



A Primer on the Direct Primary Care Model: Past, Present, and Future



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As the healthcare system continues to seek value and move away from the fee-for-service payment model, the legal relationship between patient and physician is evolving. An emerging model of care delivery, Direct Primary Care (DPC), redefines how patients access, and pay for, primary care services.

In its simplest form, DPC involves a contract for a well-defined range of healthcare services that the DPC practice provides to the patient in exchange for a specified periodic fee. The DPC model was developed from the belief that value is achieved when overall health and wellness is the focus of care, without third-party payers imposing themselves between the patient and the physician.¹

The Center for Medicare and Medicaid Innovation (CMMI) published a lengthy request for information (RFI) this spring seeking comment for ways in which the Centers for Medicare & Medicaid Services (CMS) can employ the DPC model to work for Medicare and Medicaid beneficiaries.² Part of CMMI's mission is "to test innovative person-centered and market-driven approaches that empower beneficiaries as consumers, increase choices and competition to drive quality, reduce costs and improve outcomes."

In comparing the DPC model to other innovative primary care models, such as the Comprehensive Primary Care Plus program, CMMI noted DPC places a "greater emphasis on the central role of the beneficiary in selecting a primary care practice, with beneficiary engagement tools to empower beneficiaries, their families, and their caregivers to take ownership of the beneficiary's health . . ."³ As such, the DPC model changes the dynamic in the traditional physician-patient relationship.

This white paper provides a formal definition, brief history, and present status of the DPC model. It identifies several legal and operational issues physicians and their counsel must consider as they contemplate DPC and the physician's potentially changing liability exposure. Finally, it concludes with a description of the future state of DPC.

1 Robert Doherty, *Assessing the Patient Care Implications of "Concierge" and Other Direct Patient Contracting Practices: A Policy Position Paper From the American College of Physicians*, *Annals of Internal Med.* (2015), available at <http://annals.org/aim/fullarticle/2468810/assessing-patient-care-implications-concierge-other-direct-patient-contracting-practices>.

