of DPC in the United States.

DPC practices were identified through a review of literature, practice listings from databases in the 2 states that require DPC practice registration and publication (Washington[11] and Oregon[12]), and meeting agendas of the Direct Primary Care Coalition[13] and Direct Primary Care Summit[14] held in June 2014. We included all practices that met the 3-part definition of DPC (identified via the above-described methods) either exclusively as a "pure" DPC practice or as part of a split practice model.

The following data were collected: number of physicians in the practice, number of nonphysician clinicians, lowest periodic (monthly) fee for patients older than age 29, highest periodic (monthly) fee for patients older than age 29, any per-visit fee, any enrollment fee, Medicare opt-out status, whether the practice was split, and the terminology the practice used to advertise (self-describe) its membership model.

An estimation of the total average monthly cost of care was obtained by averaging the monthly low and high costs, assuming patients visited the practice an average of 4 times per year,[15] and amortizing the first year's enrollment fee over a 12-month time period via the following formula:

$$[(\text{Monthly low fee} + \text{Monthly high fee})/2] + [\text{Per-visit fee} \times 4/12] + [\text{Enrollment fee}/12]$$

Results

DPC practices tend to fall naturally into 1 of 3 cohorts: (1) small and independent practices with varying levels of network affiliation, (2) split practices that are either independent or often entirely dependent on a network for their DPC patients, or (3) larger practices that tend to employ physicians and grow rapidly by marketing themselves directly to large employers. Many other arrangements certainly exist; of note, one hospital offers an "Affordable Access" DPC program at $30 per month,[16]

Figure 1. Monthly costs to patients. DPC, direct primary care.

and even some urgent care chains[17] are offering DPC options.

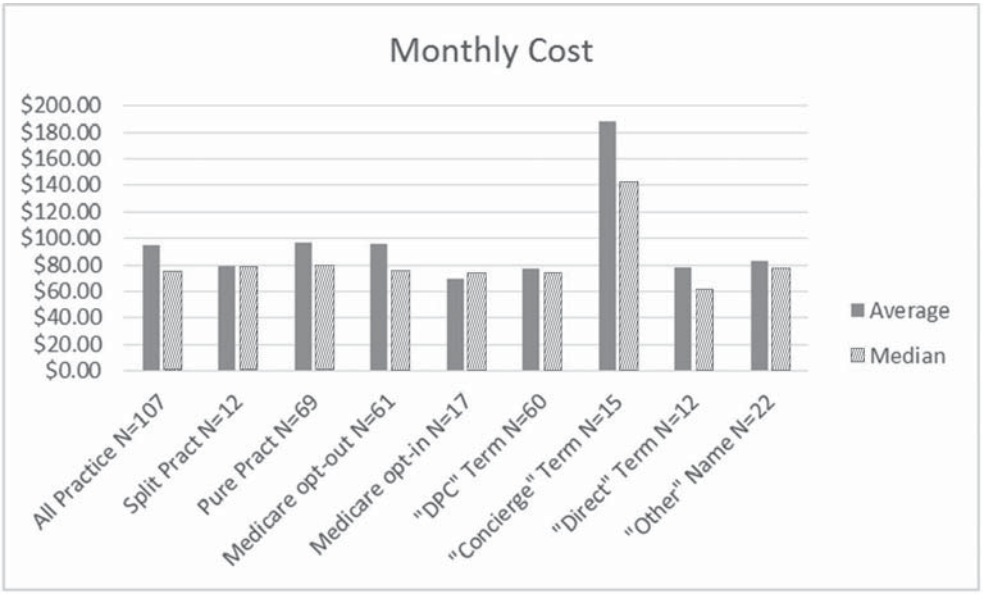
Networks may be used by providers for a variety of different purposes, from learning about the model to recruiting/enrolling patients (especially from large employers), sharing group purchasing discounts, and sharing electronic medical records and membership management platforms. Examples of networks are available in the full practice listing in the Appendix. Because of the variety of network options and lack of transparency regarding practice participation in networks, precise data could not be aggregated from this website review.

We located 141 practices with 273 locations spanning 39 states (see Figure 3 and the Appendix). Practices with ≤4 providers comprised 93.2% of those included in the study. Of the 141 practices, 87 disclosed enough information for us to determine whether they were "pure" or "split" (73 [83.9%] were pure and 14 [16.1%] were split), and 84 disclosed enough information for us to determine whether they had opted out or were accepting Medicare (65 [77.4%] opted out and 19 [22.6%] accepted Medicare). Of the 65 practices that opted out of Medicare, 1 operated in a split fashion. A practice self-description was recorded for every practice in the study. The following terms were used: *DPC* by 75 practices (53.2%), *concierge* by 21 (14.9%), *direct* by 17 (12.1%), and *other* by 22 (19.6%).

Of the 141 practices identified, 116 (82%) have cost information available online. When these 116 practices are analyzed, the average monthly cost to the patient is $93.26 (median monthly cost, $75.00; range, $26.67 to $562.50 per month). While all the practices included in our study met our definition of DPC, not all the practices used the phrase "direct primary care" to self-describe their practice model. Seventy-five of the studied practices (53%) referred to their model using the phrase "direct primary care." Practices that used the phrase DPC on average charged a lower fee than practices that used the term *concierge* to describe their model: $77.38 compared with $182.76, respectively. Of 116 practices with available price information, 28 (24%) charged a per-visit fee, and the average per-visit charge among this group was $15.59 (range, $5 to $35). Thirty-six of these 116 practices charged a one-time initial enrollment fee, and the average enrollment fee among this group was $78.39 (range, $29 to $300). Figures 1 and 2 present monthly cost data.

