

Notes

HEALTH CARE'S OTHER "BIG DEAL": DIRECT PRIMARY CARE REGULATION IN CONTEMPORARY AMERICAN HEALTH LAW

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ABSTRACT

Direct primary care is a promising, market-based alternative to the fee-for-service payment structure that shapes doctor-patient relationships in America. Instead of billing patients and insurers service by service, direct primary care doctors charge their patients a periodic, prenegotiated fee in exchange for providing a wide range of healthcare services and increased availability compared to traditional practices. This "subscription" model is intended to eliminate the administrative burdens associated with insurer interaction, which, in theory, allows doctors to spend more time with their patients and less time doing paperwork.

Direct practices have become increasingly popular since Congress passed the Affordable Care Act (ACA). This growth has been driven by legislation in several states that resolves a number of legal questions that slowed the model's growth and by the ACA's recognition of the model as a permissible way to cover primary care in "approved" health plans. Yet legal scholars have hardly focused on direct primary care. Given the model's growth, however, the time is ripe for a more focused legal inquiry.

This Note begins that inquiry. After tracing the model's evolution and its core components, this Note substantively examines the laws in states that regulate direct practices and analyzes how those laws address a number of potential policy concerns. It then analyzes direct primary care's broader role in the contemporary American healthcare

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marketplace. Based upon that analysis, this Note concludes that direct primary care is a beneficial innovation that harmonizes well with a cooperative-federalism-based healthcare policy model.

INTRODUCTION

Joe Biden was right: the ACA was a “big [expletive] deal.”¹ The Patient Protection and Affordable Care Act of 2010 (ACA)² sufficiently assaulted the status quo within the American healthcare system³ to spur frequent comparisons to sweeping domestic-policy reforms of times past.⁴ Yet when compared to the momentous social upheavals engineered by the New Deal and the Great Society, the ACA’s reforms swept far narrower.⁵ By primarily reorienting the insurance marketplace to expand coverage to millions of previously uninsured patients,⁶ the ACA channels those patients into the primary healthcare⁷ pools⁸ while leaving the current delivery structure

1. See Rachel Weiner, *Biden to Obama: “A Big [Expletive] Deal,”* WASH. POST (Mar. 23, 2010), <http://voices.washingtonpost.com/44/2010/03/did-biden-tell-obama-signing-w.html> [<http://perma.cc/C82C-WW3E>] (“After introducing Obama at Tuesday’s health-care bill signing ceremony, Vice President Biden turned to the [P]resident and said, ‘This is a big [expletive] deal.’”).

2. Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 26 U.S.C.).

3. See Thomas R. Barker, *A Critical Analysis of Provisions of the Affordable Care Act Affecting the Life Sciences Industry*, 7 J. HEALTH & BIOMEDICAL L. 67, 67 (2011) (stating that the Affordable Care Act (ACA) “made sweeping reforms to the American health care system”).

4. See, e.g., Jonathan Oberlander, *Long Time Coming: Why Health Reform Finally Passed*, 29 HEALTH AFF. 1112, 1113 (2010) (asserting that the Affordable Care Act was “ambitious” and “similar in scope to Great Society and New Deal programs”).

5. See Paul Krugman, *The Big Deal*, N.Y. TIMES, Jan. 21, 2013, at A21 (“[W]here the New Deal had a revolutionary impact, empowering workers and creating a middle-class society that lasted for 40 years, the [ACA] has been limited to equalizing policies at the margin.”).

6. See Janet L. Dolgin & Katherine R. Dieterich, *Social and Legal Debate About the Affordable Care Act*, 80 UMKC L. REV. 45, 52 (2011) (“The [Affordable Care] Act promises to extend health care coverage to millions of people.”).

7. Primary health care consists of all first-line, nonspecialized medical services, including “health promotion, disease prevention, health maintenance, counseling, patient education, diagnosis and treatment of acute and chronic illnesses in a variety of health care settings.” *Primary Care*, AM. ACAD. OF FAM. PHYSICIANS, <http://www.aafp.org/about/policies/all/primary-care.html> [<https://perma.cc/FP5E-5DKM>].

8. See Stacey A. Tovino, *I Need a Doctor: A Critique of Medicare Financing of Graduate Medical Education*, 71 WASH. & LEE L. REV. 2431, 2433 (2014) (“The United States has a growing population, an aging population, and an increasing number of residents with health insurance coverage as a result of the Affordable Care Act.”).

in place.⁹ A policy conundrum thus hides in the regulatory gaps: although the ACA prescribes many initiatives designed to counteract the acute woes afflicting our healthcare system, delivery infrastructure is equally, or perhaps more, important to the patient's long-term health.

The current infrastructure—the fee-for-service model—has arisen out of the unique interaction of a partly socialized and heavily regulated insurance marketplace¹⁰ with market-driven healthcare delivery systems.¹¹ Under the fee-for-service model, physicians charge patients a separate, unbundled price for each performed service.¹² For example, a typical fee-for-service transaction proceeds like this¹³: First, a patient with a bothersome cough visits her primary care provider for a diagnosis. Second, during her consultation, the doctor checks her throat, lymph nodes, and vital signs; draws blood and sends it off for lab work; and prescribes a common antibiotic to treat an upper respiratory infection. Third, assuming she has adequate insurance, the patient pays the co-pay for which she is responsible before leaving the appointment. Fourth, her doctor separately bills her insurance for the doctor visit, the lab work, and the prescription. Fifth, her insurance pays its share under the insurance agreement. Finally, the insurer bills the patient for the remaining balance.

Against this backdrop, a quiet and self-directed alternative to the fee-for-service delivery model has evolved since well before the ACA's enactment. Although this alternative model has not gone unnoticed,¹⁴ it has gradually expanded throughout the United States

9. Dolgin & Dieterich, *supra* note 6, at 52, 55 (2011) (observing that, at heart, “[t]he [ACA] expands health care coverage to many people” but continues to “safeguard[] the role of the profit-making health insurance industry”).

10. ROBERT I. FIELD, HEALTH CARE REGULATION IN AMERICA: COMPLEXITY, CONFRONTATION, AND COMPROMISE 3 (2006) (“Health care is among the most heavily regulated industries in America. Virtually every aspect of the system is subject to government oversight in one form or another, and often in several forms.”).

11. Michael E. Porter & Elizabeth Olmsted Teisberg, *Redefining Competition in Health Care*, HARV. BUS. REV., June 2004, at 65 (“[I]n the United States, health care is largely private and subject to more competition than virtually anyplace else in the world.”).

12. *Fee-for-Service*, MERRIAM WEBSTER'S COLLEGIATE DICTIONARY 259 (11th ed. 2003).

13. See generally Neelam K. Sekhri, *Managed Care: The US Experience*, 78 BULL. WORLD HEALTH ORG. 830 (2000) (providing an overview of fee-for-service transactions in the United States).

14. See generally Jeffrey B. Hammond, *Cash Only Doctors: Challenges and Prospects of Autonomy and Access*, 80 UMKC L. REV. 307 (2012) (discussing the rise of “cash only” medical practices).

with relatively little discussion.¹⁵ That model is direct primary care, in which patients pay a periodic—usually monthly—flat-rate fee for all or most of their primary medical care, usually without insurer involvement.¹⁶

This model is neither novel nor radical. Indeed, proponents tout it as a “throwback” to the days of individualized care and close doctor–patient relationships.¹⁷ Yet it is notable and worth examining anew because of its recent revival—a revival that has evaded extensive scholarly discussion, even though it will likely gain substantial momentum in the coming years. This momentum will be driven by a wave of recent state legislation that legitimizes direct primary care and resolves some of the legal uncertainties surrounding it. In all, fourteen states have statutorily recognized direct practices—including eight that have passed nearly identical legislation within the past three years—and more states might follow.¹⁸ Although the statutes differ in some respects, all achieve the same overarching goal of recognizing and regulating the direct primary care model. These statutes exempt direct practices from state insurance regulations, mandate certain content and disclosure requirements within direct care agreements, prohibit direct practices from billing insurers for their services, and specify the conditions and timeframes under which direct practice agreements may be terminated.¹⁹

This Note canvasses the historical development of these statutes and informs the reader of the legal and policy debates surrounding them. It also clarifies that although the direct primary care model is a subset of the general category of “concierge” practices, it differs significantly in structure and operation. Then, it provides an overview of the most important substantive provisions within the statutes and

15. See CAROL PECKHAM, MEDSCAPE, MEDSCAPE PHYSICIAN COMPENSATION REPORT 2015, at 18 (2015), <http://www.medscape.com/features/slideshow/compensation/2015/public/overview#page=18> [<http://perma.cc/2B3T-LS7C>] (noting that nonmanaged care doctors—including “concierge” and cash-only doctors—represent 8 percent of all physicians surveyed, a two-fold increase since 2011).

16. Hammond, *supra* note 14, at 307; Am. Acad. of Family Physicians, *DPC: An Alternative to Fee-for-Service*, AAFP.ORG, <http://www.aafp.org/practice-management/payment/dpc.html> [<https://perma.cc/6SQJ-KQQF>].

17. See Robert M. Portman, *Concierge Care: Back to the Future of Medicine?*, HEALTH LAW., Aug. 2003, at 1, 3 (observing that the various forms of prepaid medical practices are “frequently touted as a throwback to the way medicine used to be practiced”).

18. For further discussion of recent state legislation and possible future developments, see *infra* Parts I.D, I.F.

19. For further discussion of the statutes’ shared provisions, see *infra* Part II.

distinguishes the differences among the participating states' approaches. Finally, it examines the statutes' effectiveness in addressing the legal and policy issues that have bedeviled concierge practices since their inception as well as their broader role in the American healthcare marketplace. This Note places particular attention upon the doctor shortage, a particularly pressing challenge to healthcare policymakers in the coming years.²⁰

Based upon that analysis, this Note concludes by suggesting that despite some significant shortcomings, the direct primary care model is on balance a positive development within the contemporary American healthcare landscape. Because each state faces unique challenges to healthcare access and quality, each state should retain discretion to reform its delivery infrastructure in accordance with those challenges.²¹ And given the level of uncertainty with respect to the model's impact on the healthcare system as a whole, individual states are suitable places to evaluate pressing questions about its short- and long-term impacts, including whether the model provides better, cheaper care when compared to the traditional fee-for-service model and whether its expansion places undue stress on healthcare access. Therefore, if, as this Note suggests, state autonomy and experimentation are accepted as desirable in the healthcare marketplace, state legitimization and individual regulation of the model is exactly how the regulatory cookie should crumble.

I. A PRIMER ON DIRECT PRIMARY CARE

A. *Distinguishing Direct Primary Care Practices from Other Concierge Models*

Although commentators often use the two terms interchangeably, direct practices and concierge medicine are not always the same. The easiest way to understand this relationship is to think of direct practices as one member of the much broader

20. See, e.g., Shawn Tully, *America's Painful Doctor Shortage Is Threatening Health Care Reform*, FORTUNE (Mar. 4, 2014, 3:28 PM), <http://fortune.com/2014/03/04/americas-painful-doctor-shortage-is-threatening-health-care-reform> [<http://perma.cc/VF8L-SVM6>].

21. Notably, many of the states that have recently adopted direct practice legislation are those most heavily affected by the nationwide physician shortage. For a discussion of this shortage, see *infra* notes 201–02 and accompanying text.

concierge-medicine family.²² “Concierge medicine” is often used as a blanket term to describe an array of different healthcare delivery models united only by their departure from the traditional fee-for-service payment scheme.²³ Such a catchall term is perhaps understandable given these models’ simultaneous development since the turn of the millennium.²⁴ In addition, all concierge-medicine models, including direct primary care, share the same goal to provide more personalized and higher-quality health care for each patient-member.²⁵ But concierge care and direct primary care use different strategies to achieve that shared end goal.²⁶

For example, under one commonly discussed model, the “pure concierge model,” patients pay a premium in addition to the fees they pay to their doctor for the primary care services they receive.²⁷ Normally, those service fees are billed to third-party insurers under a normal fee-for-service arrangement.²⁸ This added revenue allows doctors to reduce the total number of patients they see while maintaining the same, or higher, net income.²⁹ As a result, waiting

22. Cf. Hammond, *supra* note 14, at 317 (noting that cash-only practices—which operate similar to, yet still distinct from, direct practices—must be distinguished from concierge practices, their “first cousin[s]”).

