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PHYSICIANS END RUNNING THE PAYERS

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Physicians End Running The Payers
By Alice G. Gosfield

For many years, physicians have declaimed both their dissatisfaction with commercial payers as well as administrative burdens under Medicare that, together, impede their quality of life and their care for patients. Recently this dissatisfaction has reached an even more fevered pitch. The American College of Physicians, in 2017, published a Position Paper on reducing administrative tasks in health care, high among them tasks imposed by payers.[1] Increasingly fed up with a host of perceived injustices payers inflict upon them, physicians are taking a variety of pathways to avoid them entirely or enhance their position with respect to them. This article explores the sources of their dissatisfactions and then considers three alternative pathways some physicians have taken: (1) direct contracting both with employers and also patients; (2) concierge medicine; and (3) opting out of Medicare.

Payer-Physician Tensions

In a 2016 AMA study of physician dissatisfaction with practice,[2] payers, both public and private, were exceeded as a source of physician dissatisfaction only by electronic health records. Wasting time on unnecessary administrative work, as well as the opacity of what actually can qualify for prior authorizations were cited as principal irritants. Medical Economics magazine has, for some time, surveyed physicians regarding their attitudes toward payers. In March, 2017, they said "Ask any doctor what they think of payers and they'll likely say things that can't be printed"[3]. The primary challenges of dealing with payers cited in their survey were number of prior authorizations, frequent unexplained denials, negotiating, customer service and narrowing of networks.

Prior authorizations come in for particular criticism in almost all surveys as an enormous time waster for physician practices. The 2017 Medical Economics survey found that, on average, physicians spend about six hours a week on prior authorizations alone, while their staff spends, in addition, an average of 13 hours a week.[4] Their biggest frustrations were time spent to get authorizations, feeling that the payers are practicing medicine and telling them how to do their job, reasons for denial, lack of clarity on what requires a prior authorization and managing the number of outstanding requests. More services are increasingly subject to prior authorizations. Drug prior authorizations are particularly problematic given the different responses individuals have to the same drugs. In its 2018

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[1] Erickson et al, "Putting Patients First By Reducing Administrative Tasks in Health Care: A Position Paper of the American College of Physicians", Ann of Int Med, 4/19/2017

[2] Colligan et al, "Sources of physician satisfaction and dissatisfaction and review of administrative tasks in ambulatory practice: A qualitative analysis of physician and staff interviews", (Oct 2016), https:/www.ama-assn.org/go/psps

[3] "2017 Payer Scorecard", Medical Economics, March 25, 2017 at 25.

[4] "Time spent weekly on prior authorizations", Medical Economics, March 25, 2017 at 16.

Regulatory Burden Survey, 82% of the respondents to the Medical Group Management Association's Survey regarding burdens on physician practices cited prior authorization as second most burdensome after the Medicare Quality Payment Program which 88% of respondents cited.[5]

The 2018 AMA survey regarding physician views of payers produced results that were virtually identical to those in 2016, demonstrating little change in payor performance as far as the physicians are concerned.[6] In response to an inquiry for the 2018 Medical Economics article posed to America's Health Insurance Plans -- the trade group for payers -- their spokesperson said in part,

> It's important to note that there's a tremendous amount of collaboration between insurance providers and physicians/clinicians/hospitals already. Insurance providers employ doctors, nurses and other clinicians to help develop approaches that ensure necessary treatments, confirm treatment regimens ahead of time, dispense appropriate amounts of prescription drugs and utilize the most cost-effective therapies.[7]

Without question, most practicing physicians would not regard the physicians and nurses employed by insurers as representing collaborators in the way the insurers apparently see them. In its call for reducing administrative tasks in health care, the American College of Physicians criticized a lack of collaboration by public and private payers with professional societies and frontline clinicians in designing their administrative programs.

In the 2018 Medical Economics scorecard where physicians rated the payers, on average physician practices dealt with 14 separate payers[8]. Physicians were asked to rate their largest payer on a variety of issues. They cited an additional litany of complaints regarding the range of their interactions with payers.

On a scale of 0-10 with 10 being excellent, on no issue except the ability to make payments did the payers score above 5 and on payment they scored a bare 6. With respect to patient information, with nothing more than a 4.2, physicians decried the clarity of information on the patient's insurance card, responsiveness to changes in patient data provided by the practice, the pre-authorization process and communication with the patient on their co-pays and deductibles. Faring worse in communicating with

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[5] MGM 2018 Regulatory Burden Survey, https://www.mgma.com/resources/government-programs/summary-of-findings,-mgma-2018-regulatory-burden-s?utm_campaign=government-affairs&utm_medium=email&utm_source=10.3.18%20Washington%20Connection&elqEmailId=7736&elqTrackId=3D35694F4C5EFE3ED80C48C4052C9375&elq=76f0601b967843e392c306ee4881745c&elqaid=7736&elqat=1&elqCampaignId=3771; See Daly, "MACRA Requirements Top Physician Practice Burdens: Survey," HFMA Aug. 9, 2017, http://www.hfma.org/content.aspx?id=55199

[6] Shryock, "Driving Change in Medicine", Medical Economics, (June 25, 2018) at 10.

[7] Id at 34.

[8] "Physicians Rate The Payers," Medical Economics, June 25, 2018 pp. 36-39

the practice, in the 3.8 range, in descending order of performance, they complained of an inability to identify who to contact with inquiries, failure to notify regarding contract changes, ease of reporting required data, difficult to navigate websites and complexity of navigating the phone system. Ranked still worse, predominately in the 3.3 range, were payer responses to inquiries on claims denied or requiring more information, response time to inquiries, time on hold and willingness to negotiate on reimbursement rates. The payers scored best (6.0) on their ability to actually make payments, but the payment experience itself did not fare very well. The overall rating by all practices was 3.9 and for solo physicians a 3.5.

This is hardly the basis for a rosy future. Against this background, physicians are taking steps to minimize their interactions with payers or to generate additional money and time despite them.

Direct Contracting with Employers

One of the techniques for avoiding these burdens has been a move to eliminate the plan as middleman with the providers contracting directly with the employer who is paying for the healthcare expenses of its employees. The direct contracting option, by definition, is available with self-funded employers who pay their employees' (and dependents if covered) healthcare expenses directly out of their own funds, without contracting with a licensed insurer. There are actually two forms of cutting out the health plan middleman, each with a different focus: (1) direct contracting with employers; and (2) direct contracting with consumers. We begin with the direct relationship with employers. They also differ in the extent to which they eliminate administrative burden, but enhanced payment may make up for the administrative pain.

Although increasingly popular today with each week bringing new stories of health systems or physician groups entering into these arrangements, provider direct contracting with employers is not new. While some transactions focus on primary care, some take into account the full scope of health care. But similar efforts were seen in the late nineties, without much subsequent traction.

1. History.

While physicians decry the administrative burdens imposed on them by health plans today, in 1997 when the movie "As Good As It Gets" played, audiences burst into spontaneous applause when Helen Hunt criticized her HMO for denying her son's asthma care. Consumers felt that denial of prior authorizations, stringent gate-keeping, narrow networks,. and disruption of the traditional doctor-patient relationship made them mistrust these relationships. Drive-by-deliveries and one day mastectomies were among the features that created consumer anxiety.[9] Whether care was actually being managed was another concern, since many health plans primarily lowered payment rates and

[9] Wehrewien, "Why Managed Care Is Getting A Bad Rap", Managed Care, Feb 1, 1997

limited hospitalizations to cut costs.[10] But some employers were bothered by the fact that despite these more aggressive control features, they were not seeing the results that managing care by insurance companies was touted as being able to produce. They moved to eliminate the middleman and contract directly with providers.