Most DPC practices are young and small and thus lack sufficient quality and cost data to assess outcomes. The larger practices (especially Qliance, Iora Health, and Paladina) are known to have patient panels as large as 40,000 and routinely grow at faster rates by marketing themselves to large employers looking to purchase DPC plans for their employees. Most DPC practices are too small or

Figure 2. Average monthly price (sorted from low to high) and grouped by practice self-description.



young to have collected quality outcomes data, but we identified 2 mature practices that have compiled information: Access Health Care and Qliance.[18]

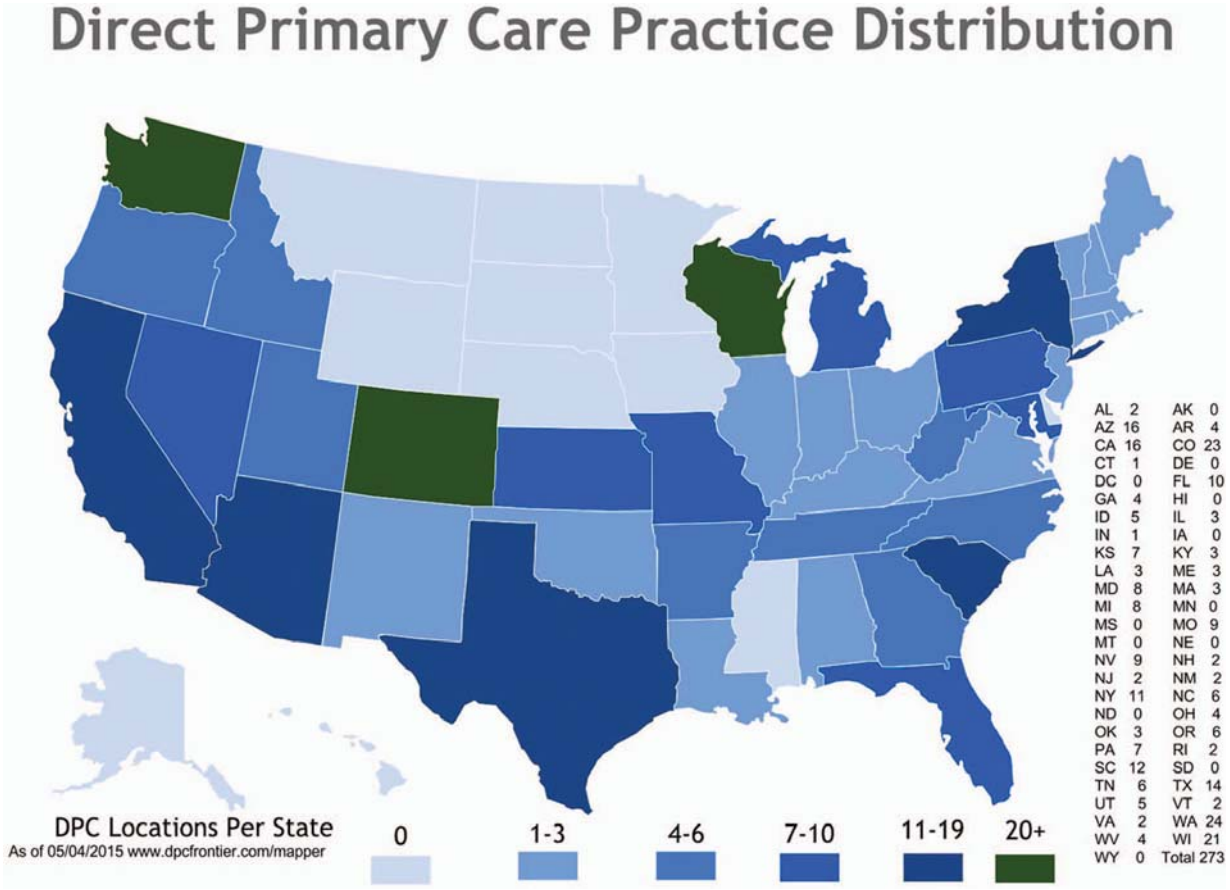
Access Health Care has been deemed a Cardiovascular Center of Excellence since 2009 by the Consortium for Southeastern Hypertension Control.[19] An unpublished study performed by the University of North Carolina School of Medicine and North Carolina State University MBA students demonstrated that the group's DPC patients spend 85% less out of pocket for their total cost of care compared with the same level and amount of care in a traditional setting. Patients receive an average of 35 minutes per visit (compared with 8 minutes in the traditional model).[20]

Qliance is the first example of a corporate, multisite DPC model.[21] Internal data from the group demonstrates that Qliance patients have a >50% reduction in emergency department visits, specialist visits, advance radiologic testing, and surgical procedures than traditional practices.[22,23] The only measure of increased utilization is the number of primary care visits, which more than doubled from an average of 2 to an average of 4 per year during the reporting period.[23] The logical inference is one that primary care advocates have insisted is true in every health system: As the utilization of low-cost comprehensive primary care increases, the need for high-cost emergency and specialty services decreases.

Though Qliance initially enrolled individual patients, currently employers (such as Expedia) contract with Qliance to pay membership fees as an employee benefit. Qliance recently enrolled an additional 20,000 patients via a Medicaid managed care contract, where Medicaid simply pays the membership fee on behalf of the patients as part of a shared savings program.[23] Another 5,000 patients signed up with Qliance via the insurance exchange. This was made possible by a provision of the Affordable Care Act that permits DPC practices to be offered in a bundled fashion in the insurance exchanges when paired with a wraparound insurance policy.[24]

The Affordable Care Act contains a provision in Section 10104 stating that the Department of Health and Human Services "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. . ."[24]; the Department of Health and Human Services later described 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 Washington."[25] This ACA provision and similar topics are discussed in detail in the article providing a legal and regulatory review of DPC by Eskew.[5]

Figure 3. Direct primary care practice distribution. DPC, direct primary care.