23. See, e.g., Sandra J. Carnahan, *Law, Medicine, and Wealth: Does Concierge Medicine Promote Health Care Choice, or Is It a Barrier to Access?*, 17 STAN. L. & POL’Y REV. 121, 122, 130–32 (2006) (categorizing three distinct alternative delivery models, including direct practices, as variations of “Concierge Medical Practice Structures”); Jeffrey M. Pecore & James F. Doherty, Jr., *Practice of “Concierge” Medicine: Models and Legal Issues*, 42 MD. B.J. 12, 14 (2009) (electing to use the term “concierge medicine” to describe multiple delivery models—including direct primary care—because that term “has become the most widely known”).

24. For further discussion on the two models’ shared history, see *infra* Part I.B.

25. See Gwendolyn Roberts Majette, *From Concierge Medicine to Patient-Centered Medical Homes: International Lessons & the Search for a Better Way to Deliver Primary Health Care in the U.S.*, 35 AM. J.L. & MED. 585, 586 (2009) (noting that concierge medicine was created by physicians in an effort “to improve the delivery of primary care”).

26. See Rachael Zimlich, *The Direct Primary Care Model Is Gaining Traction. Is It Right For You?*, MED. ECON. (July 10, 2013), <http://medicaleconomics.modernmedicine.com/medical-economics/content/tags/david-usher-md/direct-primary-care-model-gaining-traction-it-right-yo> [https://perma.cc/5Y3V-3VLB] (“Direct primary care (DPC) is a retainer-based model for primary care practices, but does not come with a standard set of rules like many other [retainer-based] models. Instead, there is a common set of goals or characteristics . . .”).

27. See J. Kevin Markwell, *Concierge Medical Practices Within the Regulated Medicine Environment: Are They Ethical, Workable, Legal?*, 2 HEALTH L. & POL’Y 22, 22 (2008).

28. See *id.* (“The more common concierge practice does accept reimbursement from private health insurance and Medicare. In fact, the annual concierge fee is not intended to pay for specific medical service such as labs, x-rays, medicines or other services covered by the patient’s primary payer.”).

29. See *id.* at 23 (“The profound allure of a concierge practice is that it offers the marvelously counterintuitive double incentive of a less hectic pace, although perhaps less

room times are eliminated or drastically reduced, and each doctor provides longer visits and more individualized care for each patient.³⁰ Some practices offer "luxury" services as well, including slippers and robes, twenty-four-hour phone or internet access to a physician, and comprehensive, personalized initial health assessments for all new patients beyond the scope of traditional preventive-care exams.³¹ Therefore, pure concierge models can be properly categorized as charging an access *premium*.

In contrast, direct practices employ a different strategy to improve primary care quality and reduce the number of patients seen by each physician.³² Rather than imposing an access premium to make up for lost revenues resulting from fewer patients, direct practices reduce overhead costs arising from billing third-party insurers³³ by directly charging their patient-members a periodic subscription fee that covers the total cost of those patients' primary care services, which cuts out insurer involvement altogether.³⁴ Unlike other concierge models, direct practices employ an access *subscription*.

B. The Origins of Concierge and Direct Primary Care

Given their shared goals and notwithstanding their divergent business strategies, direct practices and other concierge models developed simultaneously. Near the turn of the millennium, a series of industry studies revealed that primary care doctors were

predictable and, for nearly all primary care providers, a pronounced increase in their incomes.").

30. See Pecore & Doherty, *supra* note 23, at 14 (describing several features of individualized patient care, including "comprehensive physical[s]," longer office visits, and easier access to the physician); James Stathopoulos, *Concierge Medicine: Quality Care for a Price*, 19 ANNALS HEALTH L. ADVANCE DIRECTIVE 155, 156 (2010) (observing that concierge physicians typically offer "no waiting times at office visits").

31. See Carnahan, *supra* note 23, at 122 (canvassing various luxury services offered to concierge patients).

32. See CAL. HEALTHCARE FOUND., ON RETAINER: DIRECT PRIMARY CARE PRACTICES BYPASS INSURANCE 2 (2013) (noting that direct primary care physicians tout longer visit times with patients as "pivotal to reducing costs and improving outcomes").

33. Lawrence P. Casalino et al., *What Does It Cost Physician Practices to Interact with Health Insurance Plans?*, 28 HEALTH AFF. 533, 538-39 (2009) (estimating that primary care practices spend \$64,859 annually on interactions with third-party insurers, almost one-third of primary care physicians' median total yearly compensation).

34. See Pecore & Doherty, *supra* note 23, at 16 (calling the direct primary care model the "Fee for Covered Services Model").

increasingly dissatisfied with their working conditions.³⁵ In particular, physicians reported that quality-of-care concerns stemming from shortened patient visit times were substantially driving general job dissatisfaction.³⁶ Those shortened times were largely driven by lower government and private-insurer reimbursement rates for patient visits that were set to contain healthcare costs.³⁷ For example, standard reimbursement rates for doctor visits in managed care programs were typically calculated based upon average doctor–patient visit times of ten minutes or less per patient.³⁸ Physicians were driven, therefore, to see more patients each day to cover their overhead costs and mitigate their declining incomes.³⁹ Additionally, doctors reported dedicating substantial portions of their workweeks to interacting with insurers,⁴⁰ further reducing their availability to their patients. Not surprisingly,

35. See, e.g., Donald E. Pathman et al., *Physician Job Satisfaction, Dissatisfaction, and Physician Turnover*, 51 J. FAM. PRAC. 593, 593 (2002) (finding that 27 percent of surveyed physicians reported planning to leave their practices within two years, a result largely driven by “dissatisfaction with pay and with relationships with communities”); Brian Vastag, Update, *Physician Dissatisfaction Growing*, 286 J. AM. MED. ASS’N 781, 781 (2001) (reporting that “physicians’ job satisfaction ha[d] taken a hit in the past 15 years” and “[b]y 1997 . . . less than half[] [of primary care physicians] were content with the amount of time spent with patients, the amount of leisure time they had, and the incentives they received to provide high-quality care”).

36. See Mark Linzer et al., *Managed Care, Time Pressure, and Physician Job Satisfaction: Results from the Physician Worklife Study*, 15 J. GEN. INTERNAL MED. 441, 446–48 (2000) (noting that primary care “[d]octors felt time pressure in all settings . . . and acknowledged needing up to 41% more time than allotted to provide quality care during new patient visits” and that “time stress had a broad and negative impact on job satisfaction” in a study of primary care physician job satisfaction).

37. See Vicki Lawrence MacDougall, *The “Shared Risk” of Potential Tort Liability of Health Maintenance Organizations and the Defense of ERISA Preemption*, 32 VAL. U. L. REV. 855, 860–63 (1998) (discussing capitation payment plans, as plans where fixed amounts of money are reimbursed by insurers based on a per-patient calculated rate).

38. Anthony J. Linz, Paul F. Haas, L. Fleming Fallon Jr. & Richard J. Metz, *Impact of Concierge Care on Healthcare and Clinical Practice*, 105 J. AM. OSTEOPATHIC ASS’N 515, 516 (2005).

39. See Jan Carter, *What Makes a High-Earning Family Physician?*, 12 FAM. PRAC. MGMT. 16, 16 (2005) (reporting that pre-tax physician income decreased by \$20,000 per year from 1995–2003); Frank Pasquale, *The Three Faces of Retainer Care: Crafting a Tailored Regulatory Response*, 7 YALE J. HEALTH POL’Y & ETHICS 39, 44–45 (2007) (“Many primary care physicians must see at least twenty-five to thirty patients a day in order to clear between \$100,000 and \$300,000 per year in pre-tax income.” (footnote omitted)).

40. Casalino et al., *supra* note 33, at 536–37 (reporting that primary care physicians spent on average three and one-half hours per work week dealing with insurers).

average doctor–patient appointment times had been squeezed to under fifteen minutes per visit by 2005.⁴¹

Against this backdrop, concierge practices began to gain traction as patient-care-centered alternatives to this regime.⁴² At first, the small number of concierge practices represented a negligible percentage of practitioners⁴³ and garnered limited attention from scholars and regulators. But these practices continued to grow in limited but steady numbers over the next decade.⁴⁴ As this growth accelerated and concierge practices spread into a number of states, they began to draw closer scrutiny from the legal community.⁴⁵

C. Legal, Ethical, and Policy Concerns

Since the inception of direct primary care models, scholars and regulators have expressed myriad legal, ethical, and policy concerns associated with them.⁴⁶ Those concerns can be grouped into four

41. See Michael T. French et al., *Is the United States Ready to Embrace Concierge Medicine?*, 13 POPULATION HEALTH MGMT. 177, 178 (2010) (citing a CDC study indicating that “56.2% of physician visits lasted 15 minutes or less, and 93% were less than 30 minutes”).

42. For example, Howard Maron—the doctor most frequently credited with starting the first modern concierge practice—started MD2 in 1996 in Bellevue, Washington. *Concierge Medicine Founder Celebrates 18 Years of Innovation*, CONCIERGE MED. J. (Mar. 10, 2014), <https://conciergemedicaljournal.com/2014/03/10/concierge-medicine-founder-celebrates-18-years-of-innovation> [<https://perma.cc/S9T7-MGJ2>]. Dr. Maron, who had previously worked as a personal physician on retainer by the Seattle Supersonics basketball franchise, claimed to have opened MD2 to “offer the public the same access to high-level health care enjoyed by professional athletes.” Joshua J. Spooner, *Concierge Medicine: Origins, Growth, Controversies, and Implications to Medicare*, 2 MEDICARE PATIENT MGMT. 26, 26 (2007). But MD2 precluded vast swaths of the public from enjoying its services by charging “\$15,000 a year per person, and \$25,000 per family” for its comprehensive and ultrapersonalized care. Patrice O’Shaughnessy, *Michael Jackson’s Death Puts ‘Concierge Doctors’ in the Spotlight*, N.Y. DAILY NEWS (July 5, 2009, 4:27 AM), <http://www.nydailynews.com/entertainment/michael-jackson-death-puts-concierge-doctors-spotlight-article-1.426245> [<http://perma.cc/2AE4-VTY5>]. To ensure absolute convenience, MD2’s doctors rushed across the country to meet their patients’ needs, such as immunizing them on their private jets before vacations in far-flung locales. *Id.*

43. Troyen A. Brennan, *Concierge Care and the Future of General Internal Medicine*, 20 J. GEN. INTERNAL MED. 1190, 1190 (2005) (estimating that there were fewer than 200 concierge practices in the United States as of 2005).

44. See, e.g., French et al., *supra* note 41, at 178 (estimating that as many as 5,000 concierge practices existed in 2008).

45. See generally Carnahan, *supra* note 23 (discussing the implications of continued future expansion of concierge models).

46. By failing to clearly distinguish the various delivery models categorized into the “concierge medicine” family, commentators perhaps tend to generalize the legal and policy concerns associated with concierge practices too broadly. Because this general classification of various models continues to be used in framing policy debates about direct practices, this Note adopts this generalization while introducing these policy concerns to the reader.

general categories: insurance, income discrimination, patient abandonment, and healthcare access. The first issue is whether certain types of concierge practices actually operate as health insurers that should be subject to insurance regulation. Direct practices and other concierge models include treatment in their access subscriptions that is normally covered by insurance in fee-for-service practices.⁴⁷ Thus, by charging prepaid fees in exchange for as-yet undefined numbers of appointments and treatments and by assuming that subscription revenues will exceed the cost of unplanned patient visits, practices transfer a portion of financial risk from their patients onto themselves.⁴⁸ At least one state insurance agency has expressed concerns that this conduct constitutes the business of insurance.⁴⁹

Additionally, the concern about income discrimination possesses both legal and policy components. The legal component queries whether concierge models might run afoul of state healthcare-discrimination laws. Many state statutes prohibit physicians from charging different rates or offering different levels of service to patients falling within the same health classification.⁵⁰ Based on these statutes, at least one state health agency has warned that concierge practices might violate those provisions by offering services to premium-paying patients that would not be available to patients of

47. In contrast, “pure” concierge practices are not subject to this inquiry, because the access premiums they charge are for luxury services, like on-call physician access or no-wait appointments, not covered by insurance. Sandra J. Carnahan, *Concierge Medicine: Legal and Ethical Issues*, 35 J.L. MED. & ETHICS 211, 211 (2007).

