

# SO YOU WANT TO START A HEALTH PLAN?: FEDERAL LAWS SUPPORTING AND UNDERMINING THE CREATION OF PSHPs

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## INTRODUCTION

The United States spends nearly twice as much on healthcare per capita than any other developed country,<sup>1</sup> without providing better patient care.<sup>2</sup> Healthcare quality and affordability continue to be two of the biggest concerns for Americans.<sup>3</sup> Public and private actors in the healthcare industry have continuously searched for ways to decrease, or at least control, the sky-rocketing costs of healthcare in the United States, while simultaneously improving patient outcomes. Some healthcare providers believe they have found a partial solution: provider sponsored health plans (“PSHPs”).

PSHPs are health insurance plans that are fully owned and operated by healthcare providers.<sup>4</sup> By controlling the entire healthcare experience—from insurance payment to care given—providers with PSHPs believe they may be able to decrease healthcare costs and improve healthcare quality.<sup>5</sup> For a variety of factors, some of which will be discussed within this Note, there is a PSHP creation trend among healthcare systems: thirteen percent of healthcare systems

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1. Bradley Sawyer & Cynthia Cox, *How Does Health Spending in the U.S. Compare to Other Countries?*, THE PETERSON CENTER ON HEALTHCARE AND KAISER FAMILY FOUNDATION (Dec. 7, 2018), [https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/?\\_sf\\_s=health+spending#item-start](https://www.healthsystemtracker.org/chart-collection/health-spending-u-s-compare-countries/?_sf_s=health+spending#item-start) [perma.cc/3E9M-KB8M].

2. Irene Papanicolas et al., *HealthCare Spending in the United States and Other High-Income Countries*, JAMA NETWORK (Mar. 13, 2018), <https://jamanetwork.com/journals/jama/article-abstract/2674671> [perma.cc/BT8H-8VJY].

3. Robert Pearl, *Healthcare is the No.1 Issue for Voters; A New Poll Reveals Which Healthcare Issue Matters Most*, FORBES (Aug. 13, 2018), <https://www.forbes.com/sites/robertpearl/2018/08/13/midterms/#53583b363667> [perma.cc/FNR3-2DSS].

4. Jonathan Rickert, *A Quick Guide to Provider-Sponsored Plans*, GETINSURED (May 24, 2016), <https://company.getinsured.com/a-quick-guide-to-provider-sponsored-plans/> [perma.cc/GPV5-2TM5].

5. Erin E. Dine & MaryKathryn Hurd, *Health Insurer Merger Frenzy: How the Continued Arms Race Will Disrupt Traditional Market Roles*, 25 ANN. HEALTH L. 98, 104 (2016); David Gruber, *Payment Reform Risk Management: Provider Survival Strategies in an At-Risk Environment*, 20 No. 3 J. HEALTH CARE COMPLIANCE 27, 28 (2018); *Provider-Sponsored Health Plans: the Ultimate Value-Based Healthcare Plan*, VALENCEHEALTH.COM, 1 (2015), <https://www.hfma.org/downloadasset.aspx?id=46903> [perma.cc/729N-62PX]; Todd A. Zigrang, *The Re-Emergence of Provider-Sponsored Plans*, 9 HEALTH CAPITAL TOPICS (Jan. 2016), [https://www.healthcapital.com/hcc/newsletter/1\\_16/HTML/PROVIDERPLAN/9.1\\_hc-topics-1-16---healthcare-providers-as-insurers.php](https://www.healthcapital.com/hcc/newsletter/1_16/HTML/PROVIDERPLAN/9.1_hc-topics-1-16---healthcare-providers-as-insurers.php) [perma.cc/4EMA-Y46M].

in the U.S. already offer PSHPs,<sup>6</sup> and approximately fifty percent of health systems have applied or intend to apply for an insurance license so they can consider starting a PSHP in the future.<sup>7</sup> According to a study by the Atlantic Information Services, one hundred and sixty-three additional health plans offered by PSHPs entered government and commercial markets from 2013 to 2015.<sup>8</sup> Also, from 2013 to 2018, PSHPs increased by thirteen percent in the small and medium business payers market, which makes up eighty-three percent of all offered health plans.<sup>9</sup> Because of the current trend, today nearly fifty-two percent of insurance products are offered by health systems who operate PSHPs.<sup>10</sup>

PSHPs are by no means a new invention,<sup>11</sup> so the question becomes: What has legally changed to spur this trend of PSHP creation, and what legal pitfalls should healthcare providers be aware of before jumping headfirst into the health insurance industry? This Note looks to address these questions in four separate parts. Part I will provide a general overview of PSHPs by explaining how PSHPs operate, the benefits they may produce, and their history. Then, Part II will look at what laws have changed to incentivize PSHP creation. Because this PSHP creation trend seems to be nationwide in scope, this Note will focus on recent federal legal changes, although recent changes in various state laws may have also incentivized PSHP creation.<sup>12</sup> Conversely, part III will look at what federal laws might pose substantial risks to PSHP creation and operation. Lastly, Part IV will suggest how a PSHP might structure their legal relationships to minimize their federal legal risks, discussed in Part III, while maximizing the benefits of PSHPs discussed in Parts I and II. This Note hopes to uncover how PSHPs are benefiting healthcare providers, what recent changes to federal law are incentivizing providers to create PSHPs, and how PSHPs can be structured to take advantage of these laws while withstanding some federal legal pitfalls which might get in the way of PSHP success.

## I. WHAT IS A PSHP?

### A. Structure and Function

A PSHP is a health insurance plan that is fully operated, funded, and created

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6. Dine, *supra* note 5, at 133.

7. Rickert, *supra* note 4.

8. *Id.*

9. Les Masterson, *Small Medium Payers Show Growing Interests in Provider-Sponsored Plans*, INDUSTRY DIVE (Aug. 8, 2018), <https://www.healthcaredive.com/news/small-medium-payers-show-growing-interest-in-provider-sponsored-plans/529459/> [<https://perma.cc/N88R-KQ8L>].

10. Julia Kapchinskiy, *The Duality of Provider and Payer in the Current Healthcare Landscape and Related Antitrust Implications*, 55 SAN DIEGO L. REV. 617, 641 (2018).

11. *See infra* section I. C.

12. *See* David C. Szostack, *Vertical Integration in Health Care: The Regulatory Landscape*, 17 DEPAUL J. HEALTH CARE L. 65, 67 (2015).

by a healthcare provider through a process known as vertical integration. Vertical integration occurs when a business begins to “provide[] for itself some input that it might otherwise have purchased on the market.”<sup>13</sup> As businesses develop, grow and compete for consumers within a market, vertical integration is one way businesses can set themselves apart. The following is an example of vertical integration: Imagine Company A buys a part from Company B. Consequently, Company A discovers that it can produce the part at a lower cost than the amount at which it purchases it from Company B. If Company A decides to begin producing and selling that part on its own, it would be vertically integrating its company into Company B’s market. There are numerous benefits which the act of vertically integrating offers to companies, such as the possibility of increased efficiency and cost reduction.<sup>14</sup> Vertical integration is generally seen as a pro-competitive activity because it often decreases the price of a business’ product, which spurs other businesses within the market to find innovative ways to lower their costs to stay competitive with their vertically-integrated competitor.<sup>15</sup> In a way, vertical integration is business common sense. If a company can create or provide a service at a lower cost than the price it pays another individual or entity, then the company should vertically integrate into that business to become more efficient and create a similar quality product at a lower cost to consumers.

In the healthcare industry, typically healthcare providers are two separate entities who a very close, although at time strenuous, relationship. However, a provider will vertically integrate into the healthcare payor market and create a PSHP when the provider believes they can financially benefit by also operating as a healthcare payor; a typically separate entity. The following is an explanation of these two types of entities and how they traditionally jointly operate: A healthcare provider is any entity which “furnishes health care services, such as a physician, hospital, clinic, or hospice.”<sup>16</sup> In other words, healthcare providers are the organizations that are licensed to provide healthcare services to the masses. To get paid for its services, the provider will either charge the individual who received the services directly, or, in most instances, the provider will submit a claim, outlining all the care given to the individual, to the individual’s healthcare insurer.<sup>17</sup> The healthcare insurer will then reimburse the provider for the care given to the individual depending on the terms of their contracts with the individual and with the healthcare provider.<sup>18</sup>

A healthcare payor is an individual or, in most cases, an insurance company that is required “to make payment with respect to an[y healthcare] item or

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13. 3A PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW 5 (2d ed. 2000).

14. *Id.* at 6; Szostack, *supra* note 12, at 70 (stating that cost reduction is the main justification for vertical integration).

15. 3A AREEDA, *supra* note 13, at 5.

16. *Provider*, J.E. SCHMIDT, ATTORNEYS’ DICTIONARY OF MEDICINE (2018).

17. *See The Medical Billing Process*, MEDICALBILLINGANDCODING.ORG, <https://www.medicalbillingandcoding.org/billing-process/> [perma.cc/JE3Q-UUZH] (last visited Mar. 3, 2020).

18. *See What is Medicaid Billing?*, MEDICALBILLINGANDCODING.ORG, <https://www.medicalbillingandcoding.org/billing-training/> [perma.cc/UB3S-QV9X] (last visited Mar. 3, 2020).

service” which is rendered to its members.<sup>19</sup> Healthcare payors typically take the form of either government-funded programs<sup>20</sup> or privately-owned insurance companies.<sup>21</sup> Healthcare payors offer health plans to groups of individuals for monthly fees called premiums.<sup>22</sup> The payor will “provide[] or pay[] for the cost of medical care”<sup>23</sup> for the individuals who are covered under the payor’s health plan, often referred to as members, in accordance with the specific terms of the individual’s health plan. The terms of a health plan designate the amount of healthcare coverage each member of that health plan has, what services are covered under the health plan, what amounts of each service the health plan covers, and at which provider facilities the health plan can be used.

Typically, healthcare payors and providers interact when they contract with each other through a “lengthy, and tedious, ‘behind the scenes’” contractual process to determine if the healthcare payor will cover services rendered by the provider to the payor’s members, and at what amount the payor will reimburse the providers for the different care provided to the payor’s members.<sup>24</sup> Since healthcare payors control the money which is paid to reimburse the provider for its services and since the payors control where their members go to receive provider services, it is easy to see why providers often view this contracting process as favoring the healthcare payor.<sup>25</sup>

Providers have begun to, in a way, bypass this often-one-sided contracting process with health care insurers by creating their own health plans.<sup>26</sup> When a provider creates its own health plan—a PSHP—it is vertically integrating into the healthcare payor space. By creating a PSHP, the provider can skip the nontransparent contracting process and decide on its own which providers and services will be covered by its health plan, the terms of the health plan, and the reimbursement amounts received from the health plan. The provider will then insure individuals and provide care for those same individuals under its own health plan. In this way, PSHPs are created, and a provider reinvents the typical

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19. 42 C.F.R. § 411.21 (2020).

20. Government funded healthcare insurance programs include Medicare, Medicaid, CHIP, HIS, VHA, and Tricare. *See* JANET M CORRIGAN ET AL., LEADERSHIP BY EXAMPLE: COORDINATING GOVERNMENT ROLES IN IMPROVING HEALTH CARE QUALITY 28-37 (2003).

21. Some of the most prominent healthcare insurers in the market are Anthem, Cigna, Aetna, Humana, and United Healthcare. Amanda Baltazar, *The Big Five Health Insurance Companies*, VERYWELL HEALTH (Aug. 31, 2018) [perma.cc/6GMH-RFDM].

22. *How Health Insurance Works*, BLUE CROSS BLUE SHIELD OF MINNESOTA, <https://www.bluecrossmn.com/healthy/public/personal/home/shopplans/shop-individual-family-plans/shop-how-health-ins-works> [perma.cc/F4MU-FCHD] (last visited Mar. 3, 2020).

23. 45 C.F.R. § 160.103 (2019).