Discussion

A medical literature search did not identify a consistent or consensus definition of the DPC model; thus we relied on a detailed legal analysis to articulate the 3-part definition of DPC used for this study. Prior editorial publications often used terminology indiscriminately, contributing to broad misperceptions about the nuances among DPC, concierge, and other periodic fee models. A narrow majority of practices in the study self-describe as DPC. Practices are certainly free to advertise in any manner they chose, but this inconsistency in terminology certainly contributes to confusion on the part of patients and policymakers.

Selection of geographic location seems to be fairly flexible. Practices are located in both urban and rural settings across 39 states. The exact locations of DPC practices that met our definition are continuously updated online in the DPC Mapper.[26] Earlier studies demonstrated that each state's regulatory environment is different, and this may play a role in why some states have more DPC practices than others.[27] Physicians wishing to start a DPC practice may need to spend time understanding the legal and regulatory requirements at both the state and federal levels that will affect the practice.[5]

We found the public perception of the term *concierge* as having higher prices holds true. Self-described DPC practices charged a lower average monthly fee ($77.38) than DPC practices that self-described as concierge ($182.76). Concierge practices such as MDVIP and MD[2] have listed average periodic (monthly) fees of $137.50 and $2083.33, respectively; these periodic fees are billed in addition to standard fee-for-service office visit and procedural charges that would be encountered in any traditional medical practice.[28]

The third-party fee-for-service payment system compensates physicians on a per-unit basis. Physicians billing for a small number of units at high prices (common in specialties that perform expensive procedures) may find that the overhead cost associated with processing each claim is acceptable. In an outpatient-focused practice where procedures

are less frequent and/or less expensive, DPC physicians have found that the overhead associated with collecting fees on a per-unit basis is too high to be worth the effort. The administrative efficiencies gained by abandoning third-party fee-for-service overhead are often cited as one of the chief reasons that DPC is offered at minimal cost to the patient. We anticipated that the presumed lower overhead costs in "pure" DPC practices would result in lower periodic fees when "pure" practices were compared with "split" practices that should continue to carry a higher overhead burden, but there was no significant difference in periodic fees between the 2 groups.

Limitations in calculating the monthly costs include (1) complicated price structures (some practices offer family discounts, employer discounts, and other pricing options that could not be easily incorporated into this formula); (2) a lack of price transparency on many practice websites; and (3) scope of practice variance (items covered by the membership fee vary widely). Some practices provide some medications, laboratory testing, and radiologic testing without additional costs. The second most expensive DPC practice included in our website review includes hospitalist (inpatient) services without an additional physician fee.[29]

Future studies should focus on obtaining data supporting the quality claims made by DPC physicians and patients. DPC practices typically advertise open and continuous patient access to the physician and, according to preliminary, proprietary, and unpublished practice-level data, may be associated with better health outcomes with fewer hospitalizations, fewer emergency department visits, fewer specialist visits, and less radiologic testing. Proponents of DPC practices regularly refer to these benefits, but if the model is to be more widely adopted, more data about DPC practices are needed to document potential improvements. DPC practices should be described using accurate and consistent terminology to minimize confusion, and continued efforts at price transparency at all levels are recommended.

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Appendix

Listing of DPC Practices

121MD
Access Direct Care
Access Health care (Albenberg)
Access Health care (Forrest)**
Access MD
Access Medical Home
Access Medicine
Akin Family Medical Care
Alliance Concierge Care
Alonso, Lynn, MD
AMG Medical Group*
Anchor Medical Clinic
Appleton Clinics
Assurance Healthcare & Counseling Center
AtlasMD**
Austin Osteopathic Family Medicine
Balance Health
Baskin Clinic
Belleview Medical Partners
Birdwell Ferris Clinic
Bluegrass Family Wellness
Bluesky Direct
Bridge City Family Medicine
Broderick, Dawn, MD
Brooks Family Care

Care Only
Carlson, Rhonda, MD
Ciampi Family Practice
Compass Health care
Consolaré Personal Physician Services
Crescent Medical
Criscenzo, Donna, MD
Cunningham, Alicia, MD
Davinci Medical DPC
DC Clinic Northwest Arkansas
Diamond Luxury Health Care
Direct Access Family Care
Direct Doctors Inc.
Direct MD Austin
Direct Patient Services
Direct Primary Care of Austin
Direct Primary Care Carolinas
Direct Primary Care Clinics
DirectcareMD (Heritage FM)
Direct Medical Care
The Doc Shoppe
Dr. Rob Lamberts, LLC
Epiphany Health
Evolve Medical Clinics
Exceptional Health Care
Faith Family Clinic
Family Health Center Direct
Fields, Robert, MD
Flat Rock Health
Forest Direct Primary Care
Free Market Physician
Freedom Family Practice
Functional Family Medicine
Furlow, John, MD
Gold Direct Care
Good MD
GracePointe Health Care
Green Medicine
Guardian Family Care
Hannon & Maltz
Health Access Rhode Island**
A Heartbeat Away Clinic
Henjum, Philip, MD
Hendler, Jared, MD
Highland Urgent Care & Family Medicine
Icon Pediatrics
Independent MD
Innova Medical Care
Insight Primary Care
Institute for Medical Wellness
Integrative Family Medicine Asheville
Iora Health*
Island Direct Care
Ivers, Greta, MD, MPH
Izbiki Family Medicine
Kaysville Clinic Family Med
The Knope Clinic
Lacamas Medical Group
Landsdale, Thomas, MD
Live Active Primary Care
Lutz, Kevin, MD
Marable (Sublime) Health care
Megunticook Family Medicine
MDStat Urgent Care
Medical Access USA
Medlion**
Melioria Family Medicine
Morningstar Family Health Center
MyDoc Personal Physician Service
NeuCare Family Medicine
Nextera Health Care
Northwest Direct Care
Nostalgia Family Medicine
Oasis Family Medicine
One Focus Medical
Osteopathic Center Family Medicine
Our Lady of Hope Clinic
Pacific Direct Care
Paladina Health*
Palmetto Proactive Health care*
Patient Centered Physicians Group
PeaceHealth Medical Group
PeakMed Primary Care
Personal Family Physicians
Prairie Health & Wellness
Premier Personal Health Care
PrimaraCare**
Primary Care One
Priority Health Family Medicine
Priority Physicians
ProPartnersMD Direct
Qliance*
R Health Connect
Revolutionary Health Services
Rio Picos Family Practice
River Rock Medical Clinic
Roark Family Health
Rockville Concierge Doctors
Roth Medical Clinic
Salud Optima Direct
Samuel, Richard, MD
Sanctuary Medical Care & Cons