One of the most noteworthy and highly regarded of these was the Minnesota Buyers Health Care Action Group (BHCAG) which was an employer coalition that included large employers like 3M, Pillsbury, Honeywell and General Mills, representing 400,000 lives. The Twin Cities, with the Mayo Clinic and other health systems, had a proliferation of excellent providers available. Some observed that BHCAG was a group of employers

> banding together and setting standards that create a consumer-driven competition among provider-governed networks. BHCAG member employers would prefer to contract with a health plan to sponsor the care system model, but none of the plans are wiling to do so.[11]

The model was relatively complex, with tiered health systems including physicians and hospitals. Physicians were expected to be accountable for the full continuum of care, either provided directly or through sub-contracts, processing of claims through a single administrator, adherence to set quality standards, referral of patients to centers of excellence for certain high cost services, implementation and measurement of performance in accordance with guidelines and adherence to a standardized payment and risk-adjustment methodology.[12] Still, at its inception, there was hope that BHCAG might force the evolution of HMOs into more consumer-centric organizations.[13] Over time, BHCAG morphed into a for profit entity which attempted to market elsewhere outside the Twin Cities and was eventually, in 2004, purchased by the then largest health plan in the Twin Cities.[14] They went to Iowa, St. Louis, Denver and more places, with limited success and implementation. Barriers to expansion included the requirement to rely on third party administrators to actually make payments, the geographic footprint of the provider network, the size of the employer/purchasers and more. A review of their lack of

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[10] Ernst and Young, "Managed Care 2.0: everything old is new again?" Health Care Industry Post (2013), https://www.ey.com/Publication/vwLUAssets/EY-managed-care-2-0-everything-old-is-new-again/$FILE/EY-managed-care-2-0-everything-old-is-new-again.pdf

[11] Steve Wetzell, executive director of BHCAG quoted in Diamond, "Direct Contracting: Why It Hasn't Grown", Managed Care (Juy 1, 1999) https://www.managedcaremag.com/archives/1999/7/direct-contracting-why-it-hasnt-grown

[12] Bilodeau, "Direct Contracting By Physicians: How Big A Competitive Threat", Managed Care, Jan 1, 1996 https://www.managedcaremag.com/archives/1996/1/direct-contracting-physicians-how-big-competitive-threat

[13] Id.

[14] Christianson and Feldman, "Exporting The Buyers Health Care Action Group Purchasing Model: Lessons From Other Communities", The Milbank Quarterly 2005, pp149-176.

success foretells some of the myriad challenges in these approaches, including what some commentators saw as managed competition, tiering health systems and pitting them against each other for consumers to choose among. Even so, the same commentators in 2005 basically concluded that

> {T}he BHCAG model provided important evidence that a purchasing initiative That (1) is based on direct contracting with providers, (2) employs innovative payment methods focusing risk-adjusted bids submitted by providers themselves and (3) incorporates consumer incentives for making price- and quality-conscious choices, can be developed and fielded with considerable local success.[15]

Most of these efforts, however, frittered out and disappeared. There had been a fair number of skeptics when some of these programs launched. "Purchasing health care from the provider is not like buying paper for your copier, where the colors, the sizes and the amounts are standardized."[16] Most employers are small employers and if they join with other employers, they become a Multiple Employer Welfare Arrangement (MEWA) and then subject to insurance regulation. One observer noted that "You can't actually eliminate the middleman. You can only recreate him."[17] The need for claims payment, utilization review and their administrative underpinnings were not the core competencies of either the employers or the providers. Geographically dispersed employees was another challenge. Even those who were skeptical, though, admitted that very large employers with concentrated localization of employees, in concert with broader scoped providers-- in those days referred to as 'integrated delivery systems" (although they weren't very integrated) --- might be able to make such programs work.[18] And yet, they faded and have been essentially missing in action since the early aughts. Why the resurgence of interest today?

2. *The Changed Environment*

Since the last movement toward direct contracting, much in health care has changed. The adoption of the Affordable Care Act motivated many shifts in the healthcare landscape, from increased consolidation of health plans, health systems and physician groups, to significantly more physician employment by health systems, to a vastly greater increased emphasis on 'value' -- controlled costs with improved patient outcomes and better patient experience.[19] Others have observed that there was, after the law's enactment, a clear

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[15] Id at 172

[16] A benefits consultant quoted in Diamond, supra n. 11

[17] Kongstvedt quoted in Bilodeau, supra n.12.

[18] Halvorson, CEO of HealthPartners which had contracted with BHCAG to provide infrastructure, quoted in Bilodeau, supra n. 12.

[19] For a discussion of how the health reform legislation propelled new interest in value in the federal programs, see Gosfield, "The New Value on Provider "Value", HEALTH LAW HANDBOOK (Gosfield Ed) (2011 Edition), pp 1-34

change from the world of the heyday of managed care in the 1990s in factors including who was leading changes in managed, care, to methods of cost control, risk sharing, care management, quality of care, information technology and patient engagement.[20] While their comments were focused primarily around changes in health plans, they are relevant to the context for the resurgence in direct contracting.

Exhibit 1. Managed Care 1.0 versus 2.0: key differences

Element	Managed Care 1.0	Managed Care 2.0
Leadership	Led by payers	Led by accountable care delivery groups, including CMS, hospital systems, physician groups, payers and joint partnerships
Cost control	Focused on saving money through focusing only on utilization, restricting access to specialists and limiting hospital length of stay	Focused on saving money by improving care and reducing waste and redundancy
Risk sharing	Risk shifted from payers to providers, often through full capitation agreements	Risk managed by payers collaborating with physicians and hospitals
Care management	Payer-led disease management practices and episodic care	Tools to pursue continuous, coordinated care, with robust guidelines, standards of practice and decisions based on evidence and protocol
Quality of care	No incentives for providing or measuring quality care	Quality addressed through measures tied to bonus payments; providers are held accountable for achieving certain quality metrics
Information technology	Limited data on patient outcomes, use of services and physician performance	Increasing use of electronic health records (EHRs) for clinical decision support, pathway adoption and quality reporting; emerging use in predictive modeling and population health management
Patient engagement	Limited patient engagement; paternalistic approach	Patient-centered medical homes evolving; patients actively engaged in evidence-based decision making

Source: EY analysis, 2013.

2 **Health Care Industry Post** News and analysis of current issues affecting health care providers and payers

But for all the emphasis on increased collaboration, large self-funded insurers have not been impressed with the plans' responsiveness to their needs. "The interest in direct contracting is not a coincidence. It's one of the few strategies that employers can use."[21] Echoing the concern for lack of responsiveness of the plans, another representative of a large purchasing coalition observed that direct contracting makes the providers more accountable to the needs of the employer-purchasers. "We'd be thrilled if our plans came to us with standardized, comparable data on total cost of care and health outcomes for important conditions and worked with us to steer patients to the high performers",[22] with the implication that the plans do nothing of the kind.

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[20] Ernst and Young, "Managed Care 2.0: everything old is new again?", (2013) https://www.ey.com/Publication/vwLUAssets/EY-managed-care-2-0-everything-old-is-new-again/$FILE/EY-managed-care-2-0-everything-old-is-new-again.pdf

[21] Suzanne Delbanco of Catalyst for Payment Reform, quoted in "More employers go direct to providers, sidestepping payers", Healthcare Dive, March 14, 2018 https://www.healthcaredive.com/news/more-employers-go-direct-to-providers-sidestepping-payers/518269/

[22] David Lansky of the Pacific Business Group on Health, quoted in Healthcare Dive at n. 21.