24. Dine, *supra* note 5, at 129.

25. *See* Roger Fontes, *Negotiating Contracts with Insurance Companies*, MD MAGAZINE (Aug. 16, 2013), <https://www.mdmag.com/physicians-money-digest/practice-management/negotiating-contracts-with-insurance-companies-fontes> [perma.cc/J3EW-CYPW] (Referring to the situation as “David versus Goliath”).

26. Kapchinskiy, *supra* note 8, at 639 (referring to this as cutting out the middlemen).

two entity provider-payor relationship by offering both healthcare insurance and healthcare services, and ultimately reimbursing itself for the services it rendered to individuals with their insurance on terms the provider created.

PSHPs operate in almost the exact same way as private health insurance plans.<sup>27</sup> When starting a PSHP, the provider operating the PSHP must first receive a license to sell health insurance within its state.<sup>28</sup> Then, the PSHP, just like any other health insurer, outlines the terms of its various health plans which it will offer to individuals seeking to purchase health insurance. The terms of any health plan detail what services it will cover, at what expense, at what facilities, and what deductible or copay the member will have to pay for the service.<sup>29</sup> The PSHP then dictates the premium amount the individual will have to pay each month depending on the benefits of the specific health plan. The premium is determined through an actuarial risk calculation to ensure that the premiums are high enough to cover the cost of selling the policy, administering the policy, and maintaining adequate funds to pay claims relating to the medical services provided to the plan's members.<sup>30</sup> The PSHP then markets and sells its health plans to a group of individuals, who will be covered in accordance with the health plan's terms.

There are two ways in which PSHPs substantially differ from typical health care plans. The first is in the amount of risk the PSHP takes on. Health insurance is all about risk assessment. Healthcare payors try to properly assess the risk that their insured members will need to use their health insurance.<sup>31</sup> Traditionally, all of the risk of the insured remained with the health insurer, but since the 1980s, some of that risk transferred to the provider whose payments from the insurer would be determined on how efficiently they provide care to the insurer's members.<sup>32</sup> Today, a typical insurer only takes on a portion of their members' healthcare risk, and the rest is passed on to the providers, as the amount which a health insurer pays the provider ultimately depends on the quality of care they provide to the insurer's members.<sup>33</sup> As an insurer's payment to a provider focuses more and more on quality or value, providers begin to carry a larger amount of the risk of the health insurer's members.<sup>34</sup> A PSHP takes this risk-shifting from

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27. Rickert, *supra* note 4.

28. See NAT'L ASS'N OF INSURANCE COMMISSIONERS, State Licensing Handbook 93 (2013).

29. *Understanding Commercial Health Insurance*, MEDICALBILLINGANDCODING.ORG, <https://www.medicalbillingandcoding.org/health-insurance-guide/commercial-health-insurance/> [perma.cc/2pzp-6NS4] (last visited Mar. 3, 2020).

30. Brenda Long, *How are Health Insurance Premiums Calculated*, MICH. ST. U. EXTENSION (Sep. 27, 2013) [perma.cc/LL6G-RMMM].

31. *Id.*

32. Stephen S.S. Hyde & Tobin N. Watt, *Renewed Interest in Provider Sponsored Plans (What Providers Can Do on Their Own)*, AHLA SEMINAR PAPERS 17 (2011).

33. Adam D. Colvin & Max Reiboldt, *Evolving Physician/Hospital Alignment—Five New Transaction Types for 2015*, AHLA SEMINAR PAPERS 8, 13 (2015); see discussion of value-based reimbursement, *infra* Section II. B.

34. Colvin, *supra* note 31, at 13, exhibit 2.

the insurer to the provider a step further because, as provider and insurer, the PSHP assumes 100 percent of the risk of its members.<sup>35</sup> That is to say that, only if the PSHP calculates the premiums correctly and provides its members' care efficiently will the PSHP "profit directly from its members' premiums. However, if the costs of care exceed the plan's revenue, there is no limit to the PSHP's financial liability."<sup>36</sup> Therefore, one major difference between a typical insurer and a PSHP is that because a PSHP is controlled by the individual giving the healthcare, the PSHP stands to profit from the entire premium dollar it receives from its members,<sup>37</sup> or the PSHP will stand to lose the entirety of the premium due to the risk that their members' care will cost more than the members' premiums.

The second way a PSHP differs from a typical insurer is its structure. PSHPs have two minor structural qualities that differentiate them from typical health insurers. First, PSHPs are structured to be subsidiaries of their parent provider,<sup>38</sup> whereas typical insurers are stand-alone entities.<sup>39</sup> To create a PSHP, the provider company will create a subsidiary health insurance company to either create a health insurance company from scratch, team up with an active health insurer, or purchase a smaller health insurance company.<sup>40</sup> Each possibility carries with it a different amount of risk and benefit to the parent provider.<sup>41</sup> Second, unlike other private insurers, PSHPs typically structure themselves to have a narrow network of providers they cover within their region aside from the provider who created the PSHP.<sup>42</sup> These narrow networks allow PSHPs to better control the quality of the care they give, keep costs low, and keep patients at the PSHP's provider's facilities.<sup>43</sup> Beyond these minor differentiations, PSHPs operate in the exact same

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35. Michaela Poizner, *Value-Based Reimbursement: The New Norm For Health Care?*, LAW 360 (Mar. 17, 2016), <https://lrus.wolterskluwer.com/news/health-reform/value-based-reimbursement-the-new-normal/32322/> [perma: <https://perma.cc/QFM8-UH55>].

36. *Id.*

37. Dine & Hurd, *supra* note 5, at 129. Healthcare providers see at most 80 percent of any patient's premium dollar as the rest is kept by the healthcare insurer to pay for marketing, overhead, and profit. ALLAN BAUMGARTEN, ANALYSIS OF INTEGRATED DELIVERY SYSTEMS AND NEW PROVIDER-SPONSORED HEALTH PLANS 8 (2017), <https://www.rwjf.org/content/dam/farm/reports/reports/2017/rwjf437615> [perma: <https://perma.cc/98J2-PT2h>].

38. Michael R. Crowe & Lisa A. Hathaway, *Managed Care Contracting for the Post Acute World in 2016 and Beyond*, AHLA SEMINAR PAPERS 27, 1, 24 (2016).

39. Kirstin Ives & Christopher Petelle, Presentation at the Annual American Health Lawyers Association Meeting: Intercompany Pricing and the Movement Toward Integrated Health (June 2016) (Presentation available on the AHLA Health Law Archive).

40. Amy L. Mackin & Jean Wright Veilleux, *Wearing Two Hats: Opportunities and Challenges for Provider-Sponsored Health Plans* 4-6, AHLA: INSTITUTE FOR HEALTH PLAN COUNSEL (Nov. 2, 2018).

41. *Id.*

42. Terri Wagner Cammarano & Richard J. Zall, *Provider/Payer Convergence: New Models for Population Health Management*, AHLA SEMINAR PAPERS 3, 1, 2 (2015).

43. Mackin & Veilleux, *supra* note 41, at 3.

way as typical health insurers by insuring their members under their health plans for set premiums and reimbursing providers for the services the provider renders to the PSHPs' members.

When creating a PSHP, a provider typically tests the waters by first offering its plan to its employees.<sup>44</sup> This allows the PSHP to test and improve its risk management and health insurance infrastructure before offering its plan to the public.<sup>45</sup> If the provider finds that its PSHP is able to appropriately manage the risk and operate the employee health plan efficiently, then the PSHP may decide to begin selling their health plans to the public.<sup>46</sup> Providers then typically decide whether they are going to offer a Medicare Advantage plan,<sup>47</sup> often the entry point into the market for most PSHPs, or a typical commercial health plan.<sup>48</sup> In the end, the goal of a provider who operates a PSHP on an individual employee level or on a commercial level is to keep patients healthy and to do it as efficiently as possible to keep consumer premiums low, provider costs low, and profits from member premiums high.<sup>49</sup>

### *B. The Benefits of Operating a PSHP*

Although it is risky to create and operate a health insurance plan, many providers are looking into creating PSHPs because of the benefits PSHPs have the potential to create. All of the benefits a PSHP has the potential to create come from its alignment of “optimal treatment supplied by the [provider] with the cost cutting and tight controls incentivized by the insurance . . .”<sup>50</sup>

PSHPs have the potential to benefit providers in three ways. First, PSHPs may benefit providers by creating a separate stream of revenue for a provider's business through the collection of member premiums.<sup>51</sup> This revenue diversification is incredibly beneficial to some providers as revenue created through inpatient services is at an all-time low.<sup>52</sup> PSHPs allow for providers to have a financial safety net; when a provider's typical inpatient revenue is low due to lack of inpatients, their premium revenue should be high because their insured

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44. Alison M. Howard, *Back to the Future: Provider-Employer Alliance Direct Contracting for Health Benefits*, 30 HEALTH LAW. 1, 3 (2018).

45. *Id.*

46. *Id.*

47. Medicare Advantage plans are private insurance plans that offer Medicare benefits to Medicare-eligible individuals through a government-approved private insurer. See *What's a Medicare Advantage Plan*, CTR. FOR MEDICARE AND MEDICAID SERVS. (Apr. 2015), <https://www.medicare.gov/pubs/pdf/11474.pdf> [perma.cc/VN6X-U54E].

48. Mackin & Veilleux, *supra* note 41, at 6.

49. Dine & Hurd, *supra* note 5, at 130.

50. Kapchinskiy, *supra* note 10, at 639.

51. BAUMGARTEN, *supra* note 38, at 8.

52. Alex Kacik, *Not-for-profit hospitals' cost-cutting isn't keeping up with revenue decline*, MODERN HEALTHCARE (Aug. 29, 2018), <https://www.modernhealthcare.com/article/20180829/NEWS/180829884> [perma.cc/4ZLZ-SP7U].

members will not be using the inpatient services.<sup>53</sup>

Second, PSHPs may benefit providers by creating a defense against the ever-increasing bargaining strength of large insurers, as well as against the increasing competitive strength of other providers with already existing PSHPs. Recently, there have been multiple attempts for large healthcare insurers to merge.<sup>54</sup> Providers are worried that if these large payors merge that providers may lose substantial bargaining power during payor-provider contractual negotiations. In anticipation of such mega-mergers, providers have begun to create their own health plans as a form of protection.<sup>55</sup> Also, some providers consider creating PSHPs as a defensive competitive tactic against other providers in their area who operate PSHPs.<sup>56</sup> For example, two hospital systems in California created PSHPs because they were losing patients to Kaiser Permanente's fully integrated healthcare system.<sup>57</sup> In a world of lower inpatient revenue and constant mergers, providers could easily see creating a PSHP as a way to keep their business competitive and afloat.

Third, PSHPs may benefit providers by potentially increasing overall efficiency and quality in their healthcare system.<sup>58</sup> PSHPs collect valuable patient data which can greatly facilitate and benefit a provider's coordinated care activities.<sup>59</sup> Through a PSHP, providers have access to extensive claims data regarding treated patients which was previously only held by insurers. This data can help a provider see the areas of high utilization within their healthcare system and the areas where they can improve the provider operation to better accommodate their patients.<sup>60</sup> This new stream of data from PSHPs allows providers who operate PSHPs to view the gaps in their care management and mend those gaps to increase their efficiency and quality to create a better provider experience.<sup>61</sup> PSHPs' use of this health information data creates a unique opportunity for the provider to completely and more accurately manage the care of the patients' it serves as well as find areas within its healthcare system where it can improve to keep costs down.<sup>62</sup>

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53. Jacqueline LaPointe, *A Provider-Sponsored Health Plan Is A Hospital's Natural Next Step*, REVCYCLE INTELLIGENCE (July 16, 2018), <https://revcycleintelligence.com/news/a-provider-sponsored-health-plan-is-a-hospitals-natural-next-step> [perma.cc/Y3BE-VQGX].

54. See generally *U.S. District Court Blocks Aetna's Acquisition of Humana*, U.S. DEP'T OF JUSTICE (Jan. 23, 2017) <https://www.justice.gov/opa/pr/us-district-court-blocks-aetna-s-acquisition-humana> [https://perma.cc/VY2W-VBEH].