48. Carnahan, *supra* note 23, at 132–33.

49. See Portman, *supra* note 17, at 5 (reporting that Washington’s insurance agency cautioned that doctors in such practices were at risk of being criminally charged for operating as insurers without obtaining an insurance certification as required by Washington state law (citing WASH. INS. COMM’R, DRAFT TECHNICAL ASSISTANCE ADVISORY RE ENGAGING IN ACTIVITIES REQUIRING A CERTIFICATE OF REGISTRATION 1 (2003))).

50. See, e.g., N.D. CENT. CODE § 26.1-04-03(7)(b) (2016). The statute defines “prohibited discrimination” as

[m]aking or permitting any unfair discrimination between individuals of the same class and of essentially the same hazard in the amount of premium, policy fees, or rates charged for any policy or contract of accident or health insurance or in the benefits payable thereunder, or in any of the terms or conditions of such contract, or in any other manner whatsoever.

Id. Similarly, N.J. STAT. ANN. § 17B:30-12(d) (West 2006) states:

No person shall make or permit any unfair discrimination between individuals of the same class and of essentially the same hazard in the amount of premium, policy fees, or rates charged for any policy or contract of health insurance or in the benefits payable thereunder, or in any of the terms or conditions of such policy or contract, or in any other manner whatever.

Id.

the same class who could not afford those premiums.⁵¹ The policy component centers on whether concierge practices will promote stratification in healthcare quality as they increase in number. Simply put, scholars worry that only those who can afford the expensive access premiums charged by concierge practices stand to reap the benefits of the concierge model.⁵² As a result, they suggest that the extra income gained from those expensive premiums, coupled with the prospect of a slower working pace and reduced administrative headaches, will drive the best doctors into concierge practices and away from lower-income patients.⁵³ Scholars have also pointed out that discrimination concerns are not limited to income discrimination; one early study of concierge practices revealed that African-American and Hispanic patients represented less than 5 percent of patient populations in concierge practices.⁵⁴

A third concern is patient abandonment arising from cases where doctors convert their practices from traditional models into concierge models. Like the discrimination issue, this issue contains both legal and ethical concerns. But the ethical aspect is more troublesome because primary care doctors normally do not have a legal duty to treat patients outside of a few narrow exceptions.⁵⁵ The ethical concern is straightforward: What happens to the majority of a traditional practice's patients who are dropped when doctors make the switch? In such cases, many concierge practices often reduce their

51. See N.J. DEP'T OF HEALTH & SENIOR SERVS., DOBI/DHSS BULLETIN 2003-02 (Aug. 8, 2003) (concluding that concierge practices charging access premiums violated New Jersey's healthcare antidiscrimination statute and warning insurance companies not to enter into agreements with such practices).

52. See, e.g., Brennan, *supra* note 43, at 1190 (concluding that concierge practices possess the "potential for distributive injustice" in medical care); Martin Donohoe, *Luxury Primary Care, Academic Medical Centers, and the Erosion of Science and Professional Ethics*, 19 J. GEN. INTERNAL MED. 90, 93 (2004) (suggesting that state-university-affiliated hospitals that offer concierge medical services "promote an overt, two-tiered system of care").

53. See Brennan, *supra* note 43, at 1190 (suggesting that "concierge doctors do tend to build their practices by shipping those who cannot pay off to other doctors" and cautioning that the prospect of more concierge practices "would likely push more patients of color, poorer patients, and sicker patients into the remaining primary care practices").

54. G. Caleb Alexander, Jacob Kurlander & Matthew K. Wynia, *Physicians in Retainer ("Concierge") Practice: A National Survey of Physician, Patient, and Practice Characteristics*, 20 J. GEN. INTERNAL MED. 1079, 1081 (2005).

55. See Carnahan, *supra* note 23, at 148–49 (explaining that there is generally no common law duty to treat absent certain narrow exceptions, such as an implied contract or "physician-patient relationship," when doctors only have the duty to provide adequate time for the patient to find a new care provider before discontinuing care).

total patient panels by as much as 90 percent.⁵⁶ Concern has therefore been raised that the process of “firing” patients during the conversion from fee-for-service to concierge practice presents the ominous potential for these patients to fall through the healthcare system’s cracks.⁵⁷ Questions have been raised about the newly converted concierge doctor’s ongoing responsibility to care for his former patients who do not, or cannot, pay the access fee.⁵⁸

Additionally, concerns have been raised about reduced healthcare access stemming from those patient reductions. This issue is perhaps the most pressing because of its potential effects on the American healthcare system as a whole. Scholars have pointed out that the improved physician working conditions offered by concierge models might be a double-edged sword: as concierge practices become more prevalent, they could produce a general practitioner exodus from fee-for-service practices.⁵⁹ Because reduced patient-per-physician ratios are a primary benefit of concierge practices,⁶⁰ such an exodus would mean that fewer doctors would generally be available to see patients. In a fully or overstaffed primary care industry, this exodus would not be a problem, but a large majority of analysts agree that an acute and continually increasing doctor shortage is on the horizon.⁶¹ This shortage is largely driven by increased primary care

56. *Id.* at 148.

57. *See id.* at 212 (“The dark side of concierge medicine is that every physician reducing her patient load from 2500 to 500 leaves 2000 former patients who must find a new primary care physician at a time when these physicians are in increasingly short supply . . .”).

58. *Id.*

59. *See, e.g.,* Maureen Glabman, *Primary Care Rocked by Rough Seas*, 35 PHYSICIAN EXEC. J. 6, 14 (2009) (asserting that concierge medicine “reduces the supply of private practice physicians, which is already a distressed area” (quotation marks omitted)); Jackie H. Jones & Linda Treiber, *Concierge Medicine: The Perfect Storm? Implications for Nurse Practitioners*, 6 J. NURSE PRAC. 109, 112 (2010). Jones and Treiber argue:

In a time when physician shortages already exist, the exclusivity of concierge practices has the potential to create a “perfect storm” in medicine . . . [t]his is especially true when the increasing demand for health care is taken into account. As the American population ages . . . what is needed is greater coverage, not less. As medical advances increase longevity and as new knowledge and technologies emerge, the demand for health care will continue to increase. Concierge medicine will leave even fewer physicians to provide care to America’s poor and underinsured.

Id.

60. For further explanation, see *supra* note 29 and accompanying text.

61. *See, e.g.,* NAT’L CTR. FOR HEALTH WORKFORCE ANALYSIS, U.S. DEP’T OF HEALTH & HUMAN SERVS., PROJECTING THE SUPPLY AND DEMAND FOR PRIMARY CARE PRACTITIONERS THROUGH 2020, at 2 (2013) (projecting a shortage of 20,400 primary care physicians by 2020); Stephen M. Petterson, Winston R. Liaw, Carol Tran & Andrew M. Bazemore, *Estimating the Residency Expansion Required to Avoid Projected Primary Care*

demand arising from two factors. The first—a disproportionate population increase in the 65-and-older age class—is a bigger reason than the second—increased patient entry into the marketplace because of increased insurance coverage after the ACA.⁶² Any delivery model promoting fewer patients per physician risks exacerbating this shortage and causing even greater stress on the existing provider network. Further, patients who cannot afford to participate in some form of concierge practice would stand to suffer the brunt of this physician shortage.⁶³

D. Pre-ACA Regulation: The 2006 West Virginia Pilot Program and 2007 Washington Statute

Despite the controversy surrounding concierge practices, only a few states regulated them before the ACA's enactment.⁶⁴ West Virginia and Washington pioneered regulation of the model, and both legally recognized only direct practices in lieu of other concierge forms. In 2006, West Virginia became the first.⁶⁵ Vic Wood, an early direct care practitioner there, embarked upon a lengthy legislative crusade that ultimately resulted in a statute authorizing practices like his to continue under close agency supervision as part of a pilot program to explore their viability.⁶⁶ But this authorization came at a cost. The statute imposed strict licensing and disclosure requirements, mandated agency approval of all advertising materials, and left all substantive regulation jointly in the hands of the state's health care

Physician Shortages by 2035, 13 ANNALS FAM. MED. 107, 110 (2015) (estimating primary-care-physician shortages of 3,968 in 2020, 17,213 in 2025, 26,440 in 2030, and 33,283 in 2035).

62. NAT'L CTR. FOR HEALTH WORKFORCE ANALYSIS, *supra* note 61, at 23–24.

63. *Cf.* Brennan, *supra* note 43, at 1190 (“If it were to grow in popularity, concierge medicine would likely push more patients of color, poorer patients, and sicker patients into the remaining primary care practices.”).

64. *See* WASH. REV. CODE § 48.44.010(9) (2007) (recognizing direct primary care practices as distinct from “[h]ealth care service contractor[s]”); W. VA. CODE ANN. § 16-2J-3(a)(1) (LexisNexis 2006) (authorizing the implementation of direct primary care practices).

65. *See* § 16-2J-3(a)(1) (implementing West Virginia's pilot program).

66. *West Virginia Passes Bill to Create Preventive Care Pilot Program*, AM. MED. NEWS (Apr. 10, 2006), <http://www.amednews.com/article/20060410/business/304109991/7> [<http://perma.cc/8DE3-R3XY>]. Vic Wood's West Virginia practice was one of the first, if not the first, direct practices in the country that operated in the same fashion as those regulated by the post-ACA statutes discussed in this Note. Since 2004, Dr. Wood has offered unlimited primary care and x-ray diagnostics in exchange for a flat, prepaid fee pursuant to contractual agreements with his patients. He also recommends that his patients purchase insurance to cover health care beyond the scope of his agreement with them, a foreshadowing of the ACA's approach to direct practices. *See id.*

authority and the insurance commissioner.⁶⁷ The pilot program was to last through 2011,⁶⁸ but it was subsequently extended through 2016.⁶⁹

Although West Virginia was the first state to regulate direct practices in any fashion, Washington was the first to legitimize them beyond the limited confines of a pilot program. This legitimization is not surprising given that Washington was an early testing ground for concierge practices.⁷⁰ In fact, concierge practices were disproportionately concentrated in the state during the early days of the model's evolution.⁷¹ In 2007, Washington's legislature passed the first law that explicitly exempted direct practices from state insurance law.⁷² That law was necessary after Washington's insurance commissioner published guidance concluding that concierge practices were subject to state law governing "health care service contractors"⁷³ (Washington's statutory term for health insurers⁷⁴), despite the commissioner's finding in that same report that regulating them "was neither practical nor warranted."⁷⁵ In practical terms, this guidance classifies concierge practices as insurers and unleashes a torrent of regulatory hurdles, including extensive auditing requirements and a daunting "minimum net worth" threshold.⁷⁶ The minimum-net-worth threshold creates significant barriers to market entry for small or solo practitioners by requiring physicians to maintain at least three million dollars in net assets or at least "[t]wo percent of the annual [insurance] premium earned . . . on the first one hundred fifty million dollars of premium and one percent of the annual premium on the premium in excess of one hundred fifty million dollars."⁷⁷

67. See W. VA. CODE ANN. § 16-2J-4-6 (LexisNexis 2015) (setting forth the regulatory and licensing requirements under the pilot program).

68. *Id.* § 16-2J-3(a)(1) (LexisNexis 2006).

69. *Id.* § 16-2J-3(a)(1) (LexisNexis 2013). To date, the pilot program has not been renewed, and direct practices continue to operate in West Virginia. See, e.g., PRIMARYCAREONE, <https://www.primarycareone.com/index.php> [<https://perma.cc/TX6P-Y6DC>] (operating three direct primary care offices in West Virginia as of January 2017).

70. See Spooner, *supra* note 42, at 26 (identifying Seattle-based MD2 as the first known concierge practice in the United States).

71. H.R. 60-E2SSB 5958, Reg. Sess., at 2 (Wash. 2007).

72. 2007 Wash. Sess. Laws 1226.

73. WASH. STATE OFFICE OF THE INS. COMM'R, DIRECT PRACTICES: ANNUAL REPORT TO THE LEGISLATURE 4 (2014).

74. WASH. REV. CODE § 48.44.010(9) (2014).

75. WASH. STATE OFFICE OF THE INS. COMM'R, *supra* note 73, at 4.

76. See WASH. REV. CODE §§ 48.44.037, 48.44.145.

77. *Id.* § 48.44.037(1)(a)-(b).