2 Available at <https://innovation.cms.gov/Files/x/dpc-rfi.pdf>.

3 *Id.*

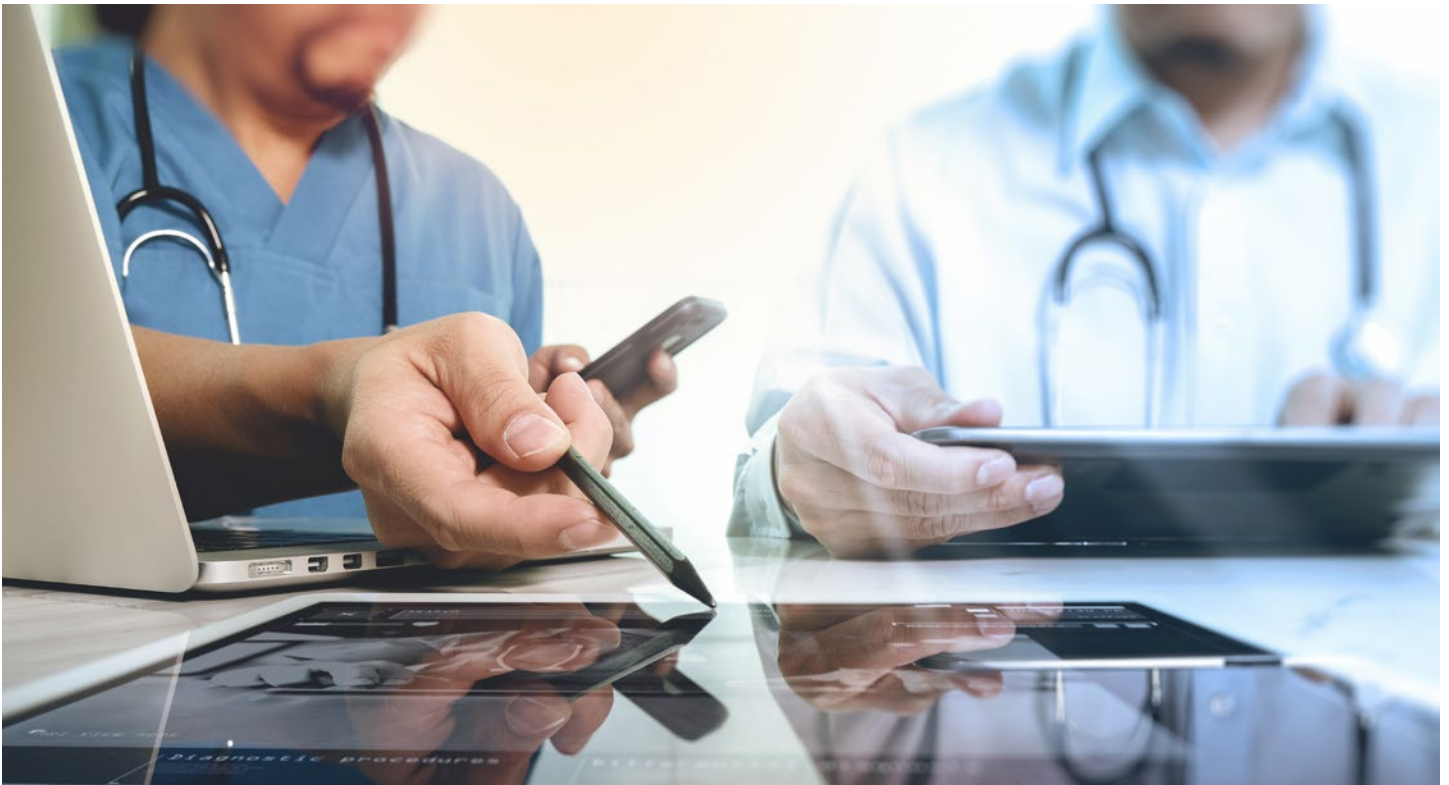
Definition of DPC

Although there are multiple variations in the marketplace, DPC generally refers to a primary care practice that offers patients a transparent, specific set of agreed-upon primary care healthcare services in exchange for a periodic fee, typically a per-member-per-month payment (PMPM).

Key features of DPC are its focus on ease of use, increased access, ongoing continuity of primary care for patients, and smaller panel sizes for physicians. DPC practices commonly close their panels when they reach approximately 800 patients, which is much smaller than the typical practice panel size of around 2,300 patients.⁴

DPC practices typically offer same-day visits, text messaging, online consultations, telehealth, and unlimited office visits. Some DPC practices also dispense medications, offer laboratory testing, and provide limited radiological testing.⁵ A critical piece of infrastructure is a shared interoperable IT platform for data sharing.

With an average 40% reduction in overhead costs associated with the savings from omitting third-party billing, DPC practices claim to offer patients affordable fees; extended individual office visits; and a focus on wellness, prevention, and customer service.⁶ Because DPC practices do not cover specialty care or hospitalization, patients are encouraged to have some form of health insurance coverage for services not offered through the DPC practice.



4 Alexander GC, Kurlander J, Wynia MK, *Physicians in retainer ("concierge") practice. A national survey of physician, patient, and practice characteristics*, 20 J. Gen. Internal Med. 1079–1083 (2005).

5 Eskew PM; Klink K, *Direct Primary Care: Practice Distribution and Cost Across the Nation*, 28 J. Am. Bd. Fam. Med. 793–801 (2015).

6 *Id.*

Brief History

The DPC model was developed in the late 1990s by a handful of pioneering physicians working to offer a new model of care, specifically in the states of Washington, West Virginia, North Carolina, New York, and Maryland.⁷ Facing regulatory challenges, these early DPC practices received letters from state insurance commissioners accusing them of engaging in the unlawful sale of insurance.⁸ If a DPC arrangement is considered a contract of insurance (as opposed to payment for healthcare services), it would be subject to a host of regulatory and economic requirements (including reserve or escrow requirements), which would render the model unworkable for most providers.