55. Mackin & Veilleux, *supra* note 41, at 2, 4.

56. BAUMGARTEN, *supra* note 38, at 8.

57. *Id.*

58. Gary Scott Davis et. al, Presentation for the American Health Lawyers Association Institute for Health Plan Counsel: The Changing Relationship between Providers and Payers (Dec. 8-9, 2016) (Presentation available on the AHLA Health Law Archive).

59. Mackin & Veilleux, *supra* note 41, at 13.

60. BAUMGARTEN, *supra* note 38, at 8.

61. *Id.*

62. Crowe, *supra* note 39; Gary Scott Davis et al., *Provider Sponsored Health Plans*, 2017



Also, if PSHPs become more prevalent within the healthcare market, they have the potential to generally benefit the healthcare system in the United States. The U.S. spends almost twice what other high-income nations spend on healthcare,<sup>63</sup> without providing better access and quality of care to its citizens.<sup>64</sup> Statistics indicate that PSHPs could potentially increase the U.S.'s access and quality of care, and lower overall healthcare spending.

Providers see PSHPs as a way to lower healthcare costs within their own system, but if PSHPs became more prevalent, they could potentially decrease healthcare costs throughout the U.S. PSHPs actively eliminate costs and streamline the operations for the healthcare providers who operate them.<sup>65</sup> PSHPs cut healthcare costs in two major ways. First, PSHPs decrease healthcare costs by actively improving care management through a process of sharing patient data with their parent provider in a way that allows the provider to provide care more efficiently.<sup>66</sup> Second, PSHPs decrease the cost of healthcare by significantly lowering a provider's administration costs associated with working with typical healthcare payors.<sup>67</sup> PSHPs have significantly lower administrative costs than traditional insurance plans, allowing the savings to be transferred to their members in the form of low premiums.<sup>68</sup> These lower administration costs likely come from PSHPs cutting out the process of interacting with another health insurer when submitting a claim and arguing over reimbursement costs for services the provider rendered to an insured patient.<sup>69</sup> Although these might seem very minor ways in which PSHPs cut healthcare costs, in a nation where healthcare spending is out of control,<sup>70</sup> any savings in healthcare is viewed as a step in the right direction and, if done on a large enough scale, could potentially minimally decrease overall healthcare costs throughout the U.S.

Providers also recognize that PSHPs have the potential to increase access of healthcare wherever their health plan is offered. Primarily due to the high cost of health insurance, 27.9 million individuals remain uninsured in the U.S.<sup>71</sup> PSHPs

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HEALTH L. HANDBOOK 9, 1, 3 (2017).

63. Around 18 percent of the United States gross domestic product is spent on healthcare. Papanicolas et. al., *supra* note 2.

64. The United States was the only country examined with a "sizable minority" of individuals who lacked basic healthcare service coverage. Also, compared to all other similarly situated countries, the U.S. had "considerably lower" rates on all clinical outcome measures. *Id.*

65. Brian J. Miller & George L. Wolfe, *Managed Care Marketplaces: Growing Drivers of Payer-Provider Vertical Integration*, 16 APR ANTITRUST SOURCE 1, 3 (2017).

66. Colvin, *supra* note 34, at 20; *see also supra* notes 46-60 and accompanying text.

67. Mike Finnerty Kaufman & Gary Scott Davis, unpublished article for the American Health Lawyers Associations Physicians and Hospitals Law Institute: Provider-Sponsored health Plans: Back to the Future 3 (Feb. 2016) (Article available on the AHLA Health Law Archive).

68. *Id.*

69. Colvin, *supra* note 34, at 20.

70. Papanicolas et. al., *supra* note 2.

71. *Key Facts about the Uninsured Population*, KAISER FAM. FOUND. (Nov. 29, 2017), <https://www.kff.org/uninsured/fact-sheet/key-facts-about-the-uninsured-population/>

typically offer health insurance at a more affordable rate than health plans from larger health insurers,<sup>72</sup> and could thus offer more affordable health insurance to some of these uninsured. PSHPs are able to reduce premiums by keeping their network limited, and by using data they received from their member's utilization of healthcare to identify ways in which they could be more efficient while maintaining a high quality of care.<sup>73</sup> The lower premiums PSHPs typically offer have the potential to get more individuals insured, increasing America's overall access to care.

PSHPs also provide providers with a way to increase the quality of the healthcare provided in America. According to a study done by the McKinsey Center for U.S. Health System Reform, PSHPs have historically received higher quality ratings compared to other private insurers.<sup>74</sup> These quality improvements likely result from increased data utilization by PSHPs that pinpoint areas where changes are needed within the overall healthcare system<sup>75</sup> and the general greater emphasis PSHPs place on preventive care services than typical large insurers.<sup>76</sup> In an age when many providers are concerned about the quality of their healthcare, it is easy to see why there is a trend toward PSHP creation.

There are some individuals who are wary to support PSHP creation. These individuals often argue that PSHP creation through vertical integration will decrease competition and consequently raise costs.<sup>77</sup> However, as demonstrated in the previous paragraphs of this section, PSHPs could lead to increased healthcare access, an improvement in healthcare quality, and a reduction in health insurance costs. Also, PSHPs are bringing competition to the healthcare insurance market where the American Medical Association has noted that there is a lack of competition and choice for consumers.<sup>78</sup> Therefore, although not every provider will be able to create and operate a PSHP, PSHPs will likely help, rather than harm, the healthcare market.

If done on a widespread scale, it appears that PSHPs could benefit both the individual providers and, more generally, American healthcare. Allen Baumgarten, a research analyst who focuses on health care policies, stated that "[t]he key to success for [PSHPs] is the ability to enunciate and then deliver on

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[<https://perma.cc/R3BM-GLUJ>].

72. Howard, *supra* note 45, at 4.

73. BAUMGARTEN, *supra* note 38, at 8; Rush, *supra* note 63, at 3.

74. Integrated delivery networks received a quality rating of 4.45 out of 5, whereas private insurers received an average of 3.89 out of 5. *Assessing the 2017 Medicare Advantage Star Ratings* 3, MCKINSEY AND COMPANY (2016).

75. LaPointe, *supra* note 54.

76. Dine & Hurd, *supra* note 5, at 133.

77. Kathleen Snow Sutton, *Wait Then Reassess: Antitrust Risks of Vertical Integration in Healthcare Remain an Open Question*, 96 DENV. L. REV. 353, 359 (2019); Szostack, *supra* note 12, at 74; Rush, *supra* note 63, at 15.

78. See Kyle Murphy, *AMA Study Finds Lack of Health Payer Competition Across US*, HEALTH PAYER INTELLIGENCE (Nov. 9, 2018), <https://healthpayerintelligence.com/news/ama-study-finds-lack-of-health-payer-competition-across-us> [perma.cc/BC7Z-UAGK].

a value proposition: a provider system and its affiliated physicians and hospitals providing high-quality medical care at a lower cost, enabling the health plan to sell insurance at a lower price than competitors.”<sup>79</sup> Although starting a health insurance company still comes with many challenges, providers throughout America are taking notice of all of the benefits operating a PSHP can provide and have either already begun to create a PSHP or have taken steps to create a PSHP in the future.<sup>80</sup>

*C. Back to the Future: A Short History of PSHPs*

The year was 1937 and Henry J. Kaiser, an industrialist, finalized a deal with Dr. Sidney Garfield, whereby Dr. Garfield and his team of physicians would provide health care to Kaiser’s shipyard workers in the California bay area at a Kaiser owned hospital.<sup>81</sup> The shipyard workers prepaid Kaiser and Dr. Garfield to obtain the healthcare services at Kaiser and Dr. Garfield’s facilities.<sup>82</sup> Thus, the first PSHP was born where a hospital began to sell “health insurance” for services provided at its own hospital.<sup>83</sup> Kaiser Permanente,<sup>84</sup> the PSHP created in 1937, is still in operation and is the largest operating PSHP in the market today, insuring more than twelve million individuals in eight states.<sup>85</sup>

Despite the success of Kaiser Permanente’s PSHP, very few PSHPs created early on were successful.<sup>86</sup> Those that were, such as Geisinger Health Plan and Health Partner, found success because they could offer health insurance prices that were competitive with national health insurers due to their maintenance of great care coordination, conservative financial practices, comprehensive benefits, and limited networks of providers.<sup>87</sup> Typical characteristics of the first-generation PSHPs that failed were that they were not able to secure enough membership

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79. BAUMGARTEN, *supra* note 38, at 20.

80. Thirteen percent of health systems in the U.S. have created PSHPs, and fifty percent more have applied, or are intending to apply, for a health insurance licenses so they can consider starting their own PSHP. Rickert, *supra* note 4.

81. Gruber, *supra* note 5, at 28; *History*, KAISER PERMANENTE <https://share.kaiserpermanente.org/about-us/history/#> [perma.cc/CD8J-H72E] (last visited Mar. 6, 2020).

82. KAISER PERMANENTE, *supra* note 81. For more information on the facts leading up to the creation of the Kaiser Permanente Health Plan, *see id.*

83. Rickert, *supra* note 4.

84. Since 1953, the name of the health plan and hospitals created from the agreement between Henry J. Kaiser and Dr. Garfield have gone by the name Kaiser, and the medical group providing the service has gone by the name Permanente. The Collaboration between health plan, hospital, and medical group has become known as Kaiser Permanente. KAISER PERMANENTE, *supra* note 81.

85. Gruber, *supra* note 5, at 28; *Kaiser Permanente at a Glance*, KAISER PERMANENTE, (last visited Feb. 2, 2019), <https://ataglace.kaiserpermanente.org/kp-12-million-people/> [perma.cc/59KE-2KPH].

86. Finnerty, *supra* note 59, at 7.

87. BAUMGARTEN, *supra* note 38, at 1.

under their health plan and, in an attempt to increase their membership, they decreased prices to an amount that was not financially sustainable for the provider.<sup>88</sup>

In the 1990s, PSHPs gained popularity as national health reform took center stage in political debates.<sup>89</sup> The overall healthcare landscape in America was ripe for a new wave of innovative insurers, as there was a lack of competition in the insurance market and a continued legal push for innovative methods of payor reimbursement.<sup>90</sup> Many believed that vertically integrated provider and payor systems could, for similar reasons as those noted in the previous section of this Note, help improve the quality of healthcare and lower healthcare costs.<sup>91</sup> Several hundred providers started PSHPs,<sup>92</sup> but the trend fizzled out and only forty-three of the PSHPs created in the 1990s are still active.<sup>93</sup>

The PSHPs of the 1990s were often ill equipped to handle running an insurance company due to lack of proper knowledge and inadequate information systems on which they could assess the quality of their care and the risk of their insured members.<sup>94</sup> Eventually, many of these early PSHPs failed due to financial pressures. To start a health plan, providers must have a substantial amount of capital to receive a license to sell health insurance in the state or states in which they wish to operate.<sup>95</sup> Even if a provider receives a license to sell health insurance, their PSHP will likely sustain significant losses in the first few years of operation, which may prevent them from being successful.<sup>96</sup> One reason providers sustain such big losses early on is that they are unable to gain a sufficient member base so that their premium incomes offset the cost they have to pay in order to provide healthcare for their members.<sup>97</sup> PSHPs have historically struggled to gain sufficient member base to stay profitable because of the large national insurance companies which had preexisting extensive membership pools and established relationships with employers offering group insurance plans.<sup>98</sup> If PSHPs are not able to gain a sufficient number of members to offset the amount they are paying out for healthcare services, then the PSHP will likely not last long. Because of this economic reality, only the largest health systems within a

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88. Finnerty, *supra* note 59, at 7.

89. BAUMGARTEN, *supra* note 38, at 5.

90. Kaufman, *supra* note 68, at 3.

91. BAUMGARTEN, *supra* note 38, at 5.

92. *Id.*

93. *Id.*

94. Hyde, *supra* note 33, at 1.

95. *See generally* IND. CODE §§ 27-1-6-14, 15 (2018) (mandating that in order to begin business, health insurers must demonstrate that they have a surplus of \$1,000,000 or \$2,000,000 to ensure that they have enough money to pay the healthcare costs of their members for the first year).