Scotland Family Medicine
Seattle Medical Associates
Seattle Premier Health
Snoqualmie Ridge Medical Clinic
Solstice Health
SparkMD
Treasure Valley Family Med
Unorthodoc
Vantage Physicians
The Village Doctor
Washington Park Direct Care
Yapha Physician Services
Wells Medical Clinic
Zenith Direct Care
*Large (>5 providers)
**Network total = 141.

A white article by Dave Chase,[31] written for the California Health Care Foundation, highlighted Iora Health, MedLion, Paladina Health, and White Glove Health. Similar helpful white articles have been published by Jarrett Flood[32] for the Louisiana Lawmakers and by Daniel McCorry[33] for the Heritage Foundation. Iora Health mainly operates employer-focused DPC practices often providing services for union groups using physicians paired with health coaches. MedLion is another type of DPC network, with >40 practices across the United States, that claims its "largest client is a 100,000 member association, and its smallest has 3 part-time employees."[34] Paladina Health is a DPC practice operated by the DaVita Corporation with at least 37 clinics across 8 states, and they also are focused on marketing DPC services directly to employers. White Glove Health is an entity focusing on house calls performed by nurse practitioners and does not offer the full scope of primary care services; therefore it did not meet our definition of DPC. Brian Forrest, of Access Health Care, also has a network known as Access Health Care Direct, and AtlasMD sells a comprehensive software solution to DPC practices that includes many features often found in a network.

Direct Primary Care: Common Legal Questions

Philip Eskew, DO, JD, MBA
Jan 25, 2017
NYSBA Health Law Section
Manhattan

Topic Categories

- State Insurance & HMO Laws
- Dispensing, Pathology & Lab Direct Billing
- Medicaid
- Affordable Care Act
- Federal Tax Implications
- Contracting (with patients)
- Medicare

DPC Defined

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

N.Y. Ins. Law § 1101(a) (McKinney Supp. 2003)

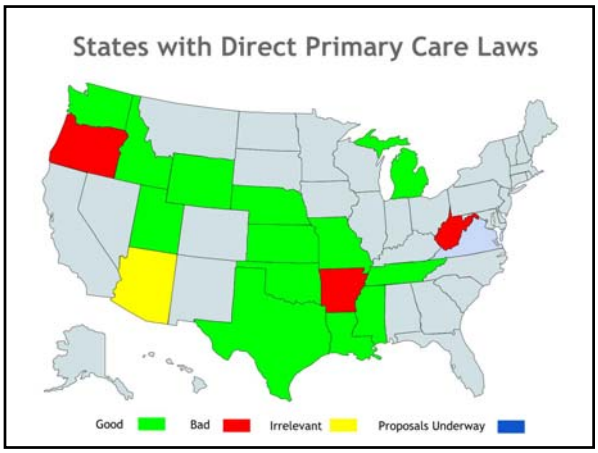
- (1) "Insurance contract" means any agreement or other transaction whereby **one party**, the "insurer", **is obligated to confer benefit** of pecuniary value upon another party, the "insured" or "beneficiary", **dependent upon the happening of a fortuitous event** in which the insured or beneficiary has, or is expected to have at the time of such happening, a material interest which will be adversely affected by the happening of such event.
- (2) "Fortuitous event" means any occurrence or failure to occur which is, or is assumed by the parties to be, to a **substantial extent beyond the control of either party**.

ARTICLE 44 of the NYS Public Health Law § 4401. Definitions (HMO defined)

- 1. "Health maintenance organization" or "organization" means any person, natural or corporate, or any groups of such persons who enter into an arrangement, agreement or plan or any combination of arrangements or plans which propose to provide or offer, or which do provide or offer, a comprehensive health services plan.
- 2. "Comprehensive health services plan" or "plan" means a plan through which each member of an enrolled population is entitled to receive comprehensive health services **in consideration for a basic advance or periodic charge**…

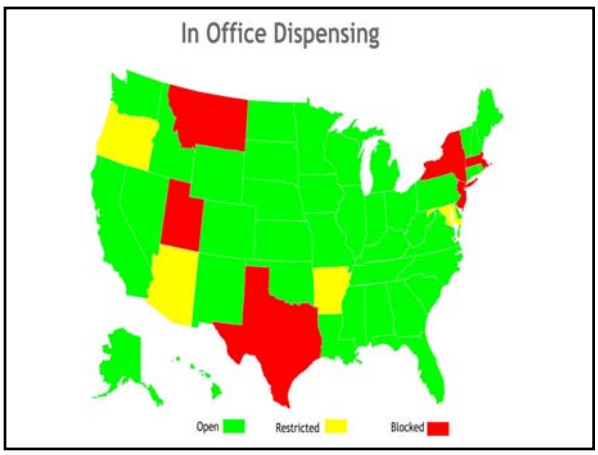
AMG Medical Group – Dr. John Muney

- $79-a-month “buffet of unlimited office visits”
- Five locations around NYC
- The $79 covers, among many other things:
  - lab tests, vaccinations, Pap smears
  - X-rays
  - Suturing, skin biopsies
- Dr. Muney ultimately agreed to begin charging a $33 fee for unscheduled "sick" visits.