Employers who have taken the modern route to direct contracting include Boeing, General Motors, Walmart, Intel, Whole Foods, Lowe's, and Jet Blue, among others.[23] The primary models for which they contract are accountable care organizations (ACO) for an entire employee population, a bundled payment, carve out or Centers of Excellence for a defined condition, and an advocacy role such as meeting with hospital leaders to advocate for quality initiatives or payment reforms. The conditions addressed most commonly at centers of excellence/experience are bariatric surgery, infertility, cardiac surgery, orthopedic surgery, oncology, maternity and transplants.[24] One problem in widely diffused provider networks dealing with expensive, high risk, complex conditions, is that the patients are frequently misdiagnosed, adding both increased cost and harms to the already expensive healthcare equation.[25] Some are also focusing on patient centered medical homes for primary care.[26]

3. *Employers Contract with Physicians*

While the first iteration of direct contracting was for the totality of the services employees needed, there is also a distinct and potentially more successful model of contracting for primary care, and specialty care for defined conditions. In these models, the physicians are far more central to the approach. This approach, in part, is intended to relieve physicians of the administrative burdens of prior authorizations, documenting medical records to justify the five levels of visit codes, and billing for each service rendered.[27] Where specialty services are involved, the physicians typically provide the full continuum of physician services associated with specialty care such as a knee replacement, from the initial work up of the patient, through the procedure to include rehabilitation services.

The American Academy of Family Physicians in advising primary care physicians about how they can approach employers[28] have suggested add on services including wellness and preventive services, traditional workers' compensation services, occupational health screenings, comprehensive primary care services for episodic illness and chronic care,

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[23] Livingston, "Left out of the game: health systems offer direct-to-employer contracting to eliminate insurers," Modern Healthcare, Jan 27, 2018; Stempniak, "Will Boeing Change Heatlh Care?" Hospitals and Health Networks, Dec 10, 2015; Henry Ford Health System Press Release, Aug 6, 2018; and supra n. 21.

[24] https://www.catalyze.org/product/get-started-direct-contracting-2/

[25] Emerick, "Specialty care component: Employee friendly direct contracting with high-quality referral centers," Health Rosetta's Principles (2017) https://healthrosetta.org/education/tom-emerick-employee-friendly-direct-contracting-with-high-quality-referral-centers/

[26] Supra n. 21.

[27] Madden, "Physicians Contract With Self-Funded Employers", Physicians Practice (Oct 28, 2015)

[28] AAFP, "Direct Contracting with Business by Family Physicians (Discussion Paper) (2018), https://www.aafp.org/about/policies/all/business-physicians.html

including at work site clinics, which are also increasing.[29] Payment models include a per employee per month fee, a negotiated flat fee that covers the total cost, including fees for the physician or any mid-level providers, and a potential additional co-payment by the patient.[30] These approaches also avoid the problems which arise in broader risk assumption where one set of providers may be paid to obtain the services of other providers. State insurance regulation may be triggered depending on how risk is assumed and shared; and the ERISA laws may be at issue if multiple employers join together to get better bargaining power.[31]

Those who have worked with employers in this way report that first the employers have to recognize that their costs are "going in the wrong direction" and that investing in enhanced primary care will drive more utilization in primary care, but that the shift will save money in the long run.[32] The physicians offer enhanced primary care for a per member per month additional payment on top of whatever capitation they would ordinarily be paid. The employers who work directly with physicians include those who take an all or nothing approach, so that their employees must use this option and others who offer more flexibility, allowing employees to enroll with participating physicians. To make these programs work, those who engage in this activity report that everyone must be on a standard electronic health record and must agree to document consistently.[33] The employers share data with the physicians, who also analyze data on a regular basis. Reportedly a consistent documented clinical work flow is useful to foster collaboration and share best practices both clinically and operationally across practice settings.

In this context, the administrative burdens are definitely reduced as reported by physicians,[34] although that may be a function of the reduced patient panel size. They have not been able to shift prior authorizations to specialists; and the pharmaceutical benefit managers (PBMs) continue to be a principal headache. That said, they have eliminated the need for referrals since these are not HMO plans with gatekeeper requirements. Obviously, the need to submit claims is eliminated. The physicians, still, reportedly are

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[29] See, Greene, "United Shore Financial contracts with direct primary care provider", Crain's Detroit Business, (Oct 2, 2016) http://www.crainsdetroit.com/article/20161002/NEWS/161009984/united-shore-financial-contracts-with-direct-primary-care-provider

[30] Supra n. 27.

[31] For a good summary of some of these issues see Howard, "Back To The Future: Provider-Employer Alliance Direct Contracting for Health Benefits, "The Health Lawyer, ABA (April 2018) pp. 1-9

[32] Interview 8/2/2018 with Mason Reiner, CEO, R-Health, Elkins Park Pa., a management company which works both with a state employer benefit direct contracting program with physicians in New Jersey and helps physicians contract directly with patients in Pennsylvania.

[33] Id.

[34] Personal communication, Steven Horvitz, DO, Moorestown NJ, by email 9/11/2018.

able to "run leaner with less clerical staff".[35] They also train their medical assistants to work as patient advocates and facilitate patient travels through the health care system.

4. Acting Through A Network

Unless a physician practice group is very large with widely located offices, it is unlikely an employer will contract with a single group alone, unless they come onsite to the employer's workplace to see employees there. More frequently, the employers contract with a network of otherwise independent practices who come together for these purposes. Independent Practice Associations (IPAs) or in today's parlance Clinically Integrated Networks (CINs) are vehicles for joint contracting, Unless the network is clinically integrated, though, otherwise competing physicians cannot bargain collectively with an employer without running afoul of the antitrust laws.[36] But integration to avoid antitrust liability is hardly sufficient motivation to sustain the difficult and serious work of integration of processes to produce better value.[37] Standardizing to the science and standardizing processes, including documentation, use of mid-level practitioners, standing orders in the office, equipping the offices, and more, produces better outcomes, saves time, and permits collective negotiation among physician practices. The key is to collect data, share that data and change performance based upon it.[38]

In the formation of or joining with an existing network, there are a range of contracting and governance issues for physician practices. Some of these are addressed in the contract between the employer and the network, and others arise within the network itself. Others turn on the payment model – whether bundled or episode-based payment or per employee per month payment.

If the agreement is for bundled payment, knowing how the budget was designed and what was included is critical.[39] Being certain when reconciliation occurs and payment is made are also essential; since most of these contracts pay fee-for-service during the course of treatment and then reward providers in a gain-sharing mode at the end of the bundle. Regardless of the payment model, data management will be critical to success. Data

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[35] Id.