96. Mackin & Veilleux, *supra* note 41, at 3.

97. *Id.* (Referring to sufficient membership base as economies of scale).

98. Howard, *supra* note 45, at 2-3.

region have been able to create successful PSHPs.<sup>99</sup>

History has proven that starting a PSHP is not easy. However, the trend of PSHP creation has been reinvigorated within the past decade. The number of PSHPs is steadily growing—one study stated that from 2015 to 2016 the number of PSHPs operated around the U.S increased from 256 to 268.<sup>100</sup> Today, around 52 percent of all insurance products are through PSHPs.<sup>101</sup> Although there might be many reasons why PSHPs have found new life in the twenty-first century, this PSHP creation trend is due in no small part to the major federal legal changes that have affected healthcare in the past decade.

## II. NOT GOING DOWN WITHOUT A FIGHT: HOW FEDERAL LAWS HAVE INCENTIVIZED PSHP CREATION

As the healthcare legal landscape in the United States continues to change, PSHPs have found a new environment for widespread success. Two major legislative initiatives are the cause of this resurgence: The Patient Protection and Affordable Care Act's ("ACA") individual exchange initiative, and the Department of Health and Human Services' ("HHS") push for value-based reimbursement.<sup>102</sup> These two major shifts in healthcare law have resurrected this old trend of PSHP creation in a new way.

### *A. Insurance Affordability for All: PSHPs and the ACA Exchanges*

Passed in 2010, the ACA's drafters hoped their ambitious piece of legislation would alter and improve many legal aspects of the U.S. healthcare system.<sup>103</sup> An unintended consequence of the ACA was that it created "a landscape that encouraged" the creation of PSHPs.<sup>104</sup> One of the ACA's key goals—to increase access to and affordability of insurance for those who were not part of a group insurance plan offered by employers—would be a catalyst for the current PSHP creation trend among providers.<sup>105</sup> The ACA attempted to reach this goal by mandating the creation of public insurance exchanges ("exchanges").<sup>106</sup> These

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99. *Why It's So Hard for Provider-Sponsored Plans to Turn a Profit*, ADVISORY BOARD (June 15, 2017), <https://www.advisory.com/daily-briefing/2017/06/15/provider-plans-struggle> [perma.cc/Q7TD-DMPT].

100. Kim Harvey Looney & Linda Rippey-Moor, *What is a Rural Health Care Provider to Do in the New Health Care World*, 2017 AHLA SEMINAR PAPERS 36, 4-5 (2017).

101. Kapchinskiy, *supra* note 10, at 641.

102. Mitch Morris, *Provider-Sponsored Plans: The Innovation Health Care Needs*, DELOITTE (Mar. 31, 2016), <https://blogs.deloitte.com/centerforhealthsolutions/provider-sponsored-plans-the-innovation-health-care-needs/> [perma.cc/HME4-Y8XX]; *see also* John Chesley & Tom Bulleit, *Blurring the Line between Health Care Provider and Payor*, LAW 360 (Sep. 20, 2017).

103. *The Affordable Care Act*, HEALTHCARE.GOV (last visited Nov. 11, 2018), <https://www.healthcare.gov/glossary/affordable-care-act/> [perma.cc/F9QZ-82LU].

104. Dine, *supra* note 5, at 103.

105. HealthCare.gov, *supra* note 103.

106. 42 U.S.C. §§ 18031(b)(1), 18041(c)(1) (2018).

exchanges allowed individuals and small business employees looking to purchase individual insurance plans to compare and purchase a variety of insurance plans in one online location.<sup>107</sup> While the ACA's legal changes did not start the renewed trend of PSHP creation, its invention of insurance exchanges encouraged the movement.<sup>108</sup>

The exchanges have allowed PSHPs to overcome the greatest obstacle they previously had to finding success: competing with larger more established insurers for substantial health plan membership.<sup>109</sup> The exchanges gave PSHPs a marketing platform on which PSHPs and other small insurers could compete with the larger and more established insurers. Prior to the implementation of these federal exchanges, it was near impossible for these smaller health insurers to gain a foothold in the health insurance market.<sup>110</sup> The exchanges created by the ACA have been the fastest growing area for PSHP membership<sup>111</sup> and are giving them the boost necessary to contend with the large insurance companies.<sup>112</sup> PSHPs discovered that the 11.8 million individuals purchasing insurance through these exchanges<sup>113</sup> are less concerned about the PSHPs narrow network of providers, and more interested in the lower premiums these PSHPs offer.<sup>114</sup> "A narrow network plan offered by a trusted area provider at the right price point might be able to beat out the large commercial insurers."<sup>115</sup> Since the year the ACA was passed, thirty-seven new PSHPs have been established, many seizing the opportunity to sell insurance on the exchanges.<sup>116</sup> Brian J. Miller, M.D., a former Special Advisor at the Federal Trade Commission and a Fellow at the Centers for Medicare & Medicaid Innovation, and George Wolfe, an Antitrust Associate at Akin Grump Strauss Hauer & Feld LLP, wrote that the ACA has "served as an impetus for enhanced vertical integration in the healthcare industry."<sup>117</sup> Stated differently, the ACA's exchanges are in large part why providers are creating PSHPs.

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107. *Id.*

108. *See generally* Miller, *supra* note 66, at 5.

109. Howard, *supra* note 45, at 2-3 (discussing how PSHPs in the 1990s could not compete for membership with the larger established insurance companies).

110. BAUMGARTEN, *supra* note 38, at 5.

111. PRWEB, *Preliminary Results of AIS's Health Plan Survey Show Continued Growth Among Provider-Sponsored Plans* (Apr. 12, 2016), <http://www.prweb.com/releases/2016/04/prweb13332414.htm> [perma.cc/NM9C-G6QM].

112. Julie A Simer & J. Scott Schoeffel, *The Wide World of Narrow Networks: How Health Care Providers Can Adapt and Succeed*, 9 No. 1 J. HEALTH & LIFE SCI. L. 9 (2015).

113. Shelby Livingston, *Final 2018 ACA Exchange Enrollment Comes up Slightly Short of 2017*, MODERN HEALTHCARE (Apr. 3, 2018), <https://www.modernhealthcare.com/article/20180403/NEWS/180409972> [perma.cc/NSC3-HXDP].

114. Mackin & Veilleux, *supra* note 41, at 7.

115. Kaufman, *supra* note 68, at 4.

116. BAUMGARTEN, *supra* note 38, at 1, 7.

117. Miller, *supra* note 66, at 5.

*B. Quality Over Quantity: PSHPs and the Value-Based Reimbursement Model*

Other than creating the exchanges, the ACA began a trend in healthcare payment that would further incentivize the creation of PSHPs. The ACA was one of the first laws that looked to incentivize payors to reimburse providers for their services on a value basis<sup>118</sup> instead of the traditional fee-for-service basis.<sup>119</sup> Insurance plans that reimburse based on value look to pay providers for their services to the insurer's members "based on the quality, rather than the quantity of care they give patients."<sup>120</sup> This political push started by the ACA has been continued by HHS's Center for Medicare and Medicaid Services ("CMS") and legislation like the Medicare Access and CHIP Reauthorization Act ("MACRA") which established additional incentives to move payment methods that reward quality and value over volume.<sup>121</sup> In 2015, the HHS Secretary, Sylvia M. Burwell, announced the federal government's goal of tying eighty-five percent of all traditional Medicare payments to value-based reimbursement models by 2016 and ninety percent by 2019.<sup>122</sup> Private payors have followed HHS's lead by tying their reimbursements to certain quality metrics, such as reductions in hospital-acquired conditions or hospital readmission rates.<sup>123</sup> Providers have responded to this change by looking for ways to improve their care management to ensure quality outcomes. From a provider's perspective, one such way to improve its value of care is by creating a PSHP where it can better control its cost and quality of care.<sup>124</sup>

This shift to value-based reimbursement has been the primary reason many hospitals have begun operating PSHPs.<sup>125</sup> This push to value-based reimbursement incentivizes the creation of PSHPs in two ways. First, healthcare providers see value-based reimbursement models as a way for them to take on

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118. 42 U.S.C. § 300gg-13(c) (2019).

119. Fee-for-service reimbursement is the process of reimbursing a provider for each service performed. *Fee For Service*, HEALTHCARE.GOV (last visited Mar. 7, 2020), <https://www.healthcare.gov/glossary/fee-for-service/> [perma.cc/G3ST-XG85].

120. *What are the Value-Based Programs?*, CTR. FOR MEDICARE AND MEDICAID SERVS. (Jan. 6, 2020), <https://www.cms.gov/medicare/quality-initiatives-patient-assessment-instruments/value-based-programs/value-based-programs.html> [perma.cc/F4M4-HHJT].

121. 42 U.S.C. § 1395w-4(p) (2019); Sutton, *supra* note 78, at 358-59.

122. *Better, Smarter, Healthier: In Historic Announcement, HHS sets Clear Goals and Timeline for Shifting Medicare Reimbursements from Volume to Value*, DEP'T OF HEALTH AND HUM. SERVS. (Jan. 26, 2015), <http://wayback.archive-it.org/3926/20170127185400/https://www.hhs.gov/about/news/2015/01/26/better-smarter-healthier-in-historic-announcement-hhs-sets-clear-goals-and-timeline-for-shifting-medicare-reimbursements-from-volume-to-value.html> [perma.cc/75PN-VA4Q].

123. Sutton, *supra* note 78, at 364.

124. Gary Scott Davis & Michael J. Finnerty, Presentation at the American Health Lawyers Association Physicians and Hospitals Law Institute: Back to the Future: Blurring the Lines Between Payers and Providers 16 (Feb. 2016) (Presentation available on the AHLA Health Law Archive).

125. Rush, *supra* note 63, at 1.

more of the financial risk of their patients.<sup>126</sup> Under a value-based model, if a provider's patients do not get better or require additional care due to provider error, the provider can potentially lose out on reimbursement. Some providers believe that since they are being forced to take on additional financial risk by tying their reimbursements to quality metrics, they should attempt to take on all of the financial risks of their patients by offering them their own health plan through a PSHP.<sup>127</sup> In taking on the entirety of the risk, providers believe they can more accurately ensure and improve the quality and value of care they provide to their patients.<sup>128</sup> PSHPs are "[p]robably the ultimate [value-based arrangement] from the standpoint of shared risk[.]"<sup>129</sup>

Second, value-based reimbursement models require providers to ensure the quality of care given, and some providers believe they can better ensure quality through the additional data they could collect and have access to if they operated a PSHP. By operating a PSHP, providers gain access to additional claims data about their members' healthcare utilization.<sup>130</sup> PSHPs then share the metrics they collect on the member utilization with the provider so that the providers may use this data to improve on clinical measures to provide better and more efficient care to their patients.<sup>131</sup> This data sharing and utilization between PSHP and provider could directly translate into a higher quality of care and higher reimbursement through value-based reimbursement methods for the provider.<sup>132</sup> Thus, providers who operate PSHPs may likely receive higher value-based reimbursements since they are able to accurately promote quality care initiatives in areas where they see their patients need the most support and attention, as displayed through the data received from operating their PSHP.<sup>133</sup> Altogether, providers seem to be looking at PSHPs as a way to take full advantage of the ACA Exchanges and the federal government's push toward value-based reimbursement.

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126. Jacqueline LaPointe, *What is Value-Based Care, What It Means for Providers?*, REVCYCLEINTELLIGENCE (June 7, 2016) <https://revcycleintelligence.com/features/what-is-value-based-care-what-it-means-for-providers> [perma.cc/74TT-CPY5].

127. *Ratings Direct: The Growing and Evolving Role of Provider-Sponsored Health Plans in U.S. Healthcare*, Standard & Poor's Rating Services (June 8, 2015), [https://www.spratings.com/documents/20184/908554/US\\_PF\\_Eve%20%20nt\\_hc1082/d6246d0c-c3e0-4e17-b166-a8afdf4b91fe](https://www.spratings.com/documents/20184/908554/US_PF_Eve%20%20nt_hc1082/d6246d0c-c3e0-4e17-b166-a8afdf4b91fe) [https://perma.cc/6V53-8XJF].