In response, the statute expressly states that “retainer practices” are not insurers or “health care service contractors” under Washington insurance law.⁷⁸ Although the statute uses the term “retainer practices,” it defines them as practices that employed contractual agreements and access subscriptions⁷⁹—the definition of direct primary care.⁸⁰ Thus, Washington’s “retainer practices” legislation was the first to legitimize and regulate direct practices beyond the confines of a limited pilot program.

In addition to requiring contractual primary care, the Washington statute prohibits discrimination based upon “race, religion, national origin, the presence of any sensory, mental, or physical disability, education, economic status, or sexual orientation,”⁸¹ and it forbids direct practices from refusing to accept new patients based solely on their “health status.”⁸² It also limits the circumstances under which physicians can terminate existing patients to cases when the patient fails to pay the access subscription, commits fraud, refuses to follow the doctor’s prescribed “treatment plan,” or acts in an abusive manner presenting “an emotional or physical danger to the [practice’s] staff or other patients.”⁸³ Finally, the statute allows practices to terminate patient agreements if they cease operating under the direct primary care model.⁸⁴ Regardless of the reason for termination, the statute requires direct practices to provide sufficient “notice and opportunity to obtain care from another physician” before ending any patient relationship.⁸⁵

Among other requirements—such as prohibiting fraud or misrepresentation with respect to the direct primary agreements—the statute mandates that physicians charge the access subscriptions on a monthly basis.⁸⁶ Additionally, the statute requires every direct care agreement to provide a disclaimer stating that the agreement does not constitute comprehensive health insurance and that the scope of the agreement is limited to the delivery services specifically named in the

78. *Id.* § 48.150.060.

79. *Id.* § 48.150.010(1)–(4).

80. For a detailed explanation of the distinction between direct primary care and other concierge models, see *supra* note 34 and accompanying text.

81. WASH. REV. CODE. § 48.150.020.

82. *Id.* § 48.150.050(1).

83. *Id.* § 48.150.050(2).

84. *Id.*

85. *Id.*

86. *Id.* § 48.150.030(1).

agreement.⁸⁷ Finally, the statute requires direct practices to submit an annual report to the Washington Office of the Insurance Commissioner disclosing “the number of providers in each practice, [the] total number of patients being served, the average direct fee being charged,” and the name of each participating physician.⁸⁸

In sum, West Virginia and Washington pioneered regulation of direct practices. In particular, Washington set forth a number of important provisions governing the conduct of such practices that would later serve as models for post-ACA state legislation.⁸⁹

E. The Turning Point: The ACA and Direct Primary Care

The ACA swept broadly and deeply,⁹⁰ and direct primary care did not elude its reach. Yet proponents of the model should hardly complain; the ACA’s approach to direct practices, though understated, can only be positive for the model’s long-term growth.

Before the ACA, the federal government largely refused to wade into the concierge-care debate. The Department of Health and Human Services (HHS) treaded lightly by simply warning “pure” concierge practices participating in Medicare against billing twice for covered services.⁹¹ HHS’s guidance concluded that double billing would not occur when practices charged premiums for services that were not covered by Medicare (such as luxury services like all-hours physician access and accoutrements like robes and slippers). But it said that double billing would occur if practices charged premiums for simply allowing access to physicians.⁹²

87. *Id.* § 48.150.110(2).

88. *Id.* § 48.150.100(1).

89. For further discussion, see *infra* Part II.

90. See, e.g., *Korte v. Sebelius*, 735 F.3d 654, 659 (7th Cir. 2013) (describing the ACA as “a sweeping legislative and regulatory overhaul of the nation’s health-care system”), *cert. denied*, 134 S. Ct. 2903 (2014).

91. The Department of Health and Human Services published a report, OFFICE OF INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUMAN SERVS., A ROADMAP FOR NEW PHYSICIANS: AVOIDING MEDICARE AND MEDICAID FRAUD AND ABUSE 14 (2015), stating:

You may see advertisements offering to help you convert your practice into a “boutique,” “concierge,” or “retainer” practice . . . If you are a [Medicare] participating or non-participating physician, you may not ask Medicare patients to pay a second time for services for which Medicare has already paid. It is legal to charge patients for services that are *not covered* by Medicare. However, charging an “access fee” or “administrative fee” that simply allows them to obtain Medicare-covered services from your practice constitutes double billing.

Id. (emphasis added).

92. *Id.* To clarify, this practice would constitute double billing because doctors would bill Medicare for covered services at the government’s preestablished reimbursement rate and

The federal government's silence on direct practices ended, albeit tacitly, with the passage of the ACA. Within that legislation, a largely unnoticed provision⁹³ both recognized direct practices and drew them into the ACA's coverage offerings. The provision appeared in the section defining "qualified health plans," meaning plans that meet all of the legal requirements necessary to be offered on the state healthcare exchanges created by the ACA.⁹⁴ The passage says:

The Secretary of Health and Human Services shall permit a qualified health plan to provide coverage through a qualified direct primary care medical home plan that meets criteria established by the Secretary, so long as the qualified health plan meets all requirements that are otherwise applicable and the services covered by the medical home plan are coordinated with the entity offering the qualified health plan.⁹⁵

Shortly after the ACA's passage, HHS further defined "direct primary care medical home plans" as plans that "include an arrangement where a fee is paid by an individual, or on behalf of an individual, directly to a medical home for primary care services."⁹⁶

There is scant legislative history to provide insight into Congress's motives behind adding this provision to the ACA.

would then bill patients for the same services, a violation of the False Claims Act. *See* 42 U.S.C. § 1320a-7a(a)(1)(B) (2012) (prohibiting "fraudulent" claims for medical services).

93. As of February 2017, only one law review article referenced this provision, and that article only referenced the relevant language in a footnote with no further discussion. *See* Hammond, *supra* note 14, at 318 n.52 (discussing the relevant language in § 10104(a)(3) of the ACA in a footnote).

94. *See generally* 42 U.S.C. § 18021 (defining requirements for plans on state exchanges).

95. *Id.* § 18021(a)(3).

96. Patient Protection and Affordable Care Act; Establishment of Exchanges and Qualified Health Plans, 76 Fed. Reg. 41,866, 41,900 (proposed July 15, 2011) (to be codified at 45 C.F.R. § 156.245). The term "medical home" is used throughout the ACA, and the ACA leaves the task of specifically defining what constitutes "medical homes" to HHS. 42 U.S.C. § 18021(a)(3). However, the term is widely recognized in the medical field to define a broad spectrum of best-practice-driven primary care delivery models consistent with direct practices. *See generally* NAT'L CONFERENCE OF STATE LEGISLATURES, THE MEDICAL HOME MODEL OF CARE (2012), <http://www.ncsl.org/research/health/the-medical-home-model-of-care.aspx> [<http://perma.cc/9G5G-WWPU>] (providing an overview medical-home regulation). Analyzing the precise contours of what constitutes a "medical home" is not necessary here because HHS's proposed rule defining "direct primary care medical homes" simply proposes to define them as "consistent with the program established in Washington." Establishment of Exchanges and Qualified Health Plans, 76 Fed. Reg. at 41,900. Therefore, the definition of "medical home" under federal law would not add any additional qualifications or legal requirements to direct practices if HHS's proposed rule is adopted.

However, HHS's interpretive guidance and commentary accompanying its 2011 proposed rule implementing the provision⁹⁷ shed considerable light on the contemporary reasoning behind it, by saying:

Commenters . . . noted that the direct primary care medical home model in the State of Washington has benefited providers by providing predictable income without added administrative costs, while consumers gain access to an affordable and reliable source of primary services that decreases reliance on emergency rooms as a source of routine care.⁹⁸

So one can infer that federal policymakers concluded that the demonstrated benefits of direct practices sufficiently outweighed their potential drawbacks.

That provision's practical impact allows for qualified health plans offered on state insurance exchanges to provide all of their patients' primary care needs through direct practices without separate insurance coverage for primary care.⁹⁹ But for qualified health plans to offer plans including direct practice agreements, they must also provide "catastrophic" coverage for medical care beyond the scope of primary care, such as emergency care, specialist treatment, or surgery.¹⁰⁰ Put differently, direct practice arrangements may be offered in combination with "wrap-around" insurance coverage—that is, insurance that covers "catastrophic" care.¹⁰¹ They may not be offered as standalone health plans without such wrap-around coverage.¹⁰²

97. Establishment of Exchanges and Qualified Health Plans, 76 Fed. Reg. at 41,900.

98. *Id.*

99. *See id.* (allowing direct primary care packages to be offered as part of "qualified health plans" on the exchanges).

100. *Catastrophic Health Plan*, U.S. DEP'T OF HEALTH & HUMAN SERVS., <https://www.healthcare.gov/glossary/catastrophic-health-plan> [<http://perma.cc/2SGK-EZ52>].

101. Establishment of Exchanges and Qualified Health Plans, 76 Fed. Reg. at 41,900.

102. Interestingly, HHS indicated that it had indeed considered allowing direct practices to independently market themselves on state exchanges, but it ultimately decided otherwise:

We considered allowing an individual to purchase a direct primary care medical home plan and separately acquire wrap-around coverage. However, 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 and that would significantly depart from the role of an Exchange. Furthermore, allowing a separate offering would require consumers to make two payments for full medical coverage, adding complexity to the process of acquiring health insurance, ensuring enrollees have access to the full

This provision's scope is limited because it only affects direct practice agreements offered on the state, and federally run insurance exchanges, which comprise only a small percentage of America's insured population.¹⁰³ Yet its most important impact may be that it finally marked an unmistakable federal affirmation of the model as a legal and desirable form of healthcare delivery. Thus, although its direct reach might be limited to a small percentage of patients, the ACA's clear recognition of direct primary care has perhaps emboldened states to promote that model's advancement.

F. Riding the Wave: Post-ACA State Regulation of Direct Primary Care

Perhaps owing in part to the ACA's qualified endorsement of direct practices, the direct primary care movement has gained newfound momentum with the passage of twelve new statutes exempting them from state insurance regulation. Oregon was the first to act in 2011.¹⁰⁴ Utah followed in 2012,¹⁰⁵ followed by Arizona¹⁰⁶ and Louisiana in 2014.¹⁰⁷ The movement saw its greatest gains, however, in 2015 when eight states passed direct primary care legislation.¹⁰⁸ In

complement of the essential health benefits to which they are entitled, and complicating the allocation of advance payments of the premium tax credit.

Id.

103. See CONG. BUDGET OFFICE, UPDATED ESTIMATES OF THE EFFECTS OF THE INSURANCE COVERAGE PROVISIONS OF THE AFFORDABLE CARE ACT, APRIL 2014, at 5–6 (2014) (estimating nationwide participation in ACA-created health insurance exchanges to be just over 6 million people in 2014 and to rise to 25 million after 2017—still well under 10 percent of the current estimated American population).

104. Act of June 23, 2011, 2011 Or. Laws 499 (codified in OR. REV. STAT. §§ 735.500–510 (2015)).

105. Act of Mar. 15, 2012, 2012 Utah Laws 50 (codified in UTAH CODE ANN. §§ 31A-4-106(2), 31A-4-106.5 (LexisNexis 2015)).

106. Act of Apr. 23, 2014, 2014 Ariz. Sess. Laws 161 (codified in ARIZ. REV. STAT. ANN. §§ 20-123, 44-1799.91–92 (2014)).

107. Act of Aug. 1, 2014, 2014 La. Acts 867 (codified in LA. STAT. ANN. §§ 37:1360.81–91 (2015)).

108. An Act to Exempt a Concierge Service Arrangement from the Insurance Laws of Arkansas; and for Other Purposes, 2015 Ark. Acts 101 (codified in ARK. CODE ANN. §§ 23-60-104, 23-76-103(c) (2015)); Idaho Direct Medical Care Act, 2015 Idaho Sess. Laws 291 (codified in IDAHO CODE §§ 39-9201 to -9209 (2015)); Act of May 7, 2015, Ch. 46, § 1, 2015 Kan. Sess. Laws 613 (codified in KAN. STAT. ANN. § 65-4978 (2015)); Act of Jan. 10, 2015, 2015 Mich. Pub. Acts 522 (codified in MICH. COMP. LAWS § 500.129 (2015)); Mississippi Direct Primary Care Act, 2015 Miss. Laws 369 (codified in MISS. CODE ANN. §§ 83-81-1 to -11 (2015)); Act of July 2, 2015, 2015 Mo. Legis. Serv. 425 (West) (codified in MO. REV. STAT. § 376.1800 (2015)); Health Care Empowerment Act, 2015 Okla. Sess. Laws 159 (codified in OKLA. STAT. tit. 36, §§

addition, several national advocacy groups have emerged to encourage further state legislation.¹⁰⁹

G. Future State Legislation

In addition to the fourteen states that have passed direct care legislation, Florida legislators introduced a similar bill in 2015.¹¹⁰ The bill was passed with overwhelming bipartisan support in the Florida House of Representatives¹¹¹ but was not voted on in the Senate.¹¹² As of this writing, the author is aware of no other pending state legislation in 2016 but, based upon the wave of 2015 statutes, future state initiatives seem almost certain.