State DPC Law Comparison

- "Not Insurance" Protections
- Clean DPC Definition (double dipping prohibition)
- Mandatory "Not Insurance" Disclosures
- Written Agreement Requirements
- Policing Authority – Ideally the medical board
- Data reporting obligations (avoid!)
- Separate licensure process (avoid!)

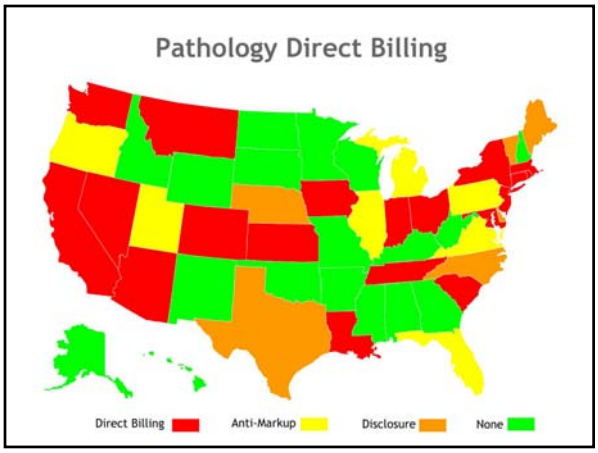


NY - Education Law, Article 137, Pharmacy §6807. Exempt persons.

- In-Office Dispensing
- This article shall not be construed to affect or prevent: Any physician… legally authorized to prescribe drugs under this title… from supplying **his patients** with such drugs as the physician… deems proper in connection with his practice, provided, however, that all such drugs **shall be dispensed in a container** labeled with the name and address of the dispenser and patient, directions for use, and date of delivery, and in addition, such drug shall bear a label containing the proprietary or brand name of the drug and, if applicable, the strength of the contents, unless the person issuing the prescription specifically states on the prescription in his own handwriting, that the name of the drug and the strength thereof should not appear on the label; provided further that if such drugs are controlled substances, they shall be dispensed pursuant to the requirements of article thirty-three of the public health law;

If more than 72 hours…

- No prescriber…, may dispense more than a seventy-two hour supply of drugs, except for:
  - persons practicing in hospitals as defined in section twenty-eight hundred one of the public health law;
  - the **dispensing of drugs at no charge** to their patients;
  - persons whose practices are situated ten miles or more from a registered pharmacy;
  - the dispensing of drugs in a clinic, infirmary or health service that is operated by or affiliated with a post-secondary institution;
  - persons licensed pursuant to article one hundred thirty-five of this title;
  - the dispensing of drugs in a medical emergency as defined in subdivision six of section sixty-eight hundred ten of this article;
  - the dispensing of drugs that are diluted, reconstituted or compounded by a prescriber;
  - the dispensing of allergenic extracts; or
  - the dispensing of drugs pursuant to an oncological or AIDS protocol.



NY Laboratory "Direct Billing"

- New York Public Health Law §§585-588
- § 586. Payment for services. 1. It **shall be unlawful for any purveyor** of clinical laboratory services, directly or indirectly, through any person, firm, corporation or association or its officers or agents, **to bill or receive payment**, reimbursement, compensation or fee from **any person other than the recipient of the services**, such recipient being the person upon whom the clinical services have been or will be rendered.

New York Medicaid

- Look for OPRA enrollment
  - Ordering/Prescribing/Referring/Attending
  - For those that do not intend to bill Medicaid
  - Presumably permits private contracting
- Contrast with Kentucky
  - Private contracting with Medicaid pts prohibited
  - Does not matter whether provider has "enrolled"

Affordable Care Act

- 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."
- A "Direct Primary Care Medical Home" plan is defined 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**."
- Insurance Requirement – Health Sharing Ministry Exception

Federal Tax Implications

- "Gap Plan" and "Health Plan" under § 223(c)
- "Qualified Medical Expense" under § 213(d)
- Health Reimbursement Arrangement?
- Health Savings Accounts?
- $100 per day "excise tax" under § 4980(d)

Contracting Outline

- Contracting
  - Insurance Companies
  - Individual Patients
  - Employers
  - Vendors & Consultants
- Pure or Hybrid
  - Early Cash Flow
  - Opting Out of Medicare
- General Compliance

Contracting – Insurance Companies

- Freedom of Contract
  - Often Individual Physician
  - Often at Physician's Employer Level
- Separate LLC?
- Inpatient Only?
- Old Non-competes?
  - Use CPOM
  - Use new DPC status
- Notice of Termination
  - Often 90 days
  - Mirrors patient abandonment requirements

Contracting – Individual Patients (1)

- Consider your state law (DPC/Insurance Code)
- Scope (precisely defined)
- Billing (in arrears)
- Disclosures
  - "Not insurance"
  - Any relevant status (with Medicare, Medicaid, etc)
- Activation
- Termination
- Refundable
  - Enrollment fee (keep), other prepaids refundable

Contracting – Individual Patients (2)

- Ongoing primary care (not insurance)
- Not an emergency (pt should call 911)
- No expectation to file 3rd party claims
- Agreement in isolation does not meet ACA
- I am enrolling voluntarily
- Nontransferable agreement
- For complaints – will first notify the practice
- Do NOT expect controlled substances