These initial regulatory challenges spurred legislative action in states across the country to clarify what DPC is and is not. Currently, 25 states have passed statutes defining DPC agreements as contracts between patients and doctors for the provision of primary care services, specifying that DPCs fall outside the scope of state insurance regulation.⁹

Initially, DPC practices were small, independent groups that contracted directly with patients. As the concept has expanded, some DPC practices also have entered into business relationships with employers, although the concept is relatively new and not without risk.¹⁰ Qliance, for example, started in 2007 with venture capital support from Amazon's Jeff Bezos, but folded in 2017 due to financial difficulties related to rapid expansion and unfavorable contract terms. Other employer-sponsored DPC companies such as Iora Health and Paladina Health Partners have enjoyed success through slow and steady growth.¹¹ More recently, some benefits managers have begun recommending DPC practices to employers as a means to control costs and improve the health status of their workforces.¹²

7 Eskew P, *Direct primary care: a legal and regulatory review of an emerging practice model*, available at https://c.ymcdn.com/sites/www.aclm.org/resource/collection/398353CC-E8B1-42EB-B6E7-0E725F1C4C42/10_Eskew_Phillip-nocover.pdf.

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

9 Keese J, Response letter to the Centers for Medicare & Medicaid Services Request for Information from the Direct Primary Care Coalition, May 25, 2018, available at <https://www.dpcare.org/copy-of-policy>.

10 Lydia Ramsey, *A small but growing movement of doctors that don't accept insurance and charge a monthly fee could be a model for big employers like Amazon and JP Morgan*, Bus. Insider, June 21, 2018, available at <https://www.businessinsider.com/how-employers-could-use-direct-primary-care-2018-3>.

11 Paladina Health, formerly owned by DaVita, was recently acquired by New Enterprise Associates for approximately \$100 million. See Christina Farr, *Silicon Valley venture fund NEA scoops up primary care clinics from DaVita for around \$100 million*, CNBC, available at <https://www.cnbc.com/2018/06/06/nea-buys-davitas-paladina-health-for-around-100-million.html>.

12 Lynn Wang, *How Direct Primary Care Practices Can Partner with Employers*, twinehealth.com, May 4, 2016, available at <https://www.twinehealth.com/blog/how-to-approach-employers-as-a-direct-primary-care>.

Present Status

The DPC model is not yet mainstream; a recent Medical Group Management Association poll found that nearly three-fourths of the 1,435 healthcare leaders who responded were not aware of the DPC model.¹³ Even so, the number of DPC practices is rapidly expanding. According to the Direct Primary Care Coalition, there are nearly 900 DPC practices across 48 states and the District of Columbia, caring for 330,000 patients.¹⁴ The regularly updated DPC Mapper¹⁵ provides the locations of DPC practices that fit the following criteria: (1) they charge a periodic fee for services, (2) they do 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.¹⁶

The expansion of DPC practices correlates with the increasing frustration and burn out experienced by primary care physicians, as overhead costs for physicians and expectations from payers, both public and private, continue to grow.¹⁷ With a shortage of primary care physicians in the United States, DPC is viewed as a potential practice model to attract and retain primary care physicians, especially those physicians desiring smaller independent practices.

However, an ongoing concern about DPC models is the extent to which healthy patients are “cherry-picked” into DPC arrangements, potentially threatening access to care for high-cost, high-need patients, with the potential to create a “two-tiered” primary care system. This concern, however, arises from confusion regarding the differences between the DPC model and concierge practices, for which cherry-picking is a significant issue. Although similar in concept, concierge practices continue to bill traditional insurance in addition to the periodic fees for enhanced patient care. As a result, “traditional” DPC practices have a more affordable price tag. A recent study found that self-described DPC practices charged a lower average monthly fee (\$77.38) than other DPC-like practices that self-described as concierge (\$182.76).¹⁸

Having obviously taken note of this expansion in the private sector, CMS is now exploring the feasibility of making the DPC model available to Medicare and/or Medicaid beneficiaries. As noted previously, CMMI recently issued an RFI seeking stakeholder input on numerous issues pertaining to DPC. (The RFI referred to DPC as “direct provider contracting,” and defined the model to include both primary care and multi-specialty practices.)