H. Proposed Federal Legislation

Despite the various state efforts and the ACA's approval of direct practices in state insurance exchanges, one legal hurdle to even greater expansion of the model persists at the federal level. Despite HHS's ACA-driven support, the IRS potentially maintains an "agency split" with its position on the tax status of direct practices. Current IRS guidelines consider direct care agreements as "health plans," rather than qualified medical expenditures under § 213(d) of the tax code.¹¹³ This position effectively prevents people with health savings accounts (HSAs)¹¹⁴ from engaging with direct practices

4604–4605 (2015)); Act of May 28, 2015, 2015 Tex. Gen. Laws 1214 (codified in TEX. OCC. CODE §§ 162.251–256 (2015)).

109. One such group, the Direct Primary Care Coalition (DPCC), has been particularly influential in advocating further legitimization of these practices, and that organization's "model bill" shares many of the same provisions and characteristics with many of the state statutes passed thus far. *Model State Legislation: Direct Primary Care Agreements*, DIRECT PRIMARY CARE COAL. (2014), <http://www.dpccare.org/#!/dpcc-model-legislation/c140b> [<http://perma.cc/MR6W-QPUZ>].

110. See generally H.B. 7047, 2015 Reg. Sess. (Fla. 2015) (exempting direct primary care agreements from insurance regulation).

111. H.B. 25A, 2015 Reg. Sess. (Fla. 2015). H.B. 25A passed by a vote of ninety-nine to one. HB 25-A: Direct Primary Care, FLA. SENATE, <http://www.flsenate.gov/Session/Bill/2015A/25A> [<https://perma.cc/5RFP-ZAX3>].

112. See FLA. SENATE, *supra* note 111 (stating that S. 7047 died in committee).

113. See IRS, PUBLICATION 502: MEDICAL AND DENTAL EXPENSES 6, 12–14 (2014) (excluding direct primary care fees from a list of qualified "medical and dental expenses" that can be paid by HSA funds).

114. HSAs are tax-exempt accounts where participants deposit preset monthly amounts to save for healthcare expenses. These accounts are required to be coupled with high-deductible ("catastrophic") insurance plans. The deposited funds generally can only be withdrawn for healthcare spending. However, they are beneficial for patients who do not have significant health expenses because the monthly deposit and accompanying catastrophic coverage

because the tax code prohibits HSA holders from supplementing their catastrophic insurance plans with a second "health plan."¹¹⁵ Until the IRS revises its position, HSA-holding patients wishing to join direct practices do so at the peril of exposing themselves to both liability for the funds in their HSAs and additional tax penalties.¹¹⁶

In response, a bipartisan group of senators proposed the Direct Primary Care Enhancement Act of 2015.¹¹⁷ This legislation would both clarify that direct practices are not "health plans" under the tax code and allow HSA participants to use their healthcare funds to pay for direct primary care access subscriptions.¹¹⁸ The bill never reached the voting floor.

Although the 114th Congress did not vote on the Direct Primary Care Enhancement Act, the model continues to garner attention from federal lawmakers. In fact, direct primary care could play an important role in Republican efforts to replace or amend the ACA. The House's 2016 ACA-replacement plan included a provision that would allow direct primary care subscription fees to be paid from HSA funds.¹¹⁹ Indeed, Tom Price, the current Secretary of HHS, included provisions in his 2016 ACA-replacement bill that would amend the Internal Revenue Code to exempt direct primary care from its definition of "insurance" and define access subscriptions as "medical care."¹²⁰ Congress, therefore, appears poised to further

premiums are considerably cheaper than the monthly premiums charged by health plans with lower deductibles and because participants can deduct their deposits made from their taxable income. *See Health Savings Accounts: Is an HSA Right for You?*, MAYO CLINIC (Apr. 8, 2013), <http://www.mayoclinic.org/healthy-lifestyle/consumer-health/in-depth/health-savings-accounts/art-20044058> [<https://perma.cc/XB64-XTAW>] (providing an overview of HSAs).

115. *See* I.R.C. § 223(c)(1)(A)(ii) (2012) (defining eligible HSA holders as individuals who are "not, while covered under a high deductible health plan, covered under any [other] plan").

116. *See id.* §§ 223(b)(8)(B)(i)(I)–(II) (imposing tax liability for all contributions made to HSAs and mandating a 10 percent tax penalty upon HSA holders who become ineligible).

117. Primary Care Enhancement Act of 2015, S. 1989, 114th Cong. The House proposed its own version of the bill in 2016. Primary Care Enhancement Act of 2016, H.R. 6015, 114th Cong. That bill was not voted on either.

118. *See id.* §§ 2–3 (clarifying that direct practices are not "health plan[s]" and classifying access subscriptions as "medical care").

119. Joseph Antos & James Capretta, *The House Republicans' Health Plan*, HEALTH AFF.: BLOG (June 22, 2016), <http://healthaffairs.org/blog/2016/06/22/the-house-republicans-health-plan> [<https://perma.cc/W7S3-9VUJ>].

120. *See* Empowering Patients First Act of 2015 §§ 127, 128, H.R. 2300, 114th Cong. (exempting direct practices from the Internal Revenue Code's definition of "insurance" and defining "medical care" to "include periodic fees paid to a primary care physician for the right to receive medical services on an as-needed basis").

expand direct primary care access to a considerable portion of the insured population.¹²¹

II. THE STATUTES: SUBSTANTIVE COMPARISON AND SUMMARY

Each of the state statutes passed since 2007 seeks to legitimize and regulate direct primary care practices. However, the statutes vary across jurisdictions, and no two are identical. This Part summarizes and compares the statutes by examining their key provisions.¹²² This Part concludes by suggesting which provisions should be included in future legislation to most effectively address the policy concerns discussed above.

A. *Shared Provisions: Insurance Exemption and “In Writing” Requirement*

The statutes share several uniform provisions. First, all state that direct practices are not insurers and exempt them from state insurance regulation.¹²³ This uniform exemption comes as no surprise given that these practices’ insurance status is critical to their continued viability and growth.¹²⁴ These provisions are also essential to the model’s continued growth, as cumbersome certification criteria like minimum net-worth requirements can preclude most physicians from operating direct practices.¹²⁵ Second, all of the statutes require the doctor–patient agreements establishing access subscriptions to be in writing and to set forth the terms and scope of the services

121. See AHIP CTR. FOR POLICY RESEARCH, 2015 CENSUS OF HEALTH SAVINGS ACCOUNT - HIGH DEDUCTIBLE HEALTH PLANS 4 (2015) (estimating that 19.7 million Americans participate in HSAs as of January 2015).

122. This analysis does not include the West Virginia statute because that statute delegates all legislative authority governing provider conduct to two state agencies, so it contains a scant amount of relevant substantive law. See W. VA. CODE ANN. § 16-2J-6 (LexisNexis 2013).

123. See, e.g., LA. STAT. ANN. § 37:1360.86 (2014) (“A direct practice that complies with the provisions of this Part is not a health insurance insurer and not subject to the provisions of nor the regulations under [Louisiana insurance law].”).

124. See, e.g., WASH. STATE OFFICE OF THE INS. COMM’R, *supra* note 73, at 4 (explaining the Washington Commissioner’s position that providers offering direct patient practices should not be subject to the full scope of state insurance regulations).

125. See Carnahan, *supra* note 23, at 133. Carnahan notes:

As a practical matter, concierge physicians deemed to be [insurers] likely would be unable to meet eligibility criteria for a certificate of registration, which includes, among many onerous requirements, that they provide documentation of an initial net worth of one million dollars, and thereafter maintain a minimum net worth equal to three million dollars.

Id. (footnote omitted).

offered.¹²⁶ These provisions ensure that participating parties will have adequate notice of the terms and conditions of the agreement and the scope of the healthcare services offered.

B. The Prohibition Against Billing Insurers

All but Missouri and Arkansas explicitly prohibit direct practices from billing insurers for any healthcare services provided.¹²⁷ Idaho and Kansas go further by also prohibiting *patients* from billing insurance.¹²⁸ These provisions seem superfluous given that reduced overhead from excluding insurers is a key benefit of the direct practice model; providers would presumably avoid insurer involvement on their own for economic reasons.¹²⁹ Although there is no legislative history to shed more light on the various state legislatures' thinking with respect to these provisions, it is possible that those legislatures sought to protect direct practices from potential conflicts with federal insurance laws—such as double-billing prohibitions¹³⁰—by removing insurance transactions from the picture entirely. Regulatory flexibility might be another consideration at play: by statutorily recognizing only cash-only practices, which comprise a narrow subset of the concierge-medicine family, the states have taken no position on “luxury” practices that bill insurers for healthcare services and patients for uncovered amenities.

C. Agreement Terms and Disclaimer Requirements

Ten states require the inclusion of specific terms in subscription agreements.¹³¹ Typical provisions include the medical services included in the agreement, the amount of the access subscription fee,

126. See, e.g., IDAHO CODE § 39-9203(2) (2015) (“‘Direct primary care agreement’ means a written contract between a primary care provider and an individual patient or a patient’s representative in which the primary care provider agrees to provide direct primary care services to the patient over a specified period of time for payment of a direct fee.”).

127. For a detailed comparison of the statutes’ billing prohibitions, see *infra* App.

128. For a detailed comparison of the statutes’ billing prohibitions, see *infra* App.

129. For explanation on how insurer involvement increases costs and shortens doctor–patient visit times, see *supra* note 36 and accompanying text.

130. For further discussion of potential conflicts with federal insurance laws, see *supra* notes 91–92 and accompanying text.

131. For a detailed comparison of the statutes’ requirements with respect to the content of written agreements, see *infra* App.

the payment interval, and the conditions and circumstances governing termination of the agreement.¹³²

With the exception of Oklahoma, all ten states also require a “disclaimer” provision stating that the agreements do not constitute insurance.¹³³ Others require additional language, such as a statement that “the agreement standing alone does not satisfy the health benefit requirements as established in the federal Affordable Care Act” and that failure to acquire additional insurance may expose the patient to ACA-mandated penalties for failing to meet minimum-coverage standards.¹³⁴ A representative provision from Louisiana reads as follows: “This agreement does not provide comprehensive health insurance coverage. It provides only the health care services specifically described.”¹³⁵ These disclosure requirements ensure that patients are both fully apprised of the services they will receive and aware of their responsibility to obtain insurance to cover services beyond the scope of the agreed services.

D. Termination Requirements

All but three states require that concierge services allow patients to terminate access subscriptions at will, provided that they give written notification.¹³⁶ However, the statutes diverge with respect to the conditions under which physicians are allowed to unilaterally terminate them. Ten of the thirteen states explicitly allow physicians to terminate agreements at will, allow them to specify cancellation terms of their choosing in the agreement, or do not speak to the issue at all, which implies that at-will termination is lawful.¹³⁷ These statutes

132. See, e.g., IDAHO CODE § 39-9204(1) (2015) (describing the required “[d]irect primary care agreement provisions”).

133. Compare *id.* (describing the required “[d]irect primary care agreement provisions”), with OKLA. STAT. tit. 36, §§ 4604–4605 (2015) (failing to specify the contents of direct primary care agreements).