[36] For a very good treatment of the antitrust issues in clinical integration, see Leibenluft and Weir, "Clinical Integration: Assessing The Antitrust Issues," HEALTH LAW HANDBOOK, WestGroup, a Thomson Reuters Company (2004 Edition) pp,. 27-47

[37] Gosfield and Reinertsen . "Achieving Clinical Integration with Highly Engaged Physicians". Unpublished manuscript; (December 2010). http://www.uft-a.com/PDF/ACI-fnl-11-29.pdf

[38] See Gosfield, "Clinical Integration Self Assessment Tool" v 2.1 (Network/IPA Version) (2012) http://www.uft-a.com/PDF/CISAT_IPA_V.2.1.pdf

[39] For a deeper consideration of bundled payment see, Gosfield, "Bundled Payment: Avoiding Surprise Packages", HEALTH LAW HANDBOOK, WestGroup, a Thomson Reuters Company (2013 edition), pp. 279-307; Gosfield, "What's Fair in Bundled Payment Contracting?" , Managed Care (October 25, 2013). https://www.managedcaremag.com/archives/2013/10/whats-fair-bundled-payment-contracting

issues have felled some of the full bore direct contracting initiatives with large health systems.[40] In a network of otherwise independent practices, what data other providers get to know about a group's performance is important, along with how current the data will be. How data errors get challenged or corrected should be addressed.

Dispute resolution has always been a concern when practices contract with payers; and in the employer direct contracting setting the issues are the same. In bundled payment it is fair to have no appeal or dispute resolution mechanism regarding the budget, the rules for triggering, breaking or ending an episode for which payment is made and the rules for severity adjustment. These would be documented in the agreement as the result of negotiations. Matters that should be subject to appeals are whether an episode is triggered or broken, whether a practice qualified for upside payment or should pay if there is downside risk, and whether the data supporting payment is accurate. Even in a per employee per month payment model, the practice should be able to appeal if the amount of payment varies with scores, along with whether a provider met quality or efficiency thresholds or targets, if they affect payment amounts. Attribution rules regarding which group gets patient results assigned to it can also create disputes and should be addressed.

Governance issues which arise in all networks include issues around ownership and voting rights, representation on the governing body and the need for super-majorities for some issues. Issues in direct contracting which might be made subject to super-majorities include changes to compensation metrics, changes to allocation or attribution rules within the network, and adding new classes of providers to the network, What happens when two groups seek to be credited for the same patients? All of these are practical realities in these new relationships with the employer who is footing the healthcare bill. The issues that arise in direct patient contracting are somewhat different.

Direct Contracting with Patients

Sometimes referred to as "Direct Primary Care" (DPC) this model of end-running the payers creates a direct contract between the physician and patient without the interposition of a third party. It has sometimes been referred to as well as 'concierge light' because it has features in common with concierge medicine (discussed more fully below), but is typically less expensive for the patient. The typical scope of services included is office visits, laboratory work, vaccinations, generic drugs and sometimes low level imaging. [41] Others have observed that some programs include more non-traditional services including electronic correspondence between physician and patient, and home visits.[42] The patients continue to carry health insurance for hospitalizations. Direct

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[40] Bannow, "Do providers have the data chops to succeed with direct contracts?", Modern Healthcare (Aug 13, 2018) pp. 6-7

[41] Beck, "With Direct Primary Care, It's Just Doctor and Patient," WSJ (Feb 27, 2017)

[42] Adashi et al, "Direct Primary Care One Step Forward, Two Steps Back", (July 12, 2018) doi:/10.001/jama.2018.8405

primary care has also been touted to employers to make available to their employees in conjunction with high deductible health plans.[43] There is a national coalition of direct primary care providers[44] and other regional ones, as in New England where there are at least two – Direct Care New England including independent practices in Connecticut, Rhode Island, New Hampshire, Maine and Massachusetts,[45] and New England Direct Primary Care Alliance with practices in Maine, New Hampshire and Massachusetts.[46]

In a 2015 study looking at the extent of the phenomenon across the country, researchers -- using such terms as direct primary care, retainer medicine, membership medicine, concierge medicine and boutique medicine -- found a paucity of published information. They defined a direct primary care practice as one 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.[47] They found 141 practices with 273 locations spanning 39 states. More than 90% of the practices had less than 4 physicians. Of the practices which disclosed enough information to make a judgment, 66 had opted out of Medicare (discussed more fully below), while 17 continued to accept Medicare. Among the respondents were some large practices—Qliance in Washington, Iora Health in Boston and Paladina in Colorado -- that, as stated in other articles[48], also contract with Medicare Advantage and, in at least one instance, a Medicaid program. A review of the year 2017 for Direct Primary Care Practices in the Direct Primary Care Journal found that three significant DPC closures had occurred but did not state in the Press Release, which they were.[49] Another source indicates that Qliance, which had been one of the earliest DPC practices, stopped operating in 2017. [50] By 2018, at least one tracker noted 884 DPC practices across 48 states.[51] Another review

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[43] Tetreault, "Outlook for Employers Privately Contracting With Physicians in Direct Primary Care and Concierge Medicine Offices", Concierge Medicine Today, (May 5, 2016) https://conciergemedicinetoday.org/2016/05/17/outlook-for-employers-privately-contracting-with-physicians-in-direct-primary-care-and-concierge-medicine-offices-2/; and "How will Direct Primary Care benefit my company and employees?" https://dpcnewengland.org/employers/

[44] Direct Primary Care Coalition, www.dpcare.org

[45] Direct Primary Care New England, https://dpcnewengland.org

[46] www.nedpca.org

[47] Eskew and Klink, "Direct Primary Care: Practice Distribution and Cost Across the Nation," J of Am Bd of Fam Med (2015) 793-801

[48] See n. 42 supra.

[49] "Direct Primary Care Journal (DPC Journal) releases 2017-2018 Annual Report and Market Trends Analysis: Highlights industry trends and efforts in the Direct Primary Care (DPC) market space",(March 20, 2018) http://dpcjournal.com/

[50] Huff, "Direct Primary Care Is About To Take Off- or Maybe Not," Managed Care (September 16, 2017) https://www.managedcaremag.com/archives/2017/9/direct-primary-care-about-take-or-maybe-not

[51] https://www.dpcfrontier.com/mapper/

found that only an estimated 13% of primary care physicians had adopted some form of direct payment.[52]

Proponents for DPC tout its ability to control costs, lower hospitalizations, give more time to patients in visits and improve patient satisfaction.[53] They argue that resources previously devoted to the administrative demands of payers can be shifted to develop therapeutic, longitudinal relationships with patients which could improve health outcomes, reduce rates of hospital readmissions, specialty visits, radiologic and laboratory testing and emergency care.[54] It has been vaunted as a cure for physician burn-out by giving physicians better control of their schedules, with fewer patients in their panels, as well as making the overhead of physician practices far less.[55] Some critics say there simply isn't enough data to make claims about cost control and improved quality; and that its expansion could aggravate already existing physician shortages.[56] Still others decry the risk of cherry picking only healthy patients, while potentially giving patients a steep cost sharing burden with a focus on high deductible wrap-around health plans for services not included in the model.[57] Others believe that DPC contracts with employers will supplant individual enrollments.[58] Others argue that creating a network of already existing practices who can dedicate some slots in their day to DPC participants is another way to go. Healthcare2U based in Austin, Texas, took this path as of September 2016, operating more than 100 clinics in at least a dozen states including Connecticut, Florida and New Jersey.[59] By August 2018 they were in 21 states,[60] marketing to employers and individuals.

The American Academy of Family Physicians has been generally supportive of DPC medicine.[61] They offer a basic explanatory webpage and provide guidance for how to

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[52] Adashi, supra n. 42

[53] See Beck, supra n. 41

[54] Adashi supra n. 42.

[55] "The rise of direct primary care," Medical Economics (April 10, 2016) http://www.medicaleconomics.com/medical-economics-blog/rise-direct-primary-care

[56] See Huff, supra n.50.