128. Gunjan Khanna et al., *Provider-Led Health Plans: The Next Frontier—Or the 1990s All Over Again?*, MCKINSEY & COMPANY (Jan. 2015), <https://healthcare.mckinsey.com/provider-led-health-plans-next-frontier%E2%80%94or-1990s-all-over-again> [perma.cc/FPX4-WLPU].

129. Crowe & Hathaway *supra* note 39, at 24.

130. Mackin & Veilleux, *supra* note 41, at 13.

131. *Id.*; Finnerty & Senty, *supra* note 59, at 7.

132. Mackin & Veilleux, *supra* note 41, at 7, 13.

133. BAUMGARTEN, *supra* note 38, at 8.



### III. WATCH YOUR STEP: FEDERAL LEGAL PIT-FALLS THAT MAY DETER PSHP OPERATION

Although these changes in the healthcare legal landscape, along with the variety of possible benefits that a provider could gain by operating a PSHP, have many providers eager and ready to test out their ability to offer health insurance,<sup>134</sup> providers should be aware of the other federal laws which could make starting a PSHP a little risky. This section assesses three major areas of federal healthcare law—antitrust, fraud and abuse, and HIPAA—that could negatively affect providers operating PSHPs.

#### *A. Playing the Game of Monopoly: PSHPs and Their Antitrust Risk*

Providers should be aware that operating a PSHP can bring with it a risk of antitrust violation. Although antitrust in healthcare is a highly litigated field, most cases typically involve cases of horizontal integration which is seen when large providers offering the same or similar services in the same market merge together.<sup>135</sup> Due to the lack of case law, provider vertical integration is new and somewhat uncharted antitrust territory.<sup>136</sup> However, there have already been three attempted antitrust lawsuits against providers and their vertically integrated PSHPs within the last four years.<sup>137</sup> These cases demonstrate a risk of violation of which providers should be acutely aware.

The area of antitrust law that creates potential antitrust risk for PSHPs is Section 2 of the Sherman Antitrust Act (the "Sherman Act").<sup>138</sup> The Sherman Act is the cornerstone of American antitrust policy, aimed at preventing illegal activity that would harm the competitive process upon which the U.S. economic system is based.<sup>139</sup> The Act looks to protect consumers by outlawing corporate practices that are harmful to the competitive process and therefore harmful to the end consumer.<sup>140</sup> "[T]he policy unequivocally laid down by the Act is competition[,]"<sup>141</sup> the idea being that competition incentivizes activities that benefit the consumer.<sup>142</sup>

Specifically, Section 2 of the Sherman Act prohibits any conduct which is harmful to competition and that may result in the illegal acquisition or

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134. See Rickert, *supra* note 4.

135. Mackin & Veilleux, *supra* note 41, at 11.

136. *Id.*

137. N.M. Oncology & Hematology Consultants v. Presbyterian Healthcare Servs., 54 F. Supp. 3d 1189 (D.N.M. 2014); NorthBay Healthcare Grp. v. Kaiser Found. Health Plan Inc., 305 F. Supp. 3d 1065 (N.D. Cal. 2018); Omni Healthcare Inc. v. Health First, Inc., No. 6:13-cv-1509-Orl-37DAB, 2016 WL 4272164 (M.D. Fla. Aug. 13, 2016).

138. 15 U.S.C. § 2 (2018).

139. 1 EARL W. KINTNER ET AL., FEDERAL ANTITRUST LAW § 4.1 (2017).

140. *Id.*

141. N. Pac. Ry. Co. v. United States, 356 U.S. 1, 4 (1958).

142. U.S. DEP'T. OF JUST., SINGLE FIRM CONDUCT REPORT: PROMOTING CONSUMER WELFARE THROUGH CLEARER STANDARDS FOR SECTION 2 OF THE SHERMAN ACT (2017).

maintenance of monopoly power.<sup>143</sup> Section 2 states that “[e]very person who shall monopolize, or attempt to monopolize, or combine or conspire with any other person or persons, to monopolize any part of the trade or commerce among the several States, or with foreign nations, shall be deemed guilty of a felony.”<sup>144</sup> It should be noted that Section 2 of the Sherman Act does not outlaw monopolies so long as the monopolies are gained through a proper means of superior business and product.<sup>145</sup> Rather, Section 2 of the Sherman Act looks to protect the process of competition, which, if successful, provides a better product at lower prices to the end consumer.<sup>146</sup> Stated differently, Section 2 was created “not to protect businesses from working of the market; it is to protect the public from the failure of the market.”<sup>147</sup>

If an individual accuses an entity of violating Section 2 of the Sherman Act, that individual has the burden of proving three things: (1) the entity has a monopoly power in a specific market or is likely to achieve it;<sup>148</sup> (2) the entity accused of violating section 2 of the Sherman Act has maintained its monopoly, or attempted to create a monopoly in an anticompetitive manner;<sup>149</sup> and (3) the anticompetitive effects of the entity’s conduct outweigh its procompetitive effects.<sup>150</sup> Proving an accusation of monopolization or attempted monopolization is incredibly fact intensive, but if the accuser can prove that the entity has maintained or created its monopoly in a given market through court defined anticompetitive conduct that outweighs its procompetitive effects, then the accused entity’s conduct could be found in violation of Section 2 of the Sherman Act.<sup>151</sup>

If a provider operating a PSHP is accused of violating Section 2 of the Sherman Act, it will have to be able to adequately demonstrate to the court why it does not violate the three-pronged Sherman Act Section 2 analysis. First, the provider will have to prove that they do not have a monopoly in the market, nor are they attempting to create a monopoly in the market.<sup>152</sup> This prong is very fact sensitive and will differ from case to case depending on the makeup of the provider and payor markets in which the provider and PSHP operate. Most providers who operate PSHPs will fail this prong of the analysis, because most providers who have the capabilities to operate PSHPs are usually the largest providers, and therefore already have monopoly power in the provider market in

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143. *Id.*

144. 15 U.S.C. § 2 (2018).

145. U.S. DEP’T OF JUST., *supra* note 140, at 8.

146. *Id.*

147. *Spectrum Sport, Inc. v. McQuillan*, 506 U.S. 447, 458 (1993).

148. U.S. DEP’T. OF JUST., *supra* note 140, at 8-9. If there is an attempted monopolization claim, the individual accusing the business must prove that there was a specific intent by the business to monopolize the market. *See Spectrum Sports*, 506 U.S. at 458.

149. U.S. DEP’T. OF JUST., *supra* note 140, at 8-9.

150. *Mackin*, *supra* note 38, at 11.

151. U.S. DEPT OF JUST., *supra* note 140, at 8-9.

152. *Id.*

the area in which they operate.<sup>153</sup> To discover if they have a monopoly in the market or are obtaining a monopoly in a market, the provider should continually assess the provider and health insurance markets in which it operates to see how much of the markets it insures and provide healthcare services. However, even if a provider does find that it has a monopoly or has acquired a monopoly in a specific market due to its PSHP, the provider is not automatically in violation of Section 2 of the Sherman Act.<sup>154</sup>

Second, if a provider or its PSHP is found to have a monopoly in either the insurance or provider market in their area, the provider must assess whether it has obtained or maintained that monopoly through some judicially recognized anticompetitive conduct. So far, there have been two judicially recognized ways in which providers and their PSHPs have been accused of participating in anticompetitive conduct. The first way is predatory pricing. Predatory pricing occurs when a firm or business sacrifices immediate profits through unreasonably low prices in order to push its competitors out of the market, knowing that it will recoup the losses later once the competitor has been forced to leave.<sup>155</sup> In, *N.M. Oncology & Hematology Consultants v. Presbyterian Healthcare Servs Inc.*, the Federal District Court of New Mexico found an allegation that the largest provider and insurer, the provider's PSHP, in Albuquerque, New Mexico, had participated in a predatory pricing scheme plausible enough to withstand a motion to dismiss.<sup>156</sup> In this case, the plaintiff—an oncology and hematology provider in the Albuquerque market—alleged that the defendant—the largest provider and insurer in Albuquerque—maintained its monopoly in the provider and insurance markets in Albuquerque by participating in a predatory pricing scheme.<sup>157</sup> The plaintiffs alleged that the defendants attempted to run the plaintiffs out of the oncology and hematology market by allowing the defendant's PSHP to "financially strangl[e]" the plaintiff by lowering its reimbursements to below competitive levels.<sup>158</sup> The defendant allegedly used its PSHP in this way so that the defendant could create a monopoly in the oncology and hematology market.<sup>159</sup> The district court judge found these allegations plausible enough to withstand a motion to dismiss, and the case is currently in the discovery phase, awaiting its court date.<sup>160</sup>

Under somewhat similar facts, a District Court in California came to the opposite conclusion.<sup>161</sup> In that case, Kaiser Permanente—the largest fully

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153. ADVISORY BOARD, *supra* note 97.

154. U.S. DEP'T OF JUST., *supra* note 140, at 8.

155. 3A PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW 22 (3d ed. 2006).

156. *N.M. Oncology & Hematology Consultants v. Presbyterian healthcare Servs.*, 54 F.Supp.3d 1189, 1197, 1216 (D.N.M. 2014).

157. *Id.* at 1214-16.

158. *Id.* at 1215.

159. *Id.* at 1214-16.

160. *Id.* at 1216 (D.N.M. 2014).

161. *NorthBay Healthcare Grp. v. Kaiser Found. Health Plan*, 305 F. Supp. 3d 1065 (N.D. Cal. 2018).

integrated health system in the U.S. and the largest healthcare provider and insurer in California—was sued by the plaintiff for an alleged predatory pricing scheme in violation of Section 2 of the Sherman Act.<sup>162</sup> The plaintiff, a provider with a hospital in Solano County California, alleged that Kaiser Permanente was reimbursing the plaintiff at rates less than half of what they deserved in order to run them out of the provider market.<sup>163</sup> Even though the plaintiff had supposedly been under-reimbursed some \$26.8 million by Kaiser Permanente's PSHP,<sup>164</sup> the court swiftly dismissed the complaint, stating that there was no anticompetitive conduct and that “[the plaintiff’s] allegations, at their core, [were] that the defendants should give it more money so that it can invest more money in its chosen projects. This does not plead an injury to competition as a whole.”<sup>165</sup>

Recently, a provider, through the use of its PSHP, has also been accused of participating in the judicially recognized anticompetitive practice of exclusive dealing. Exclusive dealing occurs when a firm does not allow itself, or another business with which it has a close relationship, to sell or accept any competitor’s version of the same product which the firm or business sells.<sup>166</sup> This conduct becomes anticompetitive when the firm or business acts with the intent of running another firm or business out of the market. In the case of PSHPs, an exclusive dealing situation would most likely occur if the provider operating the PSHP refused to allow its health plans to be used at a competing provider’s facilities.

In the case of *Omni Healthcare Inc. v. Health First, Inc.*, a group of small providers (the “Plaintiffs”) sued the Health First Health System (“Health First”)—a large vertically integrated healthcare system in Southern Brevard County Florida—alleging that Health First implemented a scheme of anticompetitive conduct in violation of Section 2.<sup>167</sup> Specifically, in counts III, IV, and VI of the Plaintiffs’ complaint, the Plaintiffs alleged that Health First was exclusively dealing by not allowing the Medicare Advantage plan offered through Health First’s PSHP to be accepted at any other provider’s facilities.<sup>168</sup> Also, Health First facilities only accepted Medicare advantage plans from Health First’s PSHP.<sup>169</sup> This meant that individuals who planned on using Health First’s extensive facilities and wanted to use Medicare Advantage insurance had to purchase Health First’s Medicare Advantage plan and, consequently, had to stay within Health First’s health system. The Plaintiffs alleged that this practice was tantamount to anticompetitive exclusive dealing as it allowed Health First to maintain its preexisting monopoly in various provider markets by requiring individuals with its insurance to only use its services, and was an attempt by

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162. *Id.* at 1067-68.