134. MISS. CODE ANN. § 83-81-9(g)(ii)–(iii) (2015).

135. LA. STAT. ANN. § 37:1360.89(A)(1) (2014).

136. For a detailed comparison of the statutes’ termination requirements, see Appendix, <http://dlj.law.duke.edu/chappell-appendix> [<https://perma.cc/N2HA-YX2S>]. See also ARIZ. REV. STAT. ANN. § 44-1799.92(C) (2015) (“An enrollee may cancel a direct primary care provider plan for any reason on written notice to the plan.”). Arizona places no limits on when agreements can be terminated but mandates that agreements “must include cancellation terms for relocation and military duty.” See *id.*

137. For a comparison of the statutes, see Appendix. See also, e.g., MO. REV. STAT. § 376.1800(4)(3) (2015) (allowing “either party to terminate the agreement on written notice to the other party”).

can be classified together because their practical effect is the same: the physician shares equal discretion with the patient to terminate the subscription.

Three statutes set forth limited circumstances under which doctors can terminate agreements.¹³⁸ All three allow physician termination when the patient fails to pay the access subscription, refuses to follow the doctor's prescribed treatment plan, acts in an abusive manner, or threatens physical violence; they also allow termination when the physician discontinues practice under the direct care model.¹³⁹ Two also allow physicians to terminate an agreement if the patient commits fraud.¹⁴⁰ Mississippi alone adds a sixth condition, allowing for physician termination when the "physician feels that the relationship is no longer therapeutic for the patient due to a dysfunctional physician/patient relationship."¹⁴¹ Only three statutes, in near-identical language, explicitly require that adequate notice be given to the patient in the event that a doctor terminates a subscription.¹⁴²

E. Prohibition Against Discrimination

Three statutes—Louisiana, Oregon, and Washington—prohibit direct practices from refusing to accept patients on the basis of race, religion, or mental or physical disability.¹⁴³ Oregon additionally prohibits discrimination based on "race, religion, gender, sexual identity, sexual preference or health status,"¹⁴⁴ and Washington prohibits discrimination based on "race, religion, national origin, the presence of any sensory, mental, or physical disability, education,

138. See LA. STAT. ANN. § 37:1360.85(A)(1)–(5) (2014) (setting forth specific circumstances where physician termination is acceptable); MISS. CODE ANN. § 83-81-11(a)–(f) (2015) (same); WASH. REV. CODE § 48.150.050(1) (2009) (same).

139. See, e.g., LA. STAT. ANN. § 37:1360.85(A)(1)–(5) (setting forth specific circumstances where physician termination is acceptable).

140. See *id.* § 37:1360.85(A)(2) (permitting a physician to discontinue care if a patient commits fraud); MISS. CODE ANN. § 83-81-11(b) (same).

141. MISS. CODE ANN. § 83-81-11(f).

142. See LA. STAT. ANN. § 37:1360.85(A) (requiring notice to a patient upon termination of a subscription); MISS. CODE ANN. § 83-81-11 (same); WASH. REV. CODE § 48.150.050(1) (2014) (same).

143. See LA. STAT. ANN. § 37:1360.82 (2014) (precluding direct practices from declining patients on the basis of race, religion, or mental or physical disability, among others); OR. REV. STAT. § 735.500(3)(g) (2011) (same); WASH. REV. CODE § 48.150.020 (same).

144. OR. REV. STAT. § 735.500(3)(g).

economic status, or sexual orientation.”¹⁴⁵ Arizona, despite failing to include these protections, prohibits price discrimination by proscribing direct primary care physicians from charging different prices to patients on the basis of gender or a preexisting medical condition.¹⁴⁶ Mississippi’s statute includes nothing about price discrimination or the traditional grounds of discrimination included in the Louisiana, Oregon, and Washington statutes, but it prohibits refusing to accept patients on the basis of preexisting conditions.¹⁴⁷ However, the remainder of the statutes fails to include any language barring discrimination.

The failure of many states to include antidiscrimination language is perhaps influenced by redundancy concerns, as numerous general antidiscrimination statutes independently govern physician conduct. For example, the federal Civil Rights Act of 1964 prohibits any entity receiving federal funding from discriminating “on the [basis] of race, color, or national origin.”¹⁴⁸ The Rehabilitation Act of 1973 similarly prohibits discrimination on the basis of disability by federal-funding recipients.¹⁴⁹ Physicians participating in Medicare or Medicaid would thus be subject to these prohibitions. Additionally, many states have their own general antidiscrimination statutes that apply to all businesses¹⁵⁰ or at least to “places of public accommodation,” which, depending on their statutory definitions, often include doctors’ offices.¹⁵¹ State legislators might have therefore felt that including

145. WASH. REV. CODE § 48.150.020.

146. See ARIZ. REV. STAT. ANN. § 44-1799.92(C) (2010) (“A direct primary care provider plan may not charge different fees for comparable services based on an enrollee’s health status or sex.”).

147. See MISS. CODE ANN. § 83-81-11 (“[D]irect primary care [practices] may not decline to accept new . . . patients or discontinue care to existing patients solely because of the patient’s health status.”).

148. Civil Rights Act of 1964, tit. VI, § 601, 42 U.S.C. § 2000d (2012).

149. Rehabilitation Act of 1973, § 504, 29 U.S.C. § 794(a) (2012).

150. See, e.g., UTAH CODE ANN. § 13-7-3 (LexisNexis 2015) (“All persons within the jurisdiction of this state . . . are entitled to full . . . goods and services in all business establishments . . . without discrimination on the basis of race, color, sex, religion, ancestry or national origin.”).

151. See, e.g., KAN. STAT. ANN. § 44-1002 (2012) (defining “[p]ublic accommodations” as “any person who . . . offers goods, services, facilities and accommodations to the public”); see also ARIZ. REV. STAT. ANN. § 41-1442(A) (2010) (declaring “[d]iscrimination in places of public accommodation against any person because of race, color, religion, sex, national origin or ancestry” to be “unlawful”); § 41-1441(2) (defining “[p]laces of public accommodation” as, among other things, “all public places which are conducted . . . for the benefit, use or accommodation of those seeking health”).

additional antidiscrimination provisions in direct primary care statutes would simply be superfluous.

But Mississippi and Texas have a potential loophole unique to direct practices with regard to suspect-class discrimination. The federal antidiscrimination provisions bind only physicians participating in Medicare and Medicaid or otherwise receiving federal funds. Because direct practices in those states cannot bill any insurers for their services¹⁵²—and thus do not receive federal funding—they are beyond the reach of those antidiscrimination provisions. Further, neither Mississippi nor Texas have enacted general “public accommodation” or physician-specific antidiscrimination laws. Therefore, unlike in traditional contexts—in which federal law covers patients even without state protections—direct practices’ statutory exemption from Medicare and Medicaid also exempts them from federal laws, potentially leaving patients unprotected.

F. Agency Oversight and Enforcement

Oregon, Louisiana, and Washington include specific enforcement mechanisms in their statutes. Oregon’s statute requires each direct practice to be certified by the state’s Department of Consumer and Business Services.¹⁵³ Although the initial certification requirements are minimal,¹⁵⁴ the statute vests the department with the authority to investigate direct practices’ statutory compliance and the discretion to suspend or revoke violators’ licenses.¹⁵⁵ Louisiana’s statute confers auditing and enforcement authority to its physician-licensing board and authorizes the board to punish violators by sanctioning them for “unprofessional conduct.”¹⁵⁶ Potential sanctions include suspension or revocation of a physician’s license as well as “probationary or other restrictions” as necessary.¹⁵⁷ Washington similarly categorizes violations of its regulations as “unprofessional conduct” under its

152. MISS. CODE ANN. § 83-81-3(c) (2015); TEX. OCC. CODE § 162.254 (2015).

153. OR. REV. STAT. § 735.500(2) (2011).

154. *See id.* (requiring only that direct practices are not “controlled” by insurers and that they were never certified to “transact insurance”).

155. *See id.* § 735.500(5) (describing the conditions under which the department may revoke a direct practice’s certification).

156. LA. STAT. ANN. § 37:1360.91 (2014).

157. *Id.* § 37:1285(A)(13) (2015).

physician-licensing laws,¹⁵⁸ subjecting violators to a variety of potential penalties that includes license revocation.¹⁵⁹

In contrast, none of the other state statutes contain enforcement mechanisms or specific penalties for noncompliance. Nor do they contain explicit private rights of action. Presumably, practices found in violation of those statutes would not qualify as direct practices under state law, meaning they would not be exempted from prohibitive insurance regulations.¹⁶⁰ Perhaps the prospect of onerous insurance regulation is itself a suitable enforcement mechanism,¹⁶¹ but the question of who has auditing and enforcement authority remains.¹⁶²

G. Suggestions for Future State Legislation

In addition to the basic patient protections and provider requirements set forth in most of the already-enacted statutes, states crafting future legislation should improve two primary shortcomings found in a number of the statutes already in force. First, they should prohibit discrimination that is not already illegal under other laws. Second, they should clarify their oversight and enforcement mechanisms.

When other general antidiscrimination laws do not apply—such as in states that do not have general antidiscrimination laws or that do not include doctors' offices in their statutory definitions of “places of public accommodation”—future statutes should prohibit suspect-class discrimination. Doing so would preclude the creation of loopholes, like those found in Mississippi and Texas, that result from statutory preclusion of Medicare and Medicaid participation.¹⁶³ There is no reason to deny direct primary care patients these protections when

158. WASH. REV. CODE § 48.150.090 (2007).

159. *See id.* § 18.130.160 (2010) (listing potential penalties).

160. *Cf.* MISS. CODE ANN. § 83-81-9 (2015) (“In order to be considered a direct primary care agreement for the purposes of this section, the direct primary care agreement must meet all of the following requirements . . .”).

161. For an explanation of how insurance regulation can cripple or destroy direct practices, see *supra* note 116 and accompanying text.

162. Although direct primary care physicians, like other physicians, are subject to the various statutory provisions and administrative regulations enforced by the physician-licensing boards in their respective states, those general physician regulations may not require the same conduct prohibited or required by the direct primary care statutes, such as including the specific language in direct care agreements or not billing insurers.

163. For a discussion of how and why Mississippi and Texas preclude direct practices from billing Medicare and Medicaid, see *supra* note 152 and accompanying text.

nearly all other patients already receive them. More importantly, a wealth of recent academic research suggests that racial and ethnic minorities continue to receive lower quality health care in the United States.¹⁶⁴ It is true that many factors other than illicit bias and the quality of primary care certainly contribute to these disparities.¹⁶⁵ But at the very least, states can combat overt discrimination and reduce its contribution to those disparities by including antidiscrimination provisions in direct primary care legislation.

Second, future state statutes should clarify their enforcement and oversight mechanisms. Some states might conclude that minimal enforcement and oversight of direct practices are desirable while others might conclude that greater regulatory intervention is necessary. There are numerous ways to implement either conclusion. For example, they can tie penalties to direct practice licenses, like Oregon does,¹⁶⁶ or they can mirror Louisiana and Washington by simply conferring the same penalties on direct primary care providers who violate their statutes as they confer on other physicians who commit "unprofessional conduct."¹⁶⁷ Indeed, they could even create a private right of action to allow aggrieved patients to sue for vindication of their legal rights, although no one has done so yet. Similarly, states have many oversight options from which to choose. Although state physician-licensing boards might be the most obvious oversight authorities, states might also choose to confer oversight on their insurance-enforcement departments. Or they can choose not to oversee direct practices at all, perhaps leaving vindication of patients' legal rights exclusively to civil litigation. This Note does not recommend a particular mechanism or attempt to find the appropriate regulatory balance, but it does recommend clarity. Regardless of the regulatory reach they intend to create, states should expressly circumscribe the scope and practical operation of their statutory requirements.

164. See generally, e.g., David R. Williams & Ronald Wyatt, Opinion, *Racial Bias in Health Care and Health Challenges and Opportunities*, 314 J. AM. MED. ASS'N 555 (2015) (discussing various studies on health disparities and the reasons for racial bias in health care).

165. See, e.g., THOMAS A. LAVEIST, *MINORITY POPULATIONS AND HEALTH: AN INTRODUCTION TO HEALTH DISPARITIES IN THE UNITED STATES* 133–202 (2005) (canvassing various theories advanced to explain the causes of health disparities among minorities).