[57] Adashi, supra n. 42.

[58] A number of direct primary care practices online have already taken this path, but they still have direct agreements with their members even though the employer pays the membership fee.

[59] Adash, supra n.42

[60] https://healthc2u.com/locations/

[61] Huff, supra n. 50 and https://www.aafp.org/about/policies/all/direct-primary.html

begin evaluating whether a DPC practice is appropriate for any group.[62] The American College of Physicians adopted a position paper that addresses the fact that these practices can be discriminatory against lower income patients, may lower access to care as physicians decrease their patient panel size and suggest that physicians consider the patient-centered medical home as a way to improve physician and patient satisfaction with care.[63] That said, they began their positions and recommendations with the statement that "The ACP supports physician and patient choice of practice and delivery models that, are accessible, ethical and viable and that strengthen the patient-physician relationship".[64]

1. State Regulation

Each of the states regulates insurance within its borders. The monthly payment in DPC medicine, typically, covers a range of services. Although this is akin to capitation, because the patient is paying it directly to the provider, there have been instances of insurance commissioners asserting that the risk transfer in the physician taking the risk of how much the patient will use his services, means that the physicians are, in effect, offering insurance, which the states regulate. Reportedly these assertions, or at a minimum inquiries, were made by insurance commissioners in Washington, West Virginia, North Carolina, New York and Maryland, where the earliest DPC practices opened around 2006 and 2007.[65] Efforts to avoid these problems led to legislation as of Aug 2018 in 27 states, recognizing DPC and in some instances "retainer medicine" as permitted.[66] In some instances the scope of permissible practice is stated (primary care only); sometimes the nature of the payment (monthly prepaid) is part of the definition of medical practices exempt from insurance regulation. Some explicitly prohibit charging an insurer while charging a membership, retainer or other fee to patients. Some prohibit dispensing of drugs. West Virginia was the first state; and it established a "preventive care pilot program" which restricted marketing, pricing and scope of practice with required reporting requirements.[67] But, in 2017, the law was amended, lifting many of the restrictions and allowing, but not requiring, regulations to be published by the State

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[62] https://www.aafp.org/news/family-doc-focus/20180709fdf-gold.html; and https://nf.aafp.org/Shop/practice-management-tools/dpc-toolkit

[63] Doherty, "Assessing the Patient Care Implications of "Concierge" and Other Direct Patient Contracting Practices: A Policy Position Paper From the American College of Physicians", Ann of Int Med (Dec 15, 2015) pp 949-952

[64] Id at 951

[65] Eskew, "Direct Primary Care Business of Insurance and State Law Considerations," , J of Legal Med (2017) pp. 145-154

[66] Id and also see, ReminderCall.com "New Direct Primary Care State Laws – Updated" (May 29, 2018) https://www.remindercall.com/direct-primary-care-state-laws/; and AAFP Backgrounder, "direct Primary Care", https://www.aafp.org/dam/AAFP/documents/advocacy/payment/dpc/BKG-DPC.pdf

[67] See Eskew, supra n. 65

Board of Medicine.[68] In Oregon, practices must be certified by the Department of Consumer and Business Services.[69]

With 27 states exempting DPC or retainer practices from insurance regulations, 23 states are silent on the subject. Commentators have suggested a range of steps that would thwart the assertion that the payment model entails the business of insurance.[70] Among them are explicitly limiting the number of patients in the panel which can reduce the risk of not being able to serve the patients enrolled. Defining the scope of practice would make it clear that the risk undertaken by the physician is limited. The contract of enrollment or participation and all marketing ought to make it clear (and explicitly disclaim) that the program is not an insurance product, and that all participants need to maintain separate insurance for services not covered in the program. Permitting the patients to terminate at any time with a pro-rated premium is also not typical of insurance premium payment. Requiring that all patients have at least one annual visit makes it clear that the payments are for actual services rendered and not insurance against unknown risks. Limiting contractually the number of visits or lab tests, or whatever is included in the scope of practice, also makes the payments more for services and lessens the risk of loss to the physician.

2. Contractual Language

Within the boundaries of state law, the contracts with patients vary somewhat, although some have significant commonality. Set forth here is a discussion of 13 separate patient agreements for direct primary care. The state where they are used is indicated. For ease of reference and to avoid footnoting each one, this section refers to them by the following number assigned to each: (1) Coastal Direct Primary Care (DE)[71]; (2) Direct Doctors, Inc., (RI)[72]; (3) Family First Medical Center (ID)[73]; (4) First Primary Care (TX)[74]; (5) Grants Pass Family Medicine (OR)[75]; (6) Inspire Health Direct Primary Care (CO)[76]; (7) Nextera Healthcare (CO)[77]; (8) Optimal Health Direct Primary Care (PA)[78]; (9) R-Health

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[68] W VA Code §30-3F-1 et seq.

[69] 2017 ORS 735.500

[70] See Eskew supra n. 65

[71] http://www.coastaldpc.com/images/PDF/Coastal_Direct_Primary_Care_Contract.pdf

[72] http://www.directdoctors.org/uploads/2/4/2/5/24250094/direct_doctors_patient_agreement.pdf

[73] http://www.familyfirstif.com/wp-content/uploads/2015/02/FFDPC-Direct-Primary-Care-Enrollment-Agreement.pdf

[74] https://www.firstprimarycare.com/patient-terms-and-conditions/

[75] http://grantspassfamilymedicine.com/wp-content/uploads/2017/05/DPC-Patient-Agreement-2.pdf

[76] http://www.inspirehealthdpc.com/patient-agreement

[77] https://nexterahealthcare.com/documents/NH-Member-Services-Agreement.pdf

State Employees (NJ)[79]; (10) R-Health Individuals or Employer based (NJ and PA)[80]; (11) Vintage Direct Primary Care (WA)[81]; (12) Whole Family Medical Center (OH)[82]; (13) a template created by DPC Frontier.[83]

The documents themselves vary in format and formality. Some are actual webpages on the practice's website (4, 6). Others, linked to the applicable website, are more informal agreements where the patient is enrolled with statements referencing their obligations with "I will…", "I acknowledge"…(1, 11). Others are unnumbered documents referencing the patient as "you"(7); while others are formal contracts (2, 3, 5, 8, 12, 13) Still others look like contracts but don't have signature lines (4, 9, 10)[84] while others have signature lines not on the agreement, but on attached exhibits or addenda (2).

2.1 Relationship to Insurance and Medicare

Every single one of them disclaims that they are an insurance policy; and most explicitly state the need for the member to maintain additional insurance to cover non-covered services, which most of them list (e.g., hospitalization, emergency visits, specialist care). Most state that they do not participate in any insurance program, although occasionally they state that they will give the patient documentation if they want to file a claim (6). Most say they will file no claims, nor facilitate claims filing. With regard to Medicare, many state specifically that they have opted out of Medicare (2, 5, 6, 12, 13) (see below for a broader discussion of opting out); and some attach an acknowledgement of the opt out for use during the term of membership or state that the patient must sign the Medicare opt out acknowledgement if they are or become Medicare eligible during the term. (2, 5, 6, 8, 11, 13) Some state that notice must be provided if the patient becomes a Medicare patient and even further that the agreement will automatically terminate if the patient becomes a Medicare patient. (3, 4, 8) Some merely state that the agreement may not

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[78] https://optimalhealthdpc.com/documents

[79] https://www.r-health.md/wp-content/uploads/2017/11/NJ-SHBP-SEHBP_Member-Agreement-terms-of-service-2017.11.7.pdf

[80] There are two sentences that distinguish the NJ state employees agreement from the one which is used for other employers or individuals outside of that program.