163. *Id.*

164. *Id.*

165. *Id.* at 1074.

166. 3A AREEDA, *supra* note 11, at 49.

167. *Omni Healthcare Inc. v. Health First, Inc.*, No. 6:13-cv-1509, 2016 WL 4272164, at \*2 (M.D. Fla. Aug. 13, 2016).

168. *Id.* at \*15, \*17, \*19.

169. *Id.*

Health First to create a monopoly in the Medicare Advantage insurance market in Southern Brevard County Florida by incentivizing individuals looking to use Medicare Advantage health plans to purchase their Medicare Advantage plan from Health First in order to have access to their healthcare services.<sup>170</sup> The court denied Health First's motion for summary judgement, noting that these claims of exclusive dealing and refusal to deal raised triable issues of fact which could be left for the jury to decide.<sup>171</sup> The case settled on the second day of trial, preventing the court from addressing the anticompetitive effects of Health First's operation.<sup>172</sup>

These three cases demonstrate that although PSHPs are increasing in popularity, PSHPs may increase a provider's antitrust risk by making it susceptible to new forms of antitrust litigation. PSHPs can easily lead a provider to act along the lines of the judicially recognized anticompetitive practices of predatory pricing and exclusive dealing. Providers who operate or are looking to operate PSHPs should be knowledgeable about the antitrust laws and aware of any past or future antitrust litigation that involves PSHPs. However, if the provider who operates a PSHP is aware of how its vertically integrated system is affecting the market around it, and if the PSHP is operated correctly, a provider should be able to mitigate its PSHP antitrust risk.

#### *B. Don't Bite the Hand That Feeds You: PSHPs' Fraud and Abuse Risk*

Operating a PSHP might also increase a provider's risk of violating one of the healthcare fraud and abuse laws. Healthcare providers should already be familiar with these healthcare fraud and abuse laws, as these laws are the way in which the largest payor for healthcare in the United States, CMS,<sup>173</sup> ensures that its reimbursements to providers are being used correctly.<sup>174</sup> The healthcare fraud and abuse laws look to penalize healthcare entities that: (1) knowingly submit false claims to a federal healthcare program in order to receive payment, (2) knowingly pay or receive remuneration to induce referrals for services reimbursable by a federal healthcare program, or (3) make prohibited referrals for certain designated healthcare services ("DHS") billable to a federal healthcare program.<sup>175</sup>

Although PSHPs are private insurers, they can still be affected by these laws in two ways. First, most PSHPs get their start in the Medicare Advantage

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170. *Id.*

171. *Id.* at \*15.

172. Miller, *supra* note 63, at 3.

173. *CMS Roadmaps Overview*, CTR. FOR MEDICARE AND MEDICAID SERVS. (last visited Mar. 4, 2020), [https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/RoadmapOverview\\_OEA\\_1-16.pdf](https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityInitiativesGenInfo/Downloads/RoadmapOverview_OEA_1-16.pdf) [perma.cc/US57-GCCC].

174. *See Medicare Fraud & Abuse: Prevention, Detection, and Reporting*, CTR. FOR MEDICARE AND MEDICAID SERVS. (Sept. 2017), [https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/fraud\\_and\\_abuse.pdf](https://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/fraud_and_abuse.pdf) [perma.cc/D64S-3C6B].

175. *Id.* at 3.

insurance market,<sup>176</sup> which is a federally funded program where private payors provide Medicare benefits for their members.<sup>177</sup> Since Medicare Advantage plans are still primarily funded by the federal government and regulated by CMS, they are still subject to the fraud and abuse laws. Second, although PSHPs are private insurers, if a PSHP reimburses individuals differently based on the individuals' referrals of Medicare or Medicaid patients, then the PSHP, or its parent healthcare provider, could be found in violation of the fraud and abuse laws. Two of the major laws in healthcare fraud and abuse are the Anti-Kickback Statute ("AKS") and the physician self-referral law ("Stark"), and if a PSHP is operated incorrectly it may be at risk of violating one or both of these laws.

*1. The Anti-Kickback Statute.*—AKS makes it illegal for a provider to offer a physician a kickback in return for the physician's referral of patients to that provider for services reimbursable in full or in part by Medicare or Medicaid.<sup>178</sup> A kickback is a sum of money or items illegally paid to someone for creating a lucrative contract.<sup>179</sup> In the context of AKS, a kickback is typically made by a provider in the form of increased compensation, or some other lucrative benefit, to a physician or physician group for the referral of Medicare or Medicaid patients to the provider, so that the provider may provide federally reimbursable services to those referred patients. The statute states that whoever knowingly and willfully solicits or receives remuneration or offers or pays any remuneration directly or indirectly in return for referring an individual for the furnishing of any item or service for which payment may be made in whole or in part under Medicare and Medicaid will be guilty of a felony conviction of up to five years and a fine of up to \$25,000.<sup>180</sup> There are a variety of statutory exceptions and regulatory "safe harbors" that protect certain arrangements from AKS enforcement.<sup>181</sup>

An AKS violation can be a death sentence for any provider, because, beyond the criminal liability and fines, if a provider is found in violation of AKS, the government can also find the provider in violation of the False Claims Act ("FCA").<sup>182</sup> If a healthcare provider violates the FCA, then the federal government may exclude the provider from participating in and receiving reimbursement from all federal health care programs (e.g. Medicare, Medicaid, CHIP, Tricare, VHA, and HIS).<sup>183</sup> Therefore, it is very important that providers ensure that all their arrangements either fall within one of the exceptions or safe harbors of AKS, or that the provider is not paying physicians in any way that can be seen as a kickback for patient referrals.

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176. Mackin, *supra* note 38, at 6.

177. *What's a Medicare Advantage Plan?*, DEP'T OF HEALTH AND HUM. SERVS. (Apr. 2015), <https://www.medicare.gov/pubs/pdf/11474.pdf> [perma.cc/9XPQ-5T3R].

178. 42 U.S.C. § 1320a-7b(b) (2018).

179. *Kickback*, BLACK'S LAW DICTIONARY (10th ed. 2014).

180. 42 U.S.C. § 1320a-7b(b)(1)-(2) (2018).

181. 42 U.S.C. § 1320a-7b(b)(3) (2018); 42 C.F.R. § 1001.952 (2018).

182. 42 U.S.C. § 1320a-7b(g) (2019); 31 U.S.C. § 3729 (2019).

183. 42 U.S.C. § 1320a-7(b)(7) (2019).

There has yet to be an AKS enforcement action brought against a provider because of the provider's relationship with a PSHP; however, providers operating a PSHP should be cautious in how they operate their PSHP and be acutely aware of how their PSHP might create a risk of AKS violation. Providers who operate PSHPs could violate AKS if the provider has an indirect compensation arrangement between a physician and the PSHP that varies based on the number of Medicare or Medicaid referrals the physician gives to the PSHP's provider.<sup>184</sup> This would occur if the PSHP and the physician have formed a relationship where the physician receives an increased reimbursement, or some other form of compensation, from the PSHP which varies based on the volume or value of Medicare or Medicaid referrals the physician makes to the PSHP's parent provider. The increased reimbursement or indirect compensation could be interpreted by the federal government as being an indirect remuneration of cash in return for a referral of patient and, therefore, in violation of AKS.<sup>185</sup> Because the AKS is an intent-based statute, if the government were to bring a case like this against a PSHP, the government would have to prove that one of the parties involved knowingly intended the compensation arrangement to be related in some way to Medicare or Medicaid patient referrals.<sup>186</sup> However, if the provider in any way intended the compensation the physician received from its PSHP to be in some way related to the physician's Medicare or Medicaid referrals, a provider could find themselves having an AKS enforcement action brought against them because of its relationship with its PSHP and the way the PSHP reimburses those referring physicians.

2. *The Stark Law*.—Another major law in healthcare fraud and abuse that has the potential to affect providers operating or looking to create PSHPs is the physician self-referral law. The physician self-referral law, commonly referred to as “Stark,” was enacted in 1989 to prohibit physicians from referring patients under Medicare or Medicaid to clinical laboratories in which they had a financial interest.<sup>187</sup> This was to prevent physicians from ordering unnecessary tests and services for Medicare patients simply because they had a financial interest in the institution.<sup>188</sup> After receiving multiple amendments, Stark currently prohibits physicians from making Medicare referrals for any of twelve enumerated designated health services (“DHS”) to an entity with which the physician has a financial relationship.<sup>189</sup> The statute defines a financial relationship in a healthcare

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184. Mackin, *supra* note 41, at 10.

185. 42 U.S.C. § 1320a-7b(b)(1)-(2) (2019).

186. 42 U.S.C. § 1320a-7b(1)-(2) (2019). The intent requirement is satisfied even if only one small purpose for the overall agreement is to induce referrals. *See* U.S. v. Greber, 760 F.2d 68 (3rd Cir. 1985) (creating the one purpose standard).

187. *Physician Self-Referral*, CTR. FOR MEDICARE AND MEDICAID SERVS., (Dec. 5, 2015), <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/> [perma.cc/3TSH-J8DQ].

188. Sherri Gordon, *Stark Law: Everything You Need to Know*, VERYWELL HEALTH (Nov. 10, 2017), <https://www.verywellhealth.com/everything-you-need-to-know-about-the-stark-law-4154006> [perma.cc/E9PC-5PUX].

189. 42 U.S.C. § 1395nn (2019).

entity as a direct or indirect ownership interest, investment interest, or compensation arrangement.<sup>190</sup> Just as in AKS, Stark has a variety of exceptions for financial relationships and compensation plans between physicians and providers which do not constitute a violation of Stark.<sup>191</sup> If a healthcare provider is found in violation of Stark, the provider will not be reimbursed for the services rendered in violation of Stark, and the provider will be required to pay back any reimbursement received in violation of Stark.<sup>192</sup> If the provider does not repay the government and knowingly files a claim for reimbursement that would violate Stark, the provider will be subject to a civil money penalty of \$15,000 for each service with which an illegal claim for reimbursement was made.<sup>193</sup> Lastly, if the provider knowingly entered into a compensation or ownership scheme with a physician that they knew would violate the Stark law, it will be fined \$100,000 for each of such arrangements and could be excluded from participating in all federal healthcare programs.<sup>194</sup>

The government has yet to seek enforcement against a PSHP for an arrangement with a physician that would violate Stark, but it is easy to see how an arrangement between a PSHP and a physician could increase a provider's risk of a Stark violation. PSHPs do not themselves receive patient referrals from physicians, so they would not qualify as a DHS entity that would typically violate Stark.<sup>195</sup> However, because a PSHP is owned and operated by a provider that does qualify as a DHS entity, it is possible that the reimbursement arrangement between a PSHP and a physician could be seen as an indirect compensation method between the provider and the physician that could violate Stark. Under Stark, an indirect compensation arrangement exists if: (1) there is an unbroken financial chain between the physician and the provider; (2) the referring physician receives compensation from an entity in that chain that considers the volume or value of referrals generated by the physician for the provider; and (3) the provider has actual knowledge of, or acts in reckless disregard or deliberate ignorance of, the fact that the physician receives compensation that varies based on his referrals.<sup>196</sup>

In the case of a PSHP, this would mean that the provider knows that its PSHP reimburses physicians in a way that considers the amount or value of referrals it would make to the PSHP's provider. Therefore, even though the physician is not directly getting paid by the provider for his referrals, it is possible that a physician could be compensated indirectly by the provider through its PSHP for referrals the physician makes to the provider, creating an ownership relationship between the physician and the provider. This would ultimately violate Stark if the physician is being paid in part by the PSHP based on how many referrals it is

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190. 42 U.S.C. § 1395nn(a)(2) (2019).

191. 42 U.S.C. § 13985nn(b)-(c) (2019).

192. 42 U.S.C. § 1395nn(g)(1)-(3) (2019).

193. 42 U.S.C. § 1395nn(g)(3) (2019).

194. 42 U.S.C. § 1395nn(g)(4) (2019); 42 U.S.C. § 1320a-7 (2019).