166. OR. REV. STAT. § 735.500(5) (2011).

167. LA. STAT. ANN. § 37:1360.91 (2014); WASH. REV. CODE § 48.150.090 (2007).

III. FACING OLD DEMONS: HOW DIRECT PRIMARY CARE STATUTES ENGAGE LONGSTANDING POLICY CONCERNS

Any policy evaluation of these statutes must begin by revisiting the longstanding policy concerns that concierge practices have presented since their inception—namely, their status under insurance law, income discrimination, patient abandonment, and healthcare access.¹⁶⁸ Canvassing the statutes reveals that the results are mixed: all of the statutes engage some of those concerns, some statutes address others, and none address them all. But these considerations are not the end of the matter. The larger questions are how these statutes interact with the current, post-ACA healthcare framework and how that interaction will change as the number of direct practices continues to grow. This Part examines the policy problems discussed above.

A. Insurance

Since their inception, the insurance status of direct practices has been critical to their continued viability.¹⁶⁹ However, extensive discussion of this matter is no longer necessary. The states that have passed direct primary care statutes have explicitly settled this legal question in the negative—direct practices are not insurers under state law. This relatively simple determination can pave the way for future growth of the use of this model. The final unresolved question in this area is whether Congress will follow suit and open the model to new audiences by defining subscription fees as “health expenses” rather than “health plans,” which would allow HSA holders to pay for access subscriptions with their tax-deductible healthcare funds.¹⁷⁰ Regardless, the state statutes’ exemption of direct practices from state insurance regulation likely ensures that the model is here to stay.

B. Income Discrimination and Quality-of-Care Disparities

Aside from the two statutes that prohibit patient refusal on the basis of income and the one that prohibits health-based price

168. For a detailed discussion of the policy concerns surrounding direct practices, see *supra* Part I.C.

169. For further discussion on how the insurance status of direct practices can impact their viability, see *supra* notes 124–25 and accompanying text.

170. For an explanation of how current law prohibits HSA participants from using their funds to pay for direct practice expenses, see *supra* Part I.H.

discrimination,¹⁷¹ the statutes are silent on the matter of economic disparity. For example, nothing in the statutes prohibits operation of an "elite" direct practice that charges exorbitant access subscriptions to those with the means to pay for ultrapersonalized care and heightened access.¹⁷²

Nevertheless, market forces driving the model's growth might largely address this longstanding concern. The statutory silence on this issue only preserves the status quo. Even critics of concierge practices who fear their widespread promulgation have noted that the high-end concierge model is likely self-limiting.¹⁷³ The idea is simple: if only the wealthy few can afford expensive access premiums, demand growth is necessarily limited.¹⁷⁴ Indeed, some have expressed relief at the observation that high-end practices have not become commonplace.¹⁷⁵ It stands to reason that widespread quality-of-care disparities stemming from higher-end concierge practices remains of little concern at this point. Instead, the growth of concierge models in general necessarily depends on their accessibility to a much larger population than the one targeted by luxury practices.

Perhaps, for this reason, the majority of direct practices promoted by these statutes have been structured to reach a less affluent customer base. Anecdotal evidence suggests that the recent increase in concierge practices has been driven by "blue collar" practices.¹⁷⁶ Blue-collar practices charge more affordable monthly subscription fees in exchange for conventional primary care services

171. For a discussion of how the various statutes address (or fail to address) price discrimination, see *supra* notes 146–47 and accompanying text.

172. See Elizabeth Ody, *Wealthy Families Skip Waiting Rooms with Concierge Medical Plans*, BLOOMBERG BUS. (Mar. 16, 2012, 12:01 AM), <http://www.bloomberg.com/news/articles/2012-03-16/wealthy-families-skip-waiting-rooms-with-concierge-medical-plans> [<http://perma.cc/W9QT-8ZHU>] (discussing PinnacleCare Private Health Advisory, a Maryland direct practice that charges access subscriptions "ranging from \$2,500 to \$30,000 a year," provides ultrapersonalized care and "has emergency physicians available around-the-clock and connects patients to a network of top doctors throughout the world").

173. See Carnahan, *supra* note 23, at 157 (noting that, though high-end concierge practices are a niche market, "one would expect the[ir] proliferation . . . to be self-limiting" based upon limited demand).

174. *Id.*

175. See Brennan, *supra* note 43, at 1190 ("We can be happy, and perhaps take some solace in the fact that luxury care is not becoming rapidly prevalent.").

176. See CAL. HEALTHCARE FOUND., *supra* note 32, at 3 (cataloguing five large direct practices and reporting that they all charge inexpensive monthly access subscription prices as follows: (1) Iora Health: \$80; (2) MedLion: \$59; (3) Paladina Health: \$69 to \$109; (4) Qliance: \$65; (5) White Glove Health: \$35 plus \$35 visit fee).

devoid of high-end luxuries, yet they aim to preserve the longer doctor–patient visits and reduced waiting times that are hallmarks of the direct primary care model.¹⁷⁷ Indeed, all of the larger and most popular franchises operating as direct practices across the country follow this model.¹⁷⁸ For example, one large direct primary care provider, Qliance,¹⁷⁹ reported that Medicaid programs subsidized about *half* of its estimated 35,000 patients.¹⁸⁰

On balance then, although none of the statutes foreclose direct practices from offering tiered care that could result in quality-of-care disparities, market realities speak loudly. And unsurprisingly, practitioners adopting the model seem to be listening thus far. Accordingly, the particular concierge model promoted by these statutes might itself be far less susceptible to income disparity than other concierge models. Perhaps it is telling then that just as the statutes are silent on economic disparity with respect to direct practices, they are equally silent on state attitudes toward “pure” concierge practices.

C. Patient Abandonment

Analyzing these statutes’ effect on patient abandonment is a brief exercise. Short of softening the initial blow by requiring adequate notice when a provider drops a patient, the statutes simply do not address this concern. But the same market forces that drove the growth in direct practices offering affordable services may mitigate some of these concerns. Because physicians converting to blue-collar concierge models are not charging exorbitant prices, more

177. See Marcia Horn Noyes, *Direct Primary Care and Concierge Medicine - Spring 2015*, 22 J. ASS’N STAFF PHYSICIAN RECRUITERS 7, 8 (2015). Noyes says:

The Izbicki’s [sic] first considered the concierge model While this ‘boutique’ level of care is becoming popular in places like California, Florida and Virginia, concierge was unlikely to thrive in fiscally conservative Erie. That’s when older brother Jon ran across the direct primary care ([DPC]) model, also referred to as a subscription or retainer model. He says, “It’s like blue collar concierge medicine – priced more affordably and a better fit for our community.”

Id. (quoting Jon Izbicki).

178. See CAL. HEALTHCARE FOUND., *supra* note 32, at 2.

179. Qliance’s access subscriptions—which include unlimited doctor visits and no-wait phone and email access to physicians—are far from prohibitive. The company’s current rates as of 2015 were \$59 per month for patients nineteen and younger, \$79 for patients twenty through forty-nine, and \$99 for patients fifty and over. See *Pricing*, QLIANCE, <http://qliance.com/tables> [<http://perma.cc/8PWJ-47PJ>].

180. David von Drehle, *Medicine Is About to Get Personal*, TIME (Dec. 22, 2014), <http://time.com/3643841/medicine-gets-personal> [<http://perma.cc/72ND-PD7J>].

of those doctors' patients can follow their doctors in making the transition to direct primary care. A greater problem remains, however. Because smaller patient populations remain a hallmark of the direct primary care model,¹⁸¹ it follows that a large percentage of doctors' old patients will have to be dropped upon conversion for the doctors to reap the benefits of transitioning. This reduction is not a problem if there are enough physicians to absorb terminated patients. But that is not always the case, as discussed below.

D. Healthcare Access

The statutes do not address what is perhaps the most serious long-term concern with all types of concierge practices: the effect of direct practices on healthcare access.¹⁸² Because direct practices derive one of their primary advantages from providing more extensive and personalized care to their patients in exchange for carefully limiting their enrollment levels,¹⁸³ their increasing popularity could cause an aggregate reduction in nationwide healthcare access. This reduction could further compound a nationwide physician shortage that scholars estimate will grow into the tens of thousands within the next decade.¹⁸⁴ Yet the statutes do not speak to this concern at all.¹⁸⁵

* * *

The statutes' effectiveness in addressing the policy concerns associated with concierge practices is a mixed bag. The statutes discuss the insurance issue most, as one of their primary functions is to exempt direct practices from insurance regulation. By narrowly recognizing a practice model that is popular because it is a cost-effective alternative to expensive insurance policies, the statutes

181. For example, MDVIP—a Florida-based direct primary care practice with nationwide offices that offers subscriptions for on average \$150 per month—claims that each of its physicians maintains a patient panel numbering 600 patients or fewer. *See Member Benefits*, MDVIP, <http://www.mdvip.com/member-benefits> [<https://perma.cc/GS47-9VJ6>].

182. For a discussion of contemporary concerns about shortages in healthcare access, see *supra* notes 59–63 and accompanying text.

183. For an explanation of business model upon which direct practices are built, see *supra* notes 32–35 and accompanying text.

184. *See, e.g.*, NAT'L CTR. FOR HEALTH WORKFORCE ANALYSIS, *supra* note 61, at 2 (projecting a shortage of 20,400 primary care physicians by 2020); Petterson et al., *supra* note 61, at 110 (estimating primary-care-physician shortages of 3,968 in 2020, 17,213 in 2025, 26,440 in 2030, and 33,283 in 2035).

185. For further discussion, see *supra* notes 59–63 and accompanying text.

indirectly address the income-disparity concerns associated with traditional concierge practices. But the statutes do little to mitigate concerns about patient abandonment or to engage the burgeoning problem of reduced primary care access in America.¹⁸⁶

IV. BROADER POLICY CONSIDERATIONS: STATES AS DIRECT PRIMARY CARE “LABORATORIES”

The analysis in Part III raises the question of whether these statutes and the models they promote are ultimately good things. Their place in the contemporary healthcare landscape suggests that they are. Despite their failure to address some of the policy concerns presented by the concierge model, these statutes are on balance a positive development in the American healthcare system.

A. *Potential Benefits of Direct Primary Care.*

Direct primary care offers numerous benefits. The allure of concierge practices to doctors and patients is well established and should not be undervalued. Although direct practices have not been studied in isolation, surveys have shown that doctors practicing in concierge practices make more money, have more time to see patients, and enjoy their jobs more.¹⁸⁷ Likewise, participating patients report higher satisfaction with their doctors.¹⁸⁸ Patients paying

186. See Richard A. Cooper, *It's Time to Address the Problem of Physician Shortages: Graduate Medical Education Is the Key*, 246 ANNALS SURGERY 527, 527 (2007) (“It is now widely accepted that the United States is on the cusp of deepening shortages of physicians.”).

187. See Pasquale, *supra* note 39, at 52. The author discusses a survey of retainer physicians, noting:

“50% of the retainer physicians said they thought they were offering more diagnostic and therapeutic services than traditional practices,” and “70% of retainer physicians said they were doing better [financially] in this type of practice than they had in traditional practice.” It is not hard to see why, given the numbers: “Retainer physicians saw an average of 11 patients per day; non-retainer physicians saw an average of 22 patients.”

Id. (alteration in original) (footnotes omitted) (quoting Jennifer Silverman, *Retainer Practices Reporting Better Care*, FAM. PRAC. NEWS, June 1, 2005, at 71–72); see also Robert Baror, *Is Direct Primary Care the Future?*, FED. BAR ASS'N: HEALTH L. CHECKUP ENEWSLETTER, <http://www.fedbar.org/Sections/Health-Law-Section/Health-Law-Checkup/Is-Direct-Primary-Care-the-Future.aspx> [<https://perma.cc/3LYT-CM64>] (positing that direct primary care offers “the chance to make medicine a rewarding and enticing profession again” and that the model “allows physicians to simultaneously spend more time with their patients, providing enhanced care, while also reducing the hours they must work and increasing their quality of life”).

188. See Peter A. Clark, Jill R. Friedman, David W. Crosson & Matthew Fadus, *Concierge Medicine: Medical, Legal and Ethical Perspectives*, 7 INTERNET J.L. HEALTHCARE & ETHICS 1, 4 (2011) (stating that “[d]espite the recession, renewal rates of concierge practices are

monthly fees for unlimited or extensive access can benefit from added spending predictability with respect to their primary care.¹⁸⁹ Finally, the prospect of longer doctor visits, better doctor–patient relationships, and increased individualized care incentivizes preventive care and regular doctor visits, which in turn reduces the need for elaborate and expensive forms of reactive treatment resulting from preventable illnesses.¹⁹⁰

Nevertheless, by failing to address healthcare access, these statutes do not attempt to deal with a potentially serious policy shortcoming. Their impact will likely be negative in the short run. Any model that finds its greatest benefit in serving fewer patients per physician must necessarily add to the burgeoning shortage—especially when doctors reduce their patient panels from 2,500 to 500.¹⁹¹ As the number of these practices increases, their popularity could substantially impact the shortage. Given the ACA's simultaneous imposition of a large number of patients onto the existing infrastructure (which only added to the other factors driving the nationwide physician shortage),¹⁹² it is hard to envision any positive short-term impact on healthcare access by direct practices.