Previously, CMMI has relied on RFI responses to inform new initiatives. For example, the agency solicited comments on new Accountable Care Organization (ACO) and specialist payment models in 2014, and then announced the NextGen ACO and Oncology Care Models the following year. It published an RFI on advanced primary care models in 2015, and then announced the Comprehensive Primary Care Plus program in 2016.¹⁹ If those previous RFIs are predictive of how CMMI will act upon new RFIs, it is likely a DPC opportunity will be announced in the near future.

13 Med. Grp. Mgmt. Ass'n, *Advantages and limitations of the direct primary care model*, available at <https://www.mgma.com/data/data-stories/advantages-and-limitations-of-the-direct-primary-c>.

14 See Keese, *supra* note 9. Many DPC physicians practice on a part-time basis, and thus do not have full patient panels.

15 DPC Frontier, DPC Mapper, available at <https://www.dpcfrontier.com/mapper/>.

16 See Eskew and Klink, *supra* note 5.

17 Agency for Healthcare Research and Quality, Physician Burnout, available at <https://www.ahrq.gov/professionals/clinicians-providers/ahrq-works/burnout/index.html>.

18 See Eskew and Klink, *supra* note 5.

19 See Ctrs. for Medicare & Medicaid Servs., Innovation Models, available at <https://innovation.cms.gov/initiatives/index.html#views=models>.

Legal and Operational Considerations

Attorneys advising physicians contemplating DPC should be prepared to address several legal and related operational considerations. Given the model's relatively recent vintage, however, there is limited legal precedent on which to rely and, as is often the case with emerging alternative payment models, one finds oneself "building it while flying it." A few of the more prevalent considerations are as follows:

Consumer Safeguards and the Business of Insurance

As referenced earlier, several states have laws on the books clarifying that DPC contracts are not insurance products. Most of these laws include specific requirements for DPC arrangements, intended to protect consumers. For example, the Kansas statute includes the following requirement:

At the top of the first page of the [DPC] agreement, the language shall prominently state in writing, in boldface type in 10-point font or greater and in the following form with all words capitalized:

NOTICE: THIS MEDICAL RETAINER AGREEMENT DOES NOT CONSTITUTE INSURANCE, IS NOT A MEDICAL PLAN THAT PROVIDES HEALTH INSURANCE COVERAGE FOR PURPOSES OF THE FEDERAL PATIENT PROTECTION AND AFFORDABLE CARE ACT AND COVERS ONLY LIMITED, ROUTINE HEALTH CARE SERVICES AS DESIGNATED IN THIS AGREEMENT.

This notice shall be followed by a short, parallel line which shall be initialed by the patient or the patient's legal representative to indicate the patient or patient's legal representative has read the notice statement.²⁰

The fact a state has not enacted such legislation does not necessarily mean DPC contracts are illegal or unenforceable in those states. While a practice pursuing the DPC model in such a state cannot rely on statutory or regulatory provisions, the practice still can defend its arrangement as one for payment of services as opposed to transfer of risk (i.e., an insurance product). Such a practice would be well-advised to incorporate those consumer protections found in other states' laws and regulations into the practice's contracts to bolster this defense.

²⁰ Kan. Stat. Ann. § 65-4978(c).



Health Insurance Exchanges

In addition to state laws and regulations clarifying that DPC contracts are not insurance products, under regulations implementing the Affordable Care Act's health insurance exchanges, the Department of Health and Human Services (HHS) permits a qualified health plan (QHP) to offer direct primary care medical homes in combination with insurance. The two together, however, must meet the requirements for essential health benefits.²¹

In developing these regulations, HHS “considered allowing an individual to purchase a direct primary care medical home plan and separately acquire wrap-around coverage.” HHS concluded, however, that “direct primary care medical homes are providers, not insurance companies which would require the Exchange to develop an accreditation and certification process that is inherently different from certifying health plans”²²

As such, direct primary care medical homes are the only non-insurance offering to be authorized in the insurance exchanges.²³ The first such product became available in the Washington state exchange in 2015.²⁴

²¹ See 45 C.F.R. § 156.245.

²² 76 Fed. Reg. 41866 at 41900 (Jul. 15, 2011).