Contracting – Employers (1)

- Employer Receives
  - Aggregated (blinded) outcomes data
  - A contract for payment
  - Charge a PMPM, not a PEPM
- Patient Receives
  - An Individual Contract
  - Flexibility to join or leave the practice
  - Privacy

Contracting – Employers (2)

- Large Employers with Stop Loss
  - Long Sales Cycle
  - On-site vs near-site
  - Brokers (different language, plan design)
  - Third Party Administrators
  - Human Resources
- Small Employers (less than 50 & ACA exempt)
  - Short Sales Cycle
  - Often no other plans to worry about
  - Consider §4980(D) of IRC ($100 per day excise tax)

Contracting - Consultants

- Fee Arrangements
  - Can implicate "Unlawful Fee Splitting"
  - Can implicate "Corporate Practice of Medicine"
- Ask about actual **DPC** Experience!
  - DPC is not Concierge – wrong experience
  - Use Free Resources first

Contracting – Vendors

- "We are HIPAA compliant!"
- Where is your BAA?
- Which services actually secure PHI?
- Training: 1) Your employees? 2) Ours?
- How is your data stored? Is it backed up?
- Have you been audited?
- Do you have a HIPAA Report on Compliance?
- How many DPC practices do you serve?
- How would you define DPC?

Medicare "Opt Out" Considerations

- "Opt Out" = pure practice open to all ages
- Remain in = hybrid, FFNCS, or not open to all
- "Opted Out" Moonlighting is possible
  - Urgent / Emergent Care Exception
  - Workers Compensation
  - Hospice (purely administrative) role
  - Correctional (prison) medicine
  - Part time on-site direct primary care clinic

Medicare "Opt Out" Logistics

- After June 17, 2015 – only need to file one affidavit (MACRA update)
- Quarterly Windows (due 30 days prior)
  - January 1, April 1, July 1,October 1
- Private Contract with the patient
- Do NOT "disenroll" or file form 1490s
- You can still order labs, prescribe, etc

Medicare "Opt Out" Private Contract Terms

- Patient accepts full responsibility for payment
- Agrees not to submit a claim to Medicare
- Agrees that Medicare limits do not apply
- Supplemental plans may elect not to pay
- This is NOT an emergency situation

Advertising Mistakes

- Unlimited
- 24/7
- Higher Quality
- Covered
- Utilization

What if the patient asks (1)?

- Can I get out of the ACA “tax” just by signing up with your practice?
- I can’t come in to pick up my meds today, will you just mail them to my house?
- Will you code this as an “annual physical?”
- Will you swipe my HSA card?
- Will you fill out this prior authorization form?

What if the patient asks (2)?

- I’m traveling out of state next week, can we just keep our follow up appointment via telemed?
- Can I NOT sign your standard HIPAA form?
- To leave the practice with a refund?
- To rejoin the practice?

Questions?

- PHIL@DPCFRONTIER.COM
- Twitter @PHILSQ

Additional resources on Philip Eskew's writings - website www.dpcfrontier.com.

1) A Summary of New York DPC Issues
2) A Summary of the Affordable Care Act's DPC language and
3) My discussion of the Federal Tax Questions commonly faced by DPC practices.

Presentation Outline for: Vito Grasso, MPA, CAE

Concierge Medicine vs. Direct Primary Care: Establishing and Structuring Innovative Physician Practice Models

Speakers: Vito Grasso, Executive VP, NYS Academy of Family Practitioners
Philip Eskew, MD, Esq., Founder DPC Frontier, General Counsel Proactive MD, WMCI Medical Director, Corizon Health
Wayne Lipton, CEO, Concierge Choice Physicians

The move to DPCPs is based on the premise that access and quality of care will be improved without third-party payers imposing themselves between the patient and the physician. Yet concerns have been raised that DPCPs may cause access issues for patients who cannot afford to pay directly for care.

Direct patient contracting practices have 1 or more of the following features:
Administrative service fees (retainer or concierge fees): Some charge a monthly or annual fee—in addition to or in lieu of some of their usual fees for billable services—which patients pay to have access to the practice. In return, patients are promised increased personalized attention.

Payment in cash at the time of service: Some do not accept insurance and require that patients pay directly for all services at the time of care. These practices are typically called direct primary care practices, direct specialty care practices, or cash-only practices. Patients that seek care from a cash-only practice may choose to obtain a health savings account or a wraparound high-deductible insurance plan.
Smaller patient panel: Some accept substantially fewer patients than traditional practices, which requires practices to "downsize" their patient panels as they transition to a DPCP.

Prevalence
A 2013 survey (1) found that approximately 6% of physicians were in concierge or cash-only practices (up from 4% in 2012); another (2) reported that 9.6% of "practice owners" are planning to convert to concierge practices in the next 1 to 3 years. Yet ACP's own 2014 membership survey found that only 1.3% selected "retainer-based practice, concierge" as the method that best describes their basic source of compensation (3).

The Affordable Care Act and Direct Primary Care
The Patient Protection and Affordable Care Act (ACA) authorizes direct primary care to be included in the insurance exchanges, as long as they are paired with a wraparound insurance policy covering everything outside of primary care (that is, direct primary care combined with a low-cost high-deductible plan). It is the only noninsurance offering to be authorized in the insurance exchanges (4). Yet before 2015, "there [were] no DPC [direct primary care] practices operating in the federally facilitated exchanges, but the first DPC offering paired with a Qualified Health Plan [became] available in the Washington state exchange in January 2015" (5).

Effect on Access

Because DPCPs often limit their patient panels to several hundred patients compared with the typical 2500-plus panel size (6), there is concern that such downsizing, especially when associated with retainer fees, could create a barrier to lower-income persons, patients with chronic diseases, and other underserved populations.