195. 42 CFR § 411.351 (2019) (listing the designated health services).

196. 42 C.F.R. § 411.354(c)(2)(i)-(iii) (2020).



making to the provider, with which it has an indirect compensation relationship, for DHS services.

*C. Data Block: HIPAA's Impact on PSHPs*

Another major federal law that could substantially impact providers who are operating or looking to operate a PSHP is the Health Insurance Portability and Accountability Act (“HIPAA”).<sup>197</sup> HIPAA was passed by Congress in 1996 as an attempt to reform outdated healthcare policies in America.<sup>198</sup> HIPAA had two primary objectives: (1) to ensure that every individual would be able to maintain their health insurance while they are between jobs, and (2) to ensure that patient health records are kept private and secure.<sup>199</sup> Under the second objective, HIPAA required the Secretary of HHS to develop regulations that would protect the privacy and security of patient information.<sup>200</sup> To do this, HIPAA created the *Standards for Privacy of Individually Identifiable Health Information* (the “Privacy Rule”)<sup>201</sup> to establish standards for what was designated protected health information (“PHI”)<sup>202</sup> and the *Security Standards for the Protection of Electronic Protected Health Information* (the “Security Rule”) to set security standards for PHI that is kept or transferred electronically.<sup>203</sup>

These rules, created through HIPAA, apply to all “covered entities” that transmit and keep patient data.<sup>204</sup> Covered entities include health plans, health care clearinghouses, and health care providers.<sup>205</sup> Both PSHPs and their providers are covered entities that actively look to transfer electronic PHI, so both entities are required comply with HIPAA's Security Rule. Generally, the Security Rule requires all covered entities to (1) “ensure the confidentiality, integrity, and availability of electronic [PHI],” (2) to protect the PHI against any reasonably anticipated security threat, (3) to protect the PHI against any improper uses or disclosure, and (4) to ensure their employees follow these protection requirements.<sup>206</sup> These rules maintain that PHI are made available to all individuals who should have access, but that those same records are not

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197. Health Insurance Portability and Accountability Act, Pub. L.104-191, 110 Stat. 1936 (1996).

198. *HIPAA Background*, Off. of Corp. Compliance, U. CHI. MEDICAL CTR. (Oct. 23, 2006), <http://hipaa.bsd.uchicago.edu/background.html> [perma.cc/2H7F-NJCG].

199. *Id.*

200. *Summary of the HIPAA Security Rule*, DEP'T OF HEALTH AND HUM. SERVS. (July 26, 2013), <https://www.hhs.gov/hipaa/for-professionals/security/laws-regulations/index.html> [perma.cc/2HFT-A6EY]. [hereinafter *Summary of the HIPAA Security Rule*].

201. See 45 C.F.R. §§ 160 & 164 subparts A and E (2019).

202. PHI is any individually identifiable health information. 45 C.F.R. § 160.103 (2019).

203. See 45 C.F.R. §§ 160 & 164 subparts A and C (2019).

204. Health Insurance Portability and Accountability Act, Pub. L.104-191, 110 Stat. 1936 (1996).

205. 45 C.F.R. § 160.103 (2019).

206. 45 C.F.R. § 164.306(a) (2019).

improperly accessed by other individuals. The Security Rule sets out a variety of general administrative, physical, and technical safeguards which every covered entity's security system must meet to ensure the proper and adequate protection of PHI.<sup>207</sup> Recognizing that every covered entity is different, the Security Rule does not give specific security requirements, but instead is "designed to be flexible and scalable so a covered entity can implement policies, procedures, and technologies that are appropriate for the entity's particular size, organizational structure, and risks to consumers' [electronic] PHI."<sup>208</sup> All covered entities must regularly "review and modify" their security measures used to protect PHI to ensure that their PHI is continually kept safe.<sup>209</sup> If a covered entity involuntarily allows PHI to be accessed by an individual or entity who should not have access, then HHS may impose civil money penalties of \$100 per such improper access.<sup>210</sup> If it is discovered that the covered entity disclosed PHI intentionally, the covered entity can face a criminal fine of up to \$250,000 and ten years imprisonment if the wrongful conduct involves the intent to sell, transfer, or use PHI for commercial advantage, personal gain, or malicious harm.<sup>211</sup>

Although there have yet to be any HIPAA enforcement actions against a PSHP, there is still a risk that a provider and a PSHP could violate HIPAA through the transferring of patient data. If a provider and its PSHP openly shared all their data collected from their patients, then it is likely that they would find themselves being either civilly or criminally charged by HHS for violating HIPAA as information received by one entity might not be permissible to be accessed by the other. For instance, if a provider allows a PSHP to access PHI of a patient whom is not insured by the PSHP, the PSHP and the provider could both be criminally liable. In the same way, if a member of a PSHP sees a separate provider, then the PSHP cannot share the claims data they receive from that patient with the PSHP's provider. This is problematic, because PSHP's cost savings and efficiency benefits rely on effective management and analysis of patient data that comes both from the provider and the PSHP.<sup>212</sup> Luckily, as will be discussed below, there is a way a PSHP can be structured and operated that will minimize its risk of violating HIPAA and still maintain its ability to share data with its provider to improve the provider's overall care.

#### IV. NAVIGATING THE FEDERAL WATERS: HOW PSHPs CAN DECREASE THEIR RISK OF FEDERAL VIOLATIONS

PSHPs are becoming increasingly popular among providers in America and for good reason. Providers and the healthcare system have the potential to benefit

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207. See 45 C.F.R. §§ 164.308, 164.310, & 164.312 (2019).

208. *Summary of the HIPAA Security Rule*, *supra* note 201; see 45 C.F.R. § 164.306(b) (2019).

209. 45 C.F.R. § 164.306(e) (2019).

210. 42 U.S.C. § 1320d-5 (2019).

211. 42 U.S.C. § 1320d-6 (2019).

212. Mackin, *supra* note 41, at 13.

immensely from PSHP operation.<sup>213</sup> However, the additional federal legal risks PSHPs could possibly create could stop providers from investing in this vertically integrated business model. This section details how providers who are operating, or looking to operate, PSHPs can structure their agreements with other providers, their agreements with other physicians, and their data sharing procedures to make their PSHPs more resilient to the aforementioned federal legal risks.

*A. Help Me Help You: How PSHPs should Contract with Other Providers*

Because PSHPs could potentially increase a provider's risk of violating Section 2 of the Sherman Antitrust Act,<sup>214</sup> it is important for providers who are looking to operate PSHPs to understand how they can actively reduce such risk. In all three court cases where a provider who operated a PSHP was accused of violating the Sherman Act, the case came about because of the PSHP's agreements, or lack thereof, with other providers.<sup>215</sup> Therefore, if a PSHP correctly negotiates and creates reimbursement agreements with other providers, then the PSHP's parent provider will reduce their risk of violating Section 2 of the Sherman Act.

If a PSHP hopes to mitigate its risk of a Sherman Act Section 2 violation, it should do the following. First, even though PSHPs typically cover a narrow network of providers, the PSHP should make a bona fide attempt to extend its health plan's coverage to other healthcare providers in its parent provider's service market. It is not wrong for a PSHP to have a narrow network in order to lower premium costs for its members, but if a PSHP's network of providers were to only include its parent provider's healthcare facilities, then it would likely be at a higher risk of violating Section 2 of the Sherman Act due to an exclusive dealing arrangement. Similarly, providers operating a PSHP should never look to exclude a provider who is the only other provider who offers a specific service in its market. If it did, it would be at an increased risk of both a predatory pricing and exclusive dealing claim.<sup>216</sup> So long as a PSHP is at least willing to contract with providers who compete with the PSHP's provider, then its antitrust risk will be diminished.<sup>217</sup> If a PSHP decides not to contract with a competing provider, the PSHP should document why such a decision was made and be prepared to explain and defend its decision to exclude such provider in a court of law.

Second, PSHPs should actively keep track of the fair market reimbursement

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213. *See supra* section I.B.

214. *See supra* section III.A.

215. *See generally* N.M. Oncology & Hematology Consultants v. Presbyterian Healthcare Servs., 54 F. Supp. 3d 1189 (D.N.M. 2014); NorthBay Healthcare Grp. v. Kaiser Found. Health Plan, 305 F. Supp. 3d 1065 (N.D. Cal. 2018); Omni Healthcare Inc. v. Health First, Inc., No 6:13-cv-1509, 2016 WL 4272164 (M.D. Fla. Aug. 13, 2016).

216. *See* N.M. Oncology & Hematology Consultants v. Presbyterian Healthcare Servs., 54 F. Supp. 3d 1189 (D.N.M. 2014); *see also* Omni Healthcare Inc. v. Health First, Inc., No 6:13-cv-1509, 2016 WL 4272164 (M.D. Fla. Aug. 13, 2016).

217. Mackin, *supra* note 41, at 11.

values for different provider services in its area. The PSHP can then use that data to decide the reimbursement values it will offer to providers in the area. PSHPs should then be prepared to demonstrate to any provider it contracts with why those reimbursement rates are at a fair level in its specific market. If the provider keeps careful documentation about its reimbursement practices and why the reimbursement values are fair to the providers, then it is less likely that the PSHP will be accused of a predatory pricing scheme in violation of Sherman Act Section 2.

Third, PSHPs should consider putting language in their contracts with other providers that state that the terms and reimbursement rates are fair and in accordance with the market and their standard of providing care. That way, if another entity whom the PSHP did have a contract with ever brought a claim, such as in *NorthBay Healthcare Grp. v. Kaiser Found. Health Plan*,<sup>218</sup> the provider would have evidence that the contracting provider agreed that the reimbursement amounts were consistent with fair market value.

Lastly, PSHPs should keep meticulous documentation of their attempts to contract with other providers within their market, so that if the PSHP gets sued for violating the Sherman Act based on an accusation of exclusive dealing, it can show they had a bona fide attempt to allow their health plan to be accepted elsewhere.

Although these recommendations do not guarantee that a provider operating a PSHP will not be sued under Section 2 of the Sherman Act, if followed, these recommendations could potentially reduce a provider's risk of a Sherman Act Section 2 violation. If, however, a provider finds themselves at the wrong end of an antitrust lawsuit because of their PSHP, it should not panic. If the suit is brought under either an accusation of exclusive dealing or predatory pricing, the plaintiff bringing the claim against the PSHP has a large burden to carry and will likely be unable to succeed so long as the provider can demonstrate that its PSHP did not create a monopoly in the relevant markets in an anticompetitive manner.<sup>219</sup>

*B. What's Up Doc?: Structuring PSHP Physician Agreements to Comply with Healthcare Fraud and Abuse*

Healthcare fraud and abuse compliance is not new to healthcare providers, but operating a health insurance company is. Therefore, providers need to be acutely aware of how PSHP operation can increase their risk of violating the aforementioned fraud and abuse laws and understand how they can mitigate that risk. Although there have yet to be any fraud and abuse enforcement actions against a provider due to the operation of its PSHP, if a fraud and abuse claim

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218. See *NorthBay Healthcare Grp. v. Kaiser Found. Health Plan*, 305 F. Supp. 3d 1065 (N.D. Cal. 2018).

219. 3A AREEDA, *supra* note 13, at 169; *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 589 (1986) (stating that "predatory pricing schemes are rarely tried, and even more rarely successful").

were brought against a PSHP and its parent provider, it would likely be because the PSHP's reimbursement agreements would be seen as inducing physicians to refer patients to the PSHP's parent provider for Medicare or Medicaid eligible services.<sup>220</sup> Therefore, if a PSHP correctly negotiates and creates their agreements with physicians, the provider could mitigate its risk for healthcare fraud and abuse violations caused by the operation of its PSHP.