[81] http://www.impcenter.org/HigherLogic/System/DownloadDocumentFile.ashx?DocumentFileKey=4cb9d032-313a-46c1-8212-17c12aaad82c

[82] http://www.wholefamilymedical.com/uploads/3/1/4/1/31410097/patient_agreement_-_whole_family_direct_care.pdf

[83] Available only on request. https://www.dpcfrontier.com/forms/

[84] Which may reflect the fact that they are on a website. The practice may have a different execution version that they actually use with individuals.

apply to Medicare. (7, 9) All state that the patient has financial liability for services rendered.[85]

2.2 Scope of Services

As to scope of services which are provided for the monthly membership fee, there is some variability. Some do not state their services in their contracts, but in ancillary guides or appendices. (1,3,8,11). Some merely reference family medicine or primary care (2,4,7,13), while others specify office visits, school, camp and sick evaluations, routine gynecologic care, chronic disease management, in office procedures, weight management and stress management (4,5). Some include some laboratory studies (12, 5, 6); some diagnostic testing (12, 6), allergy testing (7), low cost drugs (5,6,13), and minor skin lesions (6,7,12). Some specify that additional services are available for a fee and state those fees, including massage therapy (12) or osteopathic manipulations (2). Some emphasize 24/7 access, no waiting for scheduled appointments, home visits, and same day/next day services (2,7,11). One even extends their services to a visitor who is visiting for at least two weeks (11)!

Two deny availability of their program to some patients, including those who are seeking chronic controlled substances (5, 13) and to others based on their conditions that entail sufficiently expensive specialist services as to be unlikely to benefit from the program including cancer, hepatitis C, multiple sclerosis and Rh diseases like lupus (7). Many exclude high end imaging or any imaging, laboratory, obstetrical services, DME, drugs, immunization costs, and dialysis. (4, 11) One charges for more than 10 office visits a month (6); another for more than 20 visits a year (12). For some, additional laboratory services, imaging, and drugs are available at cost (11, 13).

2.3 Communication and Privacy

Many of the agreements address the more innovative and alternative communication techniques they offer to members of their programs. At the same time they state their commitment to privacy, but further that email, facsimile, video chat, cell phone, texting and other unencrypted forms of communication are not secure. (1,2,4,5,8,9,13) Two provide that if one of these forms of communication is used without a response within 24 hours, it is the member's obligation to contact the physician (2,8). One states that it covers up to 99 electronic encounters a month (12); while another states such encounters are unlimited. A number of them specifically reference HIPAA obligations and the patient's right to a notice of privacy practices, with some stating explicitly that they have conducted and will continue to conduct a risk assessment under the law (3,4,7,13). One, which is managed by a third party that manages a network of direct primary care

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[85] Except 9 which is explicitly for use with an employed group of patients where the employer is paying the membership fee. At this writing, CMS had sought information on implementing a direct purchasing program in Medicare, for which comments were offered by the ACP, the AAFP, and other groups. https://innovation.cms.gov/initiatives/direct-provider-contracting/ Comments were to have been submitted by May 2018. The fundamental proposal, not yet implemented, was for a monthly capitation rate to be paid directly for a specified constellation of office based services, with enhanced payment for quality and value.

practices, explicitly includes that entity's access to data as part of the agreement. (9) Two explicitly state that communication by unsecure electronic means is an explicit authorization that such communication is permitted by the patient (5,9), even though HIPAA itself provides otherwise.

2.4 Financial Terms

Every one of the agreements requires payment of a monthly fee. Many say their term is month to month (2,4,5,8,9,13), although one has a minimum two month requirement (8) and another a minimum six month term (10). Most charge an enrollment fee in addition to the monthly fee (1,4,5,7,8, 12,13). All allow termination at will, but another group charges a premium to rejoin from $79 (their monthly fee) up to $500 (1, 6, 7, 11, 12) and one requires that a terminating patient wait twelve months before reenrolling. (11) Some explicitly say that health savings accounts may not, by Internal Revenue Service provisions, be used to pay for them (1,8, 12).

2.5 Other Provisions

Some of the agreements have terms peculiar to them. One presents an out of office policy that tells patients that if the physician is out of the office they will be notified 48 hours in advance (1). One sets forth the patient's obligation to treat the office staff with civility and avoid exposing others to disease. (3) Two contractually require the patient to disclose all information that is relevant to the patient's treatment. (3, 11) Another has a hold harmless provision whereby the member will hold the practice harmless against the effects of circumstances beyond its control in terms of communication.(4) Yet another has an even broader indemnification by the patient for anything that happens to the practice as a result of his breach of the agreement. (12) Another specifies that the practice is limited to a select number of participants in order to be able to deliver the level of care involved and the practice reserves the right to refuse to renew an agreement.(6)

Another approach to direct contracting with patients is concierge care, with which DPC is frequently confused. There are some significant differences, though, which we explore next.

Concierge Medicine

With its name implying higher touch service to patients, concierge medicine emerged out of dissatisfactions – both from clinicians and patients -- with 10 minute visits, loss of time and touch between doctors and patients and overall unhappiness with the managed care environment of the late 1990s. The single biggest distinction between concierge medicine and DPC, is that concierge practices often continue to charge insurance for medical services, placing greater emphasis on the amenities of practice including luxury robes, shower facilities, personalized toiletries and more, aimed at patients seeking more personalized care. Some concierge practices now refer to themselves as "fee for non-

covered services" ("FNCS") practices.[86] Concierge practices typically charge much more annually for their membership than DPC practices do. Marketing their appeal to physicians struggling with burnout, like DPC practices, concierge practices consist of smaller patient panels allowing more time for the patients that are seen. They have largely been characterized by direct 24/7 access by cellphone to the physician, extended visits, help with accessing specialists and executive physicals. They have been criticized as exacerbating social disparities in the delivery of care as well as increasing the pressure on primary care by removing more primary care physicians from access by the most patients.[87]

Among the concierge practices throughout the country are several networks which brand their practices. MDVIP[88] was created in 2000 and SignatureMD[89] was created in 2007. They have other competitors as well, including ConciergeChoice Physicians, Elite Health and more[90]. Even a mere Google search produces information regarding other companies who facilitate physician practice transition to concierge medicine.[91] Many health systems have introduced concierge medicine programs[92]; and there are many solo and two person practices which offer the concierge model.[93]

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[86] Marquis, "The Politics of Concierge Medicine: The Vulnerability of the FNCS Model", (Dec 1, 2006) http://www.wnj.com/Publications/The-Politics-of-Concierge-Medicine-The-Vulner

[87] For broader considerations of the development and operation of concierge practices see, Pasquale, "The Three Faces of Retainer Care: Drafting a Tailored Regulatory Response," Yale J of Health Policy, Law, and Ethics (2007) pp. 38-60; and Portman and Romanow, "CONCIERGE MEDICINE: Legal Ethical and Policy Challenges, AHLA Annual Meeting (June 2009) For a pointed criticism of the model see Holly, "The Fraud of Concierge Medicine", Southeast Texas Medical Associates, http://www.setma.com/Letters/pdfs/the-fraud-of-concierge-medicine.pdf

[88] www.mdvip.com

[89] http://signaturemd.com/

[90] https://www.owler.com/company/mdvip

[91] Specialdocs Consultants https://specialdocs.com/about-specialdocs-concierge-medicine-company/; MD2: https://www.md2.com/