One study (7) found that retainer physicians have smaller proportions of patients with diabetes than their nonretainer counterparts, and they care for fewer African-American and Hispanic patients. The study does not definitively address whether the case mix of retainer practices is causally driven by their retainer status or whether these practices tend to emerge in high-income areas where there are fewer African-American and Medicaid patients.

The literature (8, 9) has some examples of DPCPs that charge comparatively low retainer fees, and/or do not accept health insurance, and have made their practices accessible to lower-income, uninsured, and other vulnerable populations, possibly at less cost to the patient than if the practice accepted traditional insurance.

Value of Personalized Services

Retainer fees may cover personalized services or special amenities, such as extended patient visits, preventive services, immediate access, private waiting areas, and coordination with specialists. Practices vary in what services are included in the retainer fee. No research is available to indicate the cost benefit of such amenities.

Summary

The growth of DPCPs seems to be principally motivated by physicians' frustration with paperwork, low reimbursement, and restrictions on time spent with patients. It is essential that policymakers address these and other factors. Yet it must also be recognized that DPCPs potentially exacerbate racial, ethnic, and socioeconomic disparities in health care and impose too high a cost burden on some lower-income patients.

The College supports physician and patient choice of practices that are accessible, viable, and ethical. It asserts that physicians in all types of practices must ensure that they are meeting their obligations to serve patients of all types, especially the poor and other vulnerable patients. ACP recommends that DPCPs consider ways to mitigate any adverse impact on the poor and other underserved populations.

Finally, the College calls for independent research to study the factors contributing to the growth of DPCPs and their impact on workforce, cost, and access to care especially for vulnerable populations.

1. Develop DPC products in conjunction with health insurance plans
2. Identify secondary and catastrophic levels of services for direct payment products for providers of these levels of care
3. Legislation to clarify that DPC is not insurance
4. Develop contract language for DPC agreements that satisfy regulatory requirements

Sources:

1. "Assessing the Patient Care Implications of "Concierge" and Other Direct Patient Contracting Practices: A Policy Position Paper From the American College of Physicians" by Robert Doherty, BA, published in the 12/15/15 issue of the Annals of Internal Medicine

2. Physician compensation report: 2013. Accessed at www.medscape.com/features/slideshow/compensation/2013/public on 6 June 2014

3. **The Physicians Foundation.** A survey of America's physicians: practice patterns and perspectives. Accessed at www.physiciansfoundation.org/uploads/default/Physicians_Foundation_2012_Biennial_Survey.pdf on 6 June 2014.

4. Direct Primary Care: An Innovative Alternative to Conventional Health Insurance" by Daniel McCorry from the 8/14 issue of The Heritage Foundation Report at: http://www.heritage.org/research/reports/2014/08/direct-primary-care-an-innovative-alternative-to-conventional-health-insurance

5. "Qliance Study Shows Monthly-Fee Primary Care Model Saves 20% on Claims", State of Reform, 1/15/15: file:///C:/Users/vito%20grasso/Documents/Vito/Direct%20Primary%20Care/Qliance%20study%20shows%20monthly-fee%20primary%20care%20model%20saves%2020%20percent%20on%20claims%20-%20State%20of%20Reform.html

6. "Direct Primary Care: Practice Distribution and Cost Across the Nation" by Phil Askew, DO, JD published in the November-December 2015 issue of the Journal of the American Board of Family Medicine: http://www.jabfm.org/content/28/6/793.full

7. "In Defense of Direct Primary Care" by Philip Askew, DO, JD, MBA published in the September/October issue of Family Practice Management: http://www.aafp.org/fpm/2016/0900/

8. "Is Direct Primary Care the Solution to Our Health Care Crisis?" by Edmond Weisbart, MD published in the September/October issue of Family Practice Management: http://www.aafp.org/fpm/2016/0900/

9. AAFP Direct Primary Care Primer

10. Eric Bixler, *Direct Primary Care—An Innovative Solution to Alleviate the Decline of Primary Care Physicians* (Am. Health Lawyers Ass'n Physician Orgs. Practice Grp.), Feb. 2016, at 8.

Why primary care physicians are frustrated with insurance model of practice

- More than half of practice costs are a consequence of dealing with the redundant administrative expenses of taking multiple insurance plans
- Loss of autonomy because payers dictate processes and payment unilaterally
- Time and resources required for billing & coding, prior authorization, quality assurance, data collection & reporting, and increased pressure to use technology more extensively

Problems are particularly acute for primary care physicians

- Plans pay much higher fees for specialty care
- Lower payment compels primary care physicians to rely on volume to balance revenue with expenses creating an adverse professional environment in which physicians have less and less time for patients (some studies show that the average visit is about 7 minutes)

DPC eliminates insurance problems which can enhance practice satisfaction and profitability

- More time with patients
- Smaller patient panel reduces overhead
- Greater control over practice routine; no need to comply with payer requirements
- Ability to negotiate better terms for patients with other labs, medical suppliers, specialists, etc.

Practical Challenges

- Converting requires advising patients that they can no longer use insurance
- Reducing staff
- Loss of revenue
- Deciding whether to remain in Medicare
- Impact on access by low-income population

Legal Challenges

- IRS interpretation of DPC with regard to using HSA funds to pay DPC fees
- Difficulty for physician of continuing in Medicare while operating as a DPC
- Insurance regulation of DPC practices

Interest in DPC is growing

- AAFP MIG on DPC is growing rapidly
- Formation of DPC Coalition
- DPC Summit
- A 2013 survey (Physician Compensation Report - Medscape) found that approximately 6% of physicians were in concierge or cash-only practices (up from 4% in 2012); another (The Physicians Foundation) reported that 9.6% of "practice owners" are planning to convert to concierge practices in the next 1 to 3 years

Effect on Cost

- Price transparency
- Competition
- Lower administrative costs
- Patients accepting more personal responsibility for the cost of their care
- Critics observe that DPCPs can leave the patient at risk for higher out-of-pocket costs.