A provider and PSHP should do the following four things to mitigate its fraud and abuse risk when creating reimbursement contracts with physicians. First, in analyzing fraud and abuse risk, the PSHP should only concern itself with the physicians who are not directly employed by the provider. Physicians who are employed by the provider are statutorily exempted from violating both AKS and Stark so long as they have a bona fide employment agreement.<sup>221</sup>

Second, providers should be aware of all the physicians who are reimbursed by the PSHP for services they provide to the PSHP's members. Depending on the reimbursement arrangement, the reimbursements can be seen as indirect compensation from the provider to the physicians, which can be seen as a kickback under AKS and as an ownership interest under Stark.<sup>222</sup> The PSHP could either spend the time creating a comprehensive provider database listing out all of the providers the health system works with, or the PSHP could purchase a provider directory from a health IT system vendor to keep track of all of the different physicians and physician groups in its area whom the PSHP might reimburse.<sup>223</sup> Either way, it is important that the PSHP understands and tracks the different reimbursement arrangements it has with various physicians.

Third, once the provider is aware of all the physicians whom the provider indirectly compensates through their PSHP, the provider should avoid "per case, per admission and other volume based" compensation arrangements between the physician and the PSHP that considers the volume or value of referrals the physician makes to the provider.<sup>224</sup> These sorts of arrangements can easily be seen as the provider incentivizing the physician to refer more patients to the provider through reimbursement given by the PSHP to the physician in violation of AKS and Stark.<sup>225</sup> If the PSHP wishes to create an incentive program for the physicians, it should ensure that the incentives do not look to referrals, but instead look to incentivize strictly based on quality of the care given or clinical improvement done by the physician.<sup>226</sup> An example of this type of arrangement

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220. *See supra* Section III. B.

221. 42 U.S.C. § 1320a-7b(3)(B) (Current through P.L. 116-91); 42 C.F.R. 411.357(c) (2019).

222. *See* definition of indirect compensation *supra* at note 194 and accompanying text.

223. *See* Joseph Conn, *Health IT a Key Challenge for Provider-Owned Plans*, MODERN HEALTHCARE (June 27, 2015) (noting that land of Lincoln Health spent months building its database of providers only to buy a provider directory from a vendor), <https://www.modernhealthcare.com/article/20150627/MAGAZINE/306279980/health-it-a-key-challenge-for-provider-owned-plans> [<https://perma.cc/EJ4U-WSJB>].

224. Mackin, *supra* note 41, at 10.

225. *Id.*

226. *Id.* at 9.

could be if a physician or physician group is reimbursed at a higher level if its patients have lower hospital acquired conditions or hospital readmission rates than the average of the community in which it is in.<sup>227</sup> This would be a value-based reimbursement that in no way takes into consideration the volume or value of referrals the physician would make to the PSHP's parent provider.

Lastly, PSHPs should meticulously document the physician's responsibilities and why they are being reimbursed by the PSHP at a commercially reasonable fair market rate for their services.<sup>228</sup> If this is done, the provider could accurately demonstrate to the government how the physician is in no way being compensated for referrals. If it looks as if the physician is being compensated at an above-fair-market-value rate for the services the physician offers to the PSHP's members, the federal government might infer the above-fair-market level of compensation is a kickback for potential referrals made to the provider and, therefore, in violation of AKS.<sup>229</sup> To even further solidify the appearance of fair market value reimbursements and to even further minimize the potential fraud and abuse risk, every PSHP reimbursement contract should contain language that states that the reimbursement amounts are in no way a remuneration in consideration of referrals the physician makes to the PSHP's provider. If signed by the reimbursed physician, the contract would be evidence that the PSHP and physician both believed the physician was being reimbursed at fair market value.

If the PSHP is still worried that its agreement looks as if it might violate either Stark or AKS, it can attempt to fit it into one of their numerous exceptions.<sup>230</sup> Under AKS, the only exception that might be applicable to the relationship between a PSHP and a physician is the bona fide employment exception.<sup>231</sup> However, under Stark, there are two separate exceptions where a provider could find that its PSHP's relationship with physicians could be excepted from Stark enforcement. One of such Stark exceptions that could be applicable to a PSHP's relationship with physicians is the risk-sharing compensation exception.<sup>232</sup> The exceptions, as applied to a PSHP, states that if the PSHP operates as a Managed Care Organization<sup>233</sup> and if the PSHP compensates

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227. Sutton, *supra* note 78, at 364; *see also* Vera Gruessner, *How Quality Metrics Affect Value-Based Care Reimbursements*, HEALTHPAYER INTELLIGENCE (June 29, 2016), <https://healthpayerintelligence.com/news/how-quality-metrics-affect-value-based-care-reimbursement> [perma.cc/ZJT9-GVTP].

228. Ives, *supra* note 40.

229. *See* OFF. OF INSPECTOR GEN., RECOMMENDED PRELIMINARY QUESTIONS AND SUPPLEMENTARY INFORMATION FOR ADDRESSING REQUESTS FOR OIG ADVISORY OPINIONS IN ACCORDANCE WITH SECTION 1128D OF THE SOCIAL SECURITY ACT AND 42 CFR PART 10087, <https://oig.hhs.gov/fraud/docs/advisoryopinions/prequestions.htm> [perma.cc/CXG9-ARJZ].

230. 42 U.S.C. § 1320a-7b(3) (2019); 42 C.F.R. 411.357 (2019).

231. 42 C.F.R. § 1001.952(i) (2019).

232. 42 C.F.R. 411.357(n) (2019).

233. Managed Care Organizations ("MCO") are health plans which work to provide better quality healthcare at lower costs by getting providers to agree to specific standards and costs and having the health plan cover those providers. *Types of Managed Care Organizations*, GALLAGHER

physicians who refer to the PSHP's provider pursuant to a risk-sharing arrangement for the care the physician provides to the PSHP's members, then the indirect compensation arrangement will not violate Stark.<sup>234</sup> A risk sharing arrangement is when a provider offers payment—usually a bonus—that is contingent upon a physician meeting operation goals.<sup>235</sup> Therefore, a PSHP could create a risk-sharing arrangement with a physician that gave a “bonus” reimbursement if it provided measurably higher quality and more efficient care to the PSHP's members without violating Stark.<sup>236</sup>

PSHPs could also qualify their reimbursement arrangements with physicians to fit within Stark's physician incentive plan exception.<sup>237</sup> A physician incentive plan is “a compensation arrangement between an entity and a physician . . . that may directly or indirectly have the effect of reducing or limiting services furnished with respect to individuals enrolled with the entity.”<sup>238</sup> If the PSHP were to structure its agreements to be physician incentive plans, the Stark law would permit the compensation arrangement to take into account the volume or value any referrals going to the PSHPs' parent provider so long as: (1) No specific payment is made directly or indirectly . . . to a physician . . . as an inducement to reduce or limit medically necessary services furnished with respect to a specific [patient]; (2) Upon request, the PSHP agrees to provide the Secretary of Health and Human Services with access to information that permits the Secretary to determine whether the plan is in compliance with this exception; and (3) If the plan places a physician at substantial financial risk as defined at 42 C.F.R. § 422.208, the PSHP complies with the requirements concerning physician incentive plans set forth in 42 C.F.R. § 422.208 and 422.210.<sup>239</sup> If a provider structures its PSHP physician reimbursement agreements in line with either of these exceptions, it is likely that their risk of Stark enforcement will be mitigated.

Operating a PSHP could potentially increase a provider's fraud and abuse risk, but that should not deter a provider from joining the trend of creating its own health plan. Although a provider can never truly eliminate their fraud and abuse risk, if a provider operating a PSHP follows the advice of this section and creates compliant PSHP physician reimbursement agreements that do not take into account physician referrals, or the provider fits their PSHP arrangements with physicians into a Stark or AKS exception, a provider can mitigate their PSHP's fraud and abuse risk.

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HEALTHCARE (Aug. 16, 2018), <https://www.gallaghermalpractice.com/blog/post/types-of-managed-care-organizations> [perma.cc/PJ52-LQLF].

234. 42 C.F.R. § 411.357(n) (2019).

235. *Risk-Sharing Arrangement*, ACTUARIAL STANDARDS BD. (2019), <http://www.actuarialstandardsboard.org/glossary/risk-sharing-arrangement/> [perma.cc/9EM33].

236. See *supra* note 224 and accompanying text (discussing a quality-based payment method that does not consider the volume or value of referrals).

237. 42 C.F.R. § 411.351 (2019).

238. 42 C.F.R. § 411.351 (2019).

239. 42 C.F.R. § 411.357(d)(2) (2019).

*C. Teamwork Makes the Dream Work: HIPPA Compliant PSHP Data Sharing*

As technology continues to advance, providers and insurers must continually assess how their electronic transferring of PHI complies with HIPAA. This assessment is especially important regarding PHI shared between providers and their PSHPs, because many of the benefits of PSHPs rely on data shared between the provider and the PSHP. Luckily, a provider can share data with its PSHP without fear of HIPAA violation so long as it is done in accordance with the HIPAA regulation on using and disclosing PHI for treatment, payment, or healthcare operations.<sup>240</sup>

Under the HIPAA regulation on disclosing PHI for treatment, payment, or healthcare operations, a PSHP and a provider may disclose PHI without fear of violating HIPAA under three separate circumstances. First, the PSHP is able to share PHI information it receives from its members to the provider so long as it is for treatment activities of the provider.<sup>241</sup> This means that if the provider is going to be providing healthcare services to one of the PSHP's members, then the PSHP could disclose to the provider information the PSHP has regarding the patient that might help the provider with that treatment. Second, the provider can disclose PHI to the PSHP for the PSHP's payment activities.<sup>242</sup> This means that if the provider sees a member of the PSHP, the PSHP would be able to receive PHI from the provider regarding that member in order to make a reimbursement to the provider for the provider's services. Lastly, either the provider or the PSHP could transmit PHI to each other for "healthcare operations activities" so long as both entities have had a relationship with the individual with whom the PHI concerns, the PHI pertains to that relationship, and so long as the PHI is used for conducting quality assessment and improvement activities, population-based activities relating to improving health or reducing healthcare costs, or evaluating provider or health plan performance.<sup>243</sup> This HIPAA compliant PHI sharing exception will likely be the one that PSHPs and provider use the most, as most often the data shared between PSHP and provider can be said to be used to improve overall healthcare performance while attempting to decrease cost to its members.<sup>244</sup> Still, transferring of PHI between PSHP and provider should be done very cautiously and only if the provider and PSHP both determine that the data sharing fits squarely within one of these defined categories.

Although every healthcare IT system is different, providers can take multiple steps to reduce the risk that their data sharing relationship with their PSHP might violate HIPAA. First, the provider should house the PSHP and its staff in a physically separated building from where the provider sees and provides services to all patients. If the PSHP were to be operated in the exact same building as the provider, then it is more likely that, due to human error, PHI that was not

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240. 45 C.F.R. § 164.506 (2019).

241. 45 C.F.R. § 164.506 (c)(2) (2019).

242. 45 C.F.R. § 164.506(c)(3) (2019).

243. 45 C.F.R. § 164.506(c)(4)(i) (2019); 45 C.F.R. § 164.501 (2019).

244. *See supra* section I.B.



supposed to be transferred to the PSHP or to the provider might be inadvertently transferred to such an entity, therefore violating HIPAA. This gives a layer of separation between the PSHP and the provider to ensure that no PHI is improperly or unknowingly shared between the entities. Second, the provider and PSHP should set up a proper electronic records system for the transferring of PHI to ensure that no PHI is transferred when it does not need to be. In such a system, both the provider and the health plan might transmit their potential PHI to a single platform. The system then would only allow the PSHP and the provider to have access to any individual's PHI on that platform when there is a match between the provider's patient record and the PSHP's member record that also corresponds with one of the three permitted disclosing categories stated previously.<sup>245</sup> Setting up one of these electronic health record systems is complicated, but there are multiple established healthcare IT vendors who are able to help establish proper PSHP health IT systems that will comply with the laws of HIPAA and allow providers to utilize the data from their provider and PSHP to assess areas where they can decrease costs and improve quality.<sup>246</sup> This would ensure quick transferability of information between the PSHP and the provider when it was permissible and could be used to improve the quality of care the provider provides to its patients. Lastly, a provider should implement a zero-tolerance program whereby any employee of the provider or PSHP who improperly accesses PHI