[92] Livingston, "Concierge care taking hold at some large, urban hospitals", Modern Healthcare, (Oct 20, 2017) https://www.modernhealthcare.com/article/20171021/NEWS/171019863; Bryant, "Hospitals eye concerge medicine to lure patients, boost revenue", Healthcare Dive, (March 9, 2018) https://www.healthcaredive.com/news/hospitals-eye-concierge-medicine-to-lure-patients-boost-revenue/517970/

[93] http://www.doctorellenmcdonald.com/newpatdocs/concierge-contract.pdf; http://www.livingwellfm.com/wp-content/uploads/2016/04/Patient-Agreement.pdf; http://rebeccarockmd.com/services.htm

The competition has been fierce. MDVIP sued former employees who joined SignatureMD; and SignatureMD sued MDVIP for anticompetitive practices.[94] The complaint alleged that MDVIP requires its physicians to convert all patients to concierge medicine, limit their patient panels to 600 and, in 2014, when the suit was filed, had more than 70% of the concierge medicine membership market. They challenged the length of the contracts to which physicians were held (an initial five year term), with evergreen clauses, and two year post-termination restrictions to enter into similar agreements. First introduced in 2009, the initial post-termination restriction allegedly was one year, but in 2012 was increased to two years. SignatureMD further alleged that MDVIP had a $1 million liquidated damages clause if the covenants were breached, and also held their employees to non-disclosure and restrictive covenants to work for competitors. They further asserted that the turn-key concierge medicine membership market was a distinct market. The case survived MDVIP's motion to dismiss, but was ultimately settled on a confidential basis.[95]

In the concierge network model, as alleged in the complaint cited, there is a contract between the physician practice and the network. But, much like DPC, for all concierge practices, there is also a contract between the practice and the patient. These agreements are very similar to those in DPC, except that while some practices do not submit claims to payors and opt out of Medicare, others, including MDVIP and SignatureMD, do submit to both commercial insurers and Medicare. Because some payors, however, are hostile to the concierge medicine model, particularly where the payor is an HMO, some practices have one physician who participates in concierge medicine with others who do not.

The big challenge in submitting claims is that, both in Medicare where physicians participate or commercial insurance where they have direct contracts, they are forbidden to charge the patient for covered services. When concierge medicine began, Medicare paid for very little that was preventive care and not at all for an annual physical. So the covered services typically included executive physicals, 24/7 access to the physician and enhanced communication directly with the physician. Now that Medicare pays for 26 separate screening and preventive services, along with an annual wellness exam,[96] the list of Medicare covered services is vastly more than in the beginning. The OIG opined relatively early on the issue of physicians charging an annual fee while they took assignment of Medicare claims. Citing a physician who required his patients to sign a "Personal Health Care Medical Care Contract" for $600 a year, the OIG asserted that the

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[94] SignatureMD, Inc, v MDVIP Inc.,California Central District Court , 2:14-cv-05453 (July 14, 2014; Pacenti, "'Concierge Medicine Provider MDVIP A Monopoly? Lawsuit Says So.", concierge medicine Today Sept 3, 2014, https://conciergemedicinetoday.org/2014/09/03/legal-daily-business-review-concierge-medicine-provider-mdvip-a-monopoly-lawsuit-says-so-dbr/; Brino, "Concierge medicine wars heat upa s model gains ground," (Jun 12, 2015) https://conciergemedicinetoday.org/2015/06/18/concierge-medicine-wars-heat-up-as-model-gains-ground-healthcare-finance-news/

[95] Personal communication, Jerome Hoffman, Esq., 11/17/2018

[96] https://www.medicare.gov/coverage/preventive-screening-services

services he was purporting to provide as "coordination of care with other providers,", "a comprehensive assessment and plan for optimum health" and "extra time" spent with patients were all covered services under Medicare and therefore violated the assignment agreement.[97] The physician paid a settlement. MDVIP, which encourages its physicians to participate in Medicare, emphasizes the extensive diagnostic services provided by MDVIP physicians that are not covered under Medicare or most commercial insurers. In addition, they tout their proven health outcomes, with studies in the peer reviewed literature that show that concierge services produce more efficient care with fewer hospitalizations and better control of chronic conditions.[98] Others have noted improved physician satisfaction with practice, and improved satisfaction of patients.[99] In terms of administrative burden, some have noted that with the annual fee of $1500-$2500 paid by patients, physicians do not feel compelled to churn visits and document higher level visits because they don't need to see as many patients to do well financially. With patient panels of 600 patients, by contrast with a typical primary care practice seeing 2300 patients a year, the need to interact with plans is lowered in and of itself.

In some states, by contrast with the statutes which explicitly permit direct to patient contracting, issues have been raised regarding the legitimacy of the added charges to patients beyond health insurance premiums. New Jersey's Departments of Health and Banking and Insurance jointly published a Bulletin in 2003 stating that HMOs could not permit physicians to charge extra fees, and further, that even in PPOs, physicians were not permitted to discriminate against any class of patients – those who paid the fees vs those who did not. New York took a similar position in 2004. That said, because these are administrative positions, there are no easily identifiable reports of enforcement. In Washington and Massachusetts legislation was proposed but never adopted.[100]

The legal battlefields of concierge medicine are littered with other challenges to marketing and inducing transition to the model. In 2010, a physician employed by the Lehigh Valley Health Network (LVHN) sought to explore affiliation with MDVIP. In doing so, because MDVIP evaluates and screens practices for suitability, the physician provided MDVIP with information regarding 2200 patients. Although it is legitimate under HIPAA for a potential purchaser to review information regarding the patients in the practice to be purchased,[101] Dr. Kender was not authorized by the network to make the

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[97] "OIG Alerts Physicians About Added Charges for Covered Services", March 31, 2004, https://oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA033104AssignViolationI.pdf

[98] https://www.mdvip.com/patients/health-outcomes

[99] Linz et al, "Impact of Concierge Care on Healthcare and Clinical Practice," JAOA, (ov 2005)Vol 105, pp 515-520

[100] See Marquis, supra n. 86 and Marquis, "Legal Issues Involved in Concierge Medical Practices," Health Lawyers News, March 2005, pp18-26; and among the states permitting DPC, retainer practices are often addressed. See n's 65-69 supra.

[101] 45 CFR §164.506

information available. He was fired[102], and LVHN through its physician group which employed Dr. Kender sued MDVIP,[103] for injunctive relief and return of its confidential information. It stated that it had been obligated to report the breach of its protected health information. The case was ultimately dismissed. More recently a class action was filed by a physician group against MDVIP, alleging that by its facsimile solicitation of physicians, it is in violation of the Telephone Consumer Protection Act (47 USC 227).[104] They alleged that MDVIP had solicited at least 40 additional physicians in Michigan, and sought both injunctive and damages relief in the form of the penalty under the statute of at least $500 per improper fax transmission.