Political developments

- 16 states have enacted laws that recognize DPC fees as payments for medical services
- The Primary Care Enhancement Act (S.1989) introduced in the Senate by Senator Bill Cassidy of LA would establish that DPC is a medical service and not a health plan; it would also define DPC as a qualified health expense under section 213 (d) of the Tax Code making it eligible for payment with HSA funds

Possible strategy for moving forward

- Formation of a statewide DPC network
- Alignment with the DPC Coalition to lobby for legislation to address and resolve legal issues and to expand DPC
- Partner with labor unions to use their benefits programs to make DPC available to union members
- Develop DPC products in conjunction with health insurance plans

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CONCIERGE CHOICE PHYSICIANS

Concierge Models and the Legal Challenges

By Wayne Lipton, Managing Partner

December 19, 2016

What is Concierge Medical Care?:
Concierge medical care is a consumer-driven, membership-based delivery model for patients and their physicians that includes an annual payment for defined services which are generally not covered by third parties. Medical services are charged in the traditional way—fee for service basis generally covered by third parties.

Physicians can offer a full model concierge medical program in their practice, or a partial model, known as the "hybrid" model.

Generally, the size of the practice is reduced when a physician converts to a concierge model.

Benefits of Concierge Care:

- Dedicated time for concierge member services (hybrid model)
- Longer appointment windows so that members don't feel rushed and appointments start on time
- A deeper relationship with one defined provider, as opposed to group care or midlevel care
- Enhanced connectivity to the concierge physician after hours (as opposed to covering providers)
- Same or next day appointments for non-urgent visits

Who is right for Concierge Care:
Initially, concierge medicine was only right for primary care practices that treated adults.
Now, with the adoption of a hybrid approach to concierge care, specialists who see patients on an on-going basis can also be successful in the model, including:

- Pediatrians
- Gynecologists
- Rheumatologists
- Endocrinologists
- Pulmonologists
- Gastroenterologists
- Cardiologists

The model is generally not well suited in practices that largely treat patients on an episodic basis, like:

- Urgent care
- Orthopedics

- Dermatology
- ENT
- Surgery

Why does a patient join a concierge program?

1. Patients appreciate the doctor and what the doctor has done for them in the past.
2. Patients want more time to discuss their medical and personal needs.
3. Patients are frustrated with the "wall" that is put between them and their doctor
4. Patients are fearful that there will not be an available doctor later and want to cement their relationship with their physician
5. Patients want to "travel first class" with more convenience and their doctor's cell phone number
6. Patients appreciate no waiting time
7. Patients are interested in "old fashioned care" and an enhanced relationship with their doctor

How many patients join a concierge program?

- In a full model primary care practice, where patients are asked to pay and stay, between 10% and 30% of patients will join

- In a hybrid program, between 3% and 10% of patients will join.

How does a concierge model benefit a practice?

In the hybrid approach:
There is a portion of the day that is unhurried, more personal and generates about twice the revenue per hour for the physician and the practice with no increase in overhead. There is no downside. Upside is maximized when using a concierge company to cover the design and implementation costs with revenue sharing as the basis for compensation.

Hybrid concierge medicine works. It does not disenfranchise patients or take away their ability to pay for care using entitlements or insurance benefits. It also allows physicians to maintain healthy referral networks. For those physicians who are part of large groups or delivery systems, the program integrates well within the network's business model.

The approach allows primary care physicians to care for a diversity of patients, both economically and age-based. For specialists, hybrid concierge care allows them to care for episodic cases as well as new consults. It extends the career of physicians who are dissatisfied or who are exhausted by the demands on them as they age. The hybrid approach works in a broader market—it's not just for 1%.

In short, with a hybrid concierge model:

- The physician does not have to dismiss patients. Nobody is asked to leave the physician's care
- Physician satisfaction is extremely high
- The economic health of the practice is improved, benefiting even traditional patients
- Referral networks are maintained
- The program is compatible with a variety of business models and types of medicine
- A wider market of physicians can offer a concierge model than with full model programs

What does the concierge model do on a global basis?

1. Consumer driven model rewards services based on consumer choices and demand
2. Encourage the continued participation in insurances and entitlements.
3. Extends the professional life of physicians who are challenged by productivity demands
4. Increases a patient physician relationship

What are the basic legal concerns with regard to concierge medicine?

Is concierge medicine compatible with Medicare?

HHS concluded in 2003 that a physician is free to charge for non-covered services. Therefore, as long as the concierge program is for non-covered services, then it is compatible.

Is concierge care *better care*?

The care the physician provides is the same, this is particularly important in a hybrid model. However, the service is improved. Some patients may feel the deeper relationship they have with their physician, along with more time for education, can encourage better compliance and lifestyle choices.

Is a membership fee really just an access fee?

It is not an access fee, as members are paying for a defined service that is not covered by insurance.

Is concierge medicine insurance?

The membership fee covers only the defined services that are outside of insurance. Patients still need medical insurance.

Do third party plans accept this type of program?

Historically, there is no conflict with hybrid programs as they are volitional in nature. Full model programs are sometimes against the "policies of insurers," however, that is often because the programs are for covered services. Designed properly, even full model programs can be compatible with insurance plans.

Remember, commercial insurers do not need a reason to cancel a provider. They also tend to leave the desirable providers alone, despite prohibitions.

Are there any legal concerns with a physician dismissing patients to be a concierge physician?

Physicians may reduce their panel size as long as they follow the regulations for continuity of care in their state.