In response, proponents argue that the win–win scenario offered by the model will bring more doctors in to the primary care field in the long term.¹⁹³ There, they argue that the win–win–win combination

consistently very high” and that “[h]igh renewal rates . . . indicate how satisfied the patients are with [concierge] services”).

189. See Noyes, *supra* note 177, at 8 (discussing the affordability and predictability of subscription-based primary care).

190. See French et al., *supra* note 41, at 179 (“The preventive care services made available through increased access and physician contact time with concierge medicine have the potential to result in cost savings if these services avoid expensive hospital care or emergency room visits.”).

191. See Jones & Treiber, *supra* note 59, at 110 (citing a GAO survey that found, “on average, physicians decreased their patient panel from 2716 to 491 patients per year when making the practice conversion, an 82% reduction”).

192. See Tovino, *supra* note 8, at 2433 (“The United States has a growing population, an aging population, and an increasing number of residents with health insurance coverage as a result of the Affordable Care Act.”).

193. See William N. Wu, Garrison Bliss, Erika B. Bliss & Larry A. Green, *A Direct Primary Care Medical Home: The Qliance Experience*, 29 HEALTH AFF. 959, 962 (2010). The authors conclude:

The direct care patient medical home model, with its smaller patient panels, ample time per visit, competitive pay, and manageable lifestyle, has the potential to reignite excitement among those considering a career in primary care. Although some argue that the smaller panels will exacerbate the primary care physician shortage, we believe that such models will slow and eventually help reverse the exodus

Id.

of improved working conditions, higher revenues, and greater patient relationships will halt and eventually reverse the physician exodus from primary care as the direct primary care model expands.¹⁹⁴ In the short term, they point to the accelerating rates at which primary care physicians are leaving the field entirely and argue that direct practices oftentimes “catch” otherwise-inevitable deserters.¹⁹⁵ Put simply, their argument implies that a doctor who treats fewer patients than he did before is still better than a doctor who treats no one. However, these proponents’ short-term argument is anecdotal, and their long-term argument is speculative, as there is scant empirical data upon which to evaluate either side’s claims.¹⁹⁶ This speculation will continue until there are enough practices to adequately measure their impact on the healthcare marketplace.¹⁹⁷

B. Federalism: An Appropriate Testing Ground for the Model

However, this uncertainty is a primary reason that federalism is particularly appropriate in this context. Simply put, no one knows whether the proven benefits of direct primary care outweigh their potentially negative impacts on healthcare access or even whether they will negatively impact access at all. So neither full-throated endorsement nor wholesale disqualification at the federal level is appropriate. The former would constitute a risky endorsement of an innovation whose shakedown cruise is far from complete, and the latter would effectively foreclose a promising delivery model with some demonstrated and possibly scalable benefits. Thus, experimentation at a more limited level seems warranted, especially because this innovation was likely slowed for years by considerable legal uncertainty.

194. *Id.*

195. See Thomas S. Huddle & Robert M. Centor, *Retainer Medicine: An Ethically Legitimate Form of Practice that Can Improve Primary Care*, 155 ANNALS INTERNAL MED. 633, 634–35 (2011). The authors discuss physician retention and say:

We predict that retainer physicians would find any ethical condemnation of retainer practice . . . to be highly implausible, so much so that, far from impelling such physicians to return to more usual forms of primary care practice, it would most likely lead to the loss of physicians from primary care altogether.

Id.

196. See French et al., *supra* note 41, at 180 (“[F]ew scientific studies have evaluated the clinical, economic, and policy impact of concierge medicine and virtually no long-term information is available.”).

197. See *id.* (“Quality longitudinal data are scarce . . .”).

Furthermore, the physician shortage is itself a decentralized issue: the shortage is neither equally distributed among the states nor attributable to a shared cause.¹⁹⁸ Analysts attribute the shortage to a mosaic of systemic problems that vary by jurisdiction, including problems with attracting medical students into primary practice, growing residency shortages, soaring education debt, and declining physician incomes.¹⁹⁹ And predictably, the shortage is greatest in rural and low-income jurisdictions.²⁰⁰ The shortage is not so much a uniform nationwide shortage as much as it is a patchwork of regional or local shortages being driven by various combinations of locale-specific factors.

Given the decentralized nature of the physician shortage, these statutes are appropriate vehicles to test direct primary care's scalability and impact on the national healthcare market before betting the proverbial farm in additional states or at the national level. By legitimizing the direct practice model, states can gauge the model's interplay with other initiatives to grow the physician population.²⁰¹ They can test the validity of their proponents' arguments about their ability to attract more primary care doctors in the long term while monitoring their short-term effects. Interestingly, many of the early-moving states that have recently passed direct

198. See Leighton Ku et al., *The States' Next Challenge—Securing Primary Care for Expanded Medicaid Populations*, 364 NEW ENG. J. MED. 493, 494 (2011) (projecting Oklahoma to have the highest Medicaid expansion relative to its primary care physician population—more than double the national average and six times more than Massachusetts, the state with the lowest projected shortage).

199. See, e.g., Frank Pasquale, *Access to Medicine in an Era of Fractal Inequality*, 19 ANNALS HEALTH L. 269, 288 (2010) (“The physician shortage is exacerbated by physician maldistribution.”); Tovino, *supra* note 8, at 2433 (“The nation’s doctor shortages should not come as a surprise. The United States has a growing population, an aging population, and an increasing number of residents with health insurance coverage as a result of the Affordable Care Act.”); *id.* at 2477 (“Today, these [funding] caps significantly limit the ability of teaching hospitals located in physician-shortage areas to grow their residency programs and train physicians who might stay and practice medicine in needed specialty areas . . .”).

200. See, e.g., Candice Chen et al., *Toward Graduate Medical Education (GME) Accountability: Measuring the Outcomes of GME Institutions*, 88 ACAD. MED. 1267, 1267 (2013) (“Despite . . . public investment [in graduate medical education], physician shortages in certain specialties, including primary care, general surgery, and psychiatry, and in rural and underserved areas, persist.”).

201. See, e.g., Michael Ollove, *Rural Doctor Shortage Spurs States to Act*, PBS NEWSHOUR: THE RUNDOWN (June 10, 2016, 11:34 AM), <http://www.pbs.org/newshour/rundown/rural-doctor-shortage-spurs-states-to-act> [<https://perma.cc/JM8W-BJQS>] (describing various states' initiatives to remedy their respective doctor shortages).

practice statutes are also experiencing the greatest doctor shortages.²⁰² A prime opportunity thus exists to put direct practices through worst-case scenario testing by legitimizing them in several of the regions that are already experiencing shortages. As a result, states that have taken a wait-and-see approach on direct practices will have the opportunity to gauge the model's viability in difficult access conditions. Based on those observations, they can then either adopt their own statutes with enhanced corrections to remedy the mistakes made by early-mover states or throw out direct practices entirely by simply defining them as insurers. Meanwhile, federal policymakers can examine these impacts and further flesh out the best way to harmonize the direct primary care model with the federal insurance infrastructure, whether the ACA or a replacement plan governs that infrastructure.

In that sense, these statutes are a modern, albeit perhaps unintentional, example of cooperative federalism—that is, states filling in the microscopic-level regulatory gaps in a macroscopic federal regulatory scheme.²⁰³ Here, the macroscopic scheme is the broad federal insurance framework designed to increase access, lower costs, and improve delivery.²⁰⁴ The state gap-filling function concerns delivery improvement.²⁰⁵ Further, this arrangement leaves discretion to the states to examine the impact of direct practices on healthcare access and tailor their regulatory approaches to address the jurisdiction-specific causes of their respective doctor shortages. Put another way, by putting both proponents' and critics' arguments to the test, states will learn whether these practices can in fact have a role in solving the impending doctor shortage. The ACA certainly left room for states to experiment with possible solutions to further

202. See Ku et al., *supra* note 198, at 494 (estimating the following states in order of most severe primary care shortage: Oklahoma—1st, Texas—3rd, Louisiana—4th, Arkansas—5th, Mississippi—14th). Interestingly, Washington—one of the first states to recognize direct practices—is projected to rank 44th. *Id.*

203. See Philip J. Weiser, *Towards a Constitutional Architecture for Cooperative Federalism*, 79 N.C. L. REV. 663, 665 (2001) (“[C]ooperative federalism envisions a sharing of regulatory authority between the federal government and the states that allows states to regulate within a framework delineated by federal law.”).

204. See DEMOCRATIC POLICY COMM., THE PATIENT PROTECTION AND AFFORDABLE CARE ACT 1 (2010), <https://www.dpc.senate.gov/healthreformbill/healthbill04.pdf> [<https://perma.cc/ZWQ5-LYFV>] (“The Patient Protection and Affordable Care Act will ensure that all Americans have access to quality, affordable health care and will create the transformation within the health care system necessary to contain costs.”).

205. It might also operate in the area of cost, but that determination is merely speculative at this point.

improve delivery and access.²⁰⁶ Further, proposed ACA replacements heavily emphasize state experimentation and market-driven innovations.²⁰⁷ Thus, those states that have chosen to recognize the direct primary care model can determine whether it can play a role in addressing this problem. This innovation-testing arrangement is what ultimately answers the broader question posed by its evolution: these statutes—and the delivery models they endorse—are meritorious developments in the American healthcare landscape.

CONCLUSION

The direct primary care statutes are a unique example of innovation in a highly regulated industry. Furthermore, they represent an example of unintended, yet still cooperative, federalism in a partisan political climate. Indeed, states considered to be primarily conservative, liberal, and moderate have passed these statutes. It is rare to see a Louisiana statute modeled directly after a Washington statute, but that is exactly the case here. Although the statutes simultaneously promote and regulate a growing trend in the healthcare industry, their effectiveness in addressing several longstanding policy concerns associated with concierge practices is a decidedly mixed bag. Nevertheless, these statutes' greatest asset lies within their principle rather than their language. That principle—empirically testing the virtues of policy innovation—is particularly appropriate here, where an untested innovation with considerable promise has grafted itself onto a complex and high-risk industry. Thus, the concept of states as laboratories of democracy²⁰⁸ works

206. See 42 U.S.C. § 18052 (2012) (allowing states to apply for a “waiver for state innovation,” which exempts states from the ACA’s insurance requirements upon successful submission of an alternative proposal); Ctr. For Consumer Info. & Ins. Oversight, Ctrs. For Medicare & Medicaid Servs., *Section 1332: State Innovation Waivers*, CMS.GOV, https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Section_1332_state_Innovation_Waivers-.html [https://perma.cc/MVL9-42Q5] (“Section 1332 of the Affordable Care Act (ACA) permits a state to apply for a State Innovation Waiver to pursue innovative strategies for providing their residents with access to high quality, affordable health insurance while retaining the basic protections of the ACA.”).

207. See, e.g., Antos & Capretta, *supra* note 119 (describing the various ways in which the House Republicans’ 2016 ACA-replacement plan propose to incentivize state experimentation and innovation, including \$25 billion in federal funds for “statewide reform efforts,” potential grants for improving care quality and insurance access, and “bonus payments” based on demonstrated reform progress).

208. See *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (Brandeis, J., dissenting) (1932) (“It is one of the happy incidents of the federal system that a single courageous state may, if its

particularly well in this context: the states that have chosen to recognize the direct primary care model can actively test whether that model alleviates or exacerbates the symptoms associated with their systemic doctor shortages.

In sum, direct practices present some promising benefits while also creating some concerning potential dilemmas. Each of these potential benefits, along with their potential harmful effects, are made testable by the state action discussed here. These statutes promote an experimental, innovative delivery model in full accordance with the end goals of state and federal policymakers alike. And that is indeed “a big [expletive] deal.”²⁰⁹

citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country.”).

209. Weiner, *supra* note 1.