Interestingly as well, in terms of legal issues, MDVIP was found liable for $8.5 million in a malpractice case where a patient's estate sued them for physician care which resulted in a leg amputation.[105] The patient's estate had claimed MDVIP had vicarious liability based on misleading advertising and fraudulent misrepresentation in its claim that it would provide "exceptional doctors, exceptional care and exceptional results." The patient, however, had had a relationship with the physician before either had ever joined MDVIP. Despite the introduction of a litany of representations made by MDVIP regarding the high quality of its physicians, the court, on appeal, found that no evidence had been introduced that MDVIP knew the statements were false when they were made. Moreover, evidence was introduced that MDVIP had provided a written statement to the patient that "Your doctor owns the practice, and MDVIP has absolutely no involvement whatsoever in any medical decisions. Our job is simply to remove all obstacles that exist to the highest level of care." The verdict was overturned. The case was remanded for a new trial; but it was settled before the trial took place. Nonetheless, the fact of the initial verdict led to a host of warning articles in the legal literature regarding this risk of liability for these third party managed concierge practices. Obviously when there is no third party, but a provider itself makes claims about the quality of its care and why it merits the additional payments concierge medicine programs require, there is no one else to look to for liability claims. Concierge medicine has increased its reach throughout the country since it began. Some believe it will continue to expand as more patients want more personalized care and are willing to pay extra for it.

The last end run of the payers to be considered here is opting out of Medicare, which is required under DPC contracts, since almost all DPC services are covered by Medicare.

Opting Out of Medicare

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[102] "LVHN fires doctor after patient records shared", Insurance Techno logy Industry News, (Dec 7, 2010) http://insurance-technology.tmcnet.com/news/2010/12/07/5178873.htm

[103] Lehigh Valley Physician Group v. MDVIP, 5:10-cv-05413 (ED PA, 10/14/10).

[104] Michigan Urgent & Prtimary Care Physciains, PC v MDVIP and John Does 1-10, 2:18-cv-10643-DML-DRG (ED Mich., 2/23/18)

[105] MDVIP v. Beber, No 54D15-1648, FL Dist Ct. of App., (May 31, 2017)

As much as physicians have decried the administrative burdens imposed by private payors, they have also been beleaguered by demands made by Medicare. Going back to 1997, when the opportunity was first made available, a small number of physicians have chosen simply to opt out of Medicare in favor of "private contracts" with patients. For many years, it was essentially unknown as to how many physicians had taken this path until the Affordable Care Act included a provision that required that the number be made public. Even as CMS is moving to decrease the number of evaluation and management codes for which physicians must document the extent of the history, the scope of the physical examination and the complexity of the clinical decision-making in the form of required bullet points, physicians have left Medicare completely. By 2010, nationally, only 130 physicians had opted out. The numbers increased to over 1600 in 2013, more than doubling to 3500 in 2015 to a high of 7400 in 2016. In 2017 that number dropped to 3732.[106] When the rules were first made available, physicians had to renew the request to be opted out every two years. Now they may maintain their opted out status indefinitely. Opt out is essential to physicians treating Medicare patients under DPC models. The effect of opting out is that no claims may be submitted either by the physician or the beneficiary for the otherwise covered Medicare services provided by the opted out physician. The services rendered by the physician are considered not covered,[107] whether paid for by capitation or fee for service. Medicare will pay for services provided by others but ordered by an opted out physician if they otherwise meet coverage criteria.[108] Medicare will pay for services by the physician in an emergency or if the physician failed to opt out effectively by not having a proper beneficiary private contract.

The fundamental mechanism for opting out is to enter into a private contract with the patient, and to file an affidavit with the Medicare Administrative Contractor (MAC) stating the opted out status. A physician may not pick and choose among patients. If he opts out, he opts out for all patients. The affidavit has to be filed with every MAC to whom the physician submits claims. Since 2015, filed affidavits will automatically renew for additional two year periods.[109] CMS does not provide a template for the affidavit, but many MACs do.

The affidavit must be in writing and signed by the physician, containing his demographic information and NPI number or, if none has been assigned, his tax identification number. It must state that except in emergencies, the physician will provide Medicare services only through a private contract with the beneficiary and he will not submit and will not allow any others to submit claims for his services. It must state that he recognizes his

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[106] Dickson, "Fewer doctors are opting out of Medicare", Modern Healthcare (Jan 30, 2018) https://www.modernhealthcare.com/article/20180130/NEWS/180139995/; CMS data https://data.cms.gov/Medicare-Enrollment/Opt-Out-Affidavits/7yuw-754z

[107] MBPM Chptr 15,§40.2

[108] Id at §40.5

[109] The details of the program and the requirements as administered by the MACs are set forth in the Medicare Benefit Policy Manual, Chptr 15, Section 40. See also 42 CFR 405.410

services will not be covered under Medicare, whether in traditional Medicare or a Medicare Advantage program. It must state he agrees to be bound by the affidavit and the private contracts he enters with the beneficiary. If he has been participating it must state he recognizes his participation ends with the filing of the affidavit. It must state that a beneficiary who has not entered into a private contract and requires emergency or urgent care will not be required or asked to enter into a private contract in order to obtain such care. The affidavit must be filed within 10 days of the physician completing his first private contract with a beneficiary.[110]

The private contract must be in writing and in print sufficiently large that a beneficiary can read it easily. It must "clearly state whether the physician is excluded from Medicare".[111] It must state that the beneficiary (or representative) accepts full financial responsibility for all services furnished by the physician and that Medicare limits do not apply to the physician's charges as they would for a non-participating physician. The beneficiary must agree not to submit claims for services and must acknowledge that no claims will be submitted for him. It must also state that the beneficiary knows that he has the right to obtain Medicare-covered items and services from physicians and others who have not opted out; and that the beneficiary is not compelled to enter into the contract. It must state that the term of the opt out is two years and that unless the physician terminates that status, it will continue indefinitely. It must state that the beneficiary understands that Medigap insurers may not pay either, since the services are considered non-covered. It must be signed by the beneficiary or representative, who must be given a copy before any services are provided pursuant to the contract. The physician must retain the original for the duration of the opt out. It must be provided to CMS upon request.[112]

A physician who fails to opt out effectively must submit claims, will be held to the limiting charge and may not reassign any of his claims (as to his professional corporation or employer, for example). If he fails to opt out effectively, he is permitted to reapply for opt out at any time.[113] A physician may also be deemed to have failed to maintain opt out if he neglects to enter into private contracts with all Medicare patients, if he submits any claim to Medicare or accepts payment directly or indirectly, if he fails to follow the rules regarding emergency services, or he fails to maintain a copy of the original private contract.[114] The failure would typically be discovered by the MAC who may permit the physician to cure the problem by repaying any monies collected within 45 days of notice. Otherwise the opt out will be nullified. If a MAC receives a claim from an opted out

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[110] MBPM Chptr. 15, §40.9

[111] Id at §40.8

[112] Id.

[113] Id at §40.10

[114] Id at §40.11

physician it must contact the physician to determine if it was filed in error or in an emergency or urgent situation.[115]

The number of physicians who have opted out is small. Opting out is not required for concierge care which really is fee for non-covered services care if implemented correctly,. For direct to patient care, however, opting out is essential because the primary care services at issue are covered under Medicare.

Conclusion

Physician dissatisfaction with the burdens on them from payors has not decreased and has further been exacerbated by decreased payment with no alleviation of administrative demands. Cutting out the middleman by contracting with employers is really a viable option for large groups with closely geographically focused employers and employees or networks of physicians. Direct to patient contracting offers another option for primary care, but is not likely to dominate any market. Concierge medicine has the advantage of permitting insurance to remain available, but lowers administrative burden by lowering both the volume of patients in the practice while it provides additional revenues. The complexity of the market challenges to concierge medicine are inevitably reflective of a specific local healthcare market. Depending on the direction CMS moves with Medicare, and the extent to which commercial payors expand their flexibility and lower administrative burden, all of these strategies may see increased play throughout the country.

[115]Id at §40.12