²³ Robert Doherty, *Assessing the Patient Care Implications of “Concierge” and Other Direct Patient Contracting Practices: A Policy Position Paper From the American College of Physicians*, *Annals of Internal Med.*, Dec. 15, 2015, available at <http://annals.org/aim/fullarticle/2468810/assessing-patient-care-implications-concierge-other-direct-patient-contracting-practices>.

²⁴ Wash. Rev. Code § 43.71.065(3).

Federal Tax Law

According to Section 223(c) of the Internal Revenue Code, an individual with a high-deductible health plan (HDHP)²⁵ is ineligible to make tax-deductible contributions to a Health Savings Account (HSA) if he or she has a second health plan that covers the same services as the HDHP. The IRS maintains that a DPC arrangement constitutes a second health plan for purposes of this provision.²⁶ (The IRS, however, does not take the position that a DPC contract is an insurance product, noting “health plan” as used in Section 223[c] is not limited to insurance).²⁷ Thus, an individual cannot make tax-deductible contributions to an HSA for any month in which he or she is covered by both an HDHP and a DPC arrangement.

The IRS’ position has hindered the growth of DPC, as those individuals with HDHPs, who might consider entering into such an arrangement, are placed at a significant tax disadvantage. DPC advocates are seeking a legislative solution,²⁸ and this summer a bill passed the U.S. House of Representatives that would “protect HSA-eligible individuals who participate in a direct primary care (DPC) arrangement from losing their HSA eligibility and allow DPC provider fees to be covered with HSAs (capped monthly at \$150 per individual and \$300 per family).”²⁹

Medicare Regulations

The Social Security Act prohibits a Medicare-participating provider from “balance billing” a Medicare beneficiary, i.e., charging more than the authorized cost-sharing amount for Medicare covered services.³⁰ Thus, a DPC practice cannot charge a beneficiary for expanded primary care services that may be considered a covered Medicare benefit.

Accordingly, many DPC practices elect to “opt out” of Medicare so that they may privately contract with Medicare patients. Those DPC practices that remain participating providers must carefully thread the needle to ensure that all charges are levied for “non-covered services.”³¹

Contracting

Historically, a physician-patient relationship is formed when a physician examines, diagnoses, or treats an individual, or agrees to do so.³² At such time, a legal contract is formed in which the physician owes a duty to that patient to provide care in accordance with the community standard of care, or to properly terminate the relationship.

Therefore, the nature and scope of the physician’s duties to his or her patient are defined by professional standards of conduct, as opposed to specific contract terms. A patient alleging harm caused by his or her physician’s breach of duty asserts a claim of negligence, as opposed to a breach of contract.

25 26 U.S.C. § 223(c)(1).

26 See June 17, 2014, Letter to IRS Commissioner John Koskinen from Senators Maria Cantwell and Patty Murray and Rep. Jim McDermott, available at https://docs.wixstatic.com/ugd/677d54_d6cf9ad6556a4e99b73123d735f7aa25.pdf.

27 See June 30, 2014, Letter to Senator Patty Murray from IRS Commissioner John Koskinen, available at <https://www.dpcfrontier.com/tax-treatment/>.

28 H.R. 6199, The Restoring Access to Medication and Modernizing Health Savings Accounts Act of 2018, passed the House of Representatives in late July 2018; the Senate has not taken up the measure. See also H.R. 365, the Primary Care Enhancement Act of 2017.

29 Stephen Miller, House Passes Bills Enhancing HSAs, Society for Human Resource Management, July 27, 2018, available at <https://www.shrm.org/resourcesandtools/hr-topics/benefits/pages/house-passes-bills-enhancing-hsas-fsas-hras.aspx>.

30 42 U.S.C. § 1396a(n)(3)(b).

31 See DPC Frontier, Opting Out of Medicare, available at <https://www.dpcfrontier.com/opting-out-of-medicare/>.

32 Bush S, *Formation of the Physician-Patient Relationship: the Oregon Court of Appeals Clarifies, But Questions Remain*, 13 Physician Orgs. 11-13 (2010).



A physician owes his or her patient a duty to adhere to the community standard of care as it relates to specific episodes of care, e.g., diagnosis and management of a medical condition or performance of a surgery. Generally, physicians are not legally required to make available timely appointments, arrange for preventive services, provide education and ongoing management of health conditions, engage in shared decision-making, or coordinate care among multiple providers.

The DPC model introduces such accountability for a patient's health status through contractual duties, i.e., by defining the scope of primary care services the practice will provide in exchange for the specified fee. The DPC contract, therefore, should describe the parties' respective responsibilities with a high degree of specificity and transparency, as this model centers on trust and communication between physicians and their patients. For example, the contract should define the level of access the practice will provide (e.g., same-day appointments, telephonic consultations, remote patient monitoring) and the practice's responsibility regarding services outside the scope of the DPC arrangement (e.g., specialty referrals, orders for advanced diagnostic testing).

At the same time, the DPC contract presents an opportunity for the provider to define expectations for the patient and the remedy for non-compliance. This could include, for example, the duty to receive specified preventive services, to participate in smoking cessation classes, to engage in care plan development, or to complete advance directives.

Additionally, the contract should specify the consequences of the patient's failure to make timely payment. A physician cannot avoid his or her ethical and legal duties by contract. Such consequences, therefore, should be consistent with established practices for terminating the physician-patient relationship. The contract also should define the method by which the parties will address any issues that may arise, such as mediation or arbitration.

If a third party (e.g., an employer) will be responsible for payment, a DPC practice likely will have a separate agreement with that party addressing other issues, such as patient selection and reporting requirements. Such a contract may incorporate key performance metrics to demonstrate value. For example, the amount of the monthly payment may be tied, in part, to the provider's performance on key performance metrics and patient outcomes, which reflect greater value to the patient and the contracting entity.

Malpractice

There is general agreement that open and honest communication between a physician and his or her patients is one of the most effective strategies for reducing malpractice claims. Given the DPC model promotes stronger physician-patient relationships, one would expect that DPC practices experience fewer lawsuits. In fact, some malpractice carriers offer significant discounts for physicians in DPC practices.³³

In the future, however, courts will likely have to grapple with the proper remedy for a DPC patient who has been the alleged victim of malpractice. One may argue that malpractice constitutes a breach of the DPC contract, with corresponding contractual remedies, while the other party will contend it is a breach of a duty of care, with the attendant remedies for negligence (including, as appropriate, economic damages, pain and suffering, and punitive damages).

The Future of the DPC Model

As CMS Administrator Seema Verma stated recently, “Early results indicate that we get better outcomes in terms of quality and cost when providers are responsible for managing a budget. Unfortunately, only about 11% of providers in Medicare are participating in this type of payment.”³⁴ Most physicians, especially small independent practices, have been reluctant to take on risk without commensurate reduction of administrative burden and assurances of financial stability.

Results from government-funded primary care transformation efforts suggest that the limited financial rewards inherent in fee-for-service payment models are not sizable enough to alter physician behavior substantially.³⁵ By contrast, the DPC model—with its break from traditional fee-for-service reimbursement—holds the potential to move more independent physicians to value-based care and enhance primary care services for patients and their families.

How PYA Can Help

PYA helps healthcare organizations evaluate DPC opportunities in their communities and develop and execute DPC strategies. PYA also assists employers in assessing DPC as an alternative method of contracting for healthcare services.

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33 See, e.g., CunninghamGroup, Direct Primary Care and Concierge Physicians: Discount Medical Malpractice Insurance Program, available at <https://www.cunninghamgroupins.com/direct-primary-care-concierge>.

34 CMS, Medicare Remarks by CMS Administrator Seema Verma at the Commonwealth Club of California, July 25, 2018, available at <https://www.cms.gov/Newsroom/MediaReleaseDatabase/Press-releases/2018-Press-releases-items/2018-07-25-2.html>.

35 See, e.g., Mathematica Policy Research, Evaluation of the Comprehensive Primary Care Initiative: Fourth Annual Report, available at <https://www.mathematica-mpr.com/our-publications-and-findings/publications/evaluation-of-the-comprehensive-primary-care-initiative-fourth-annual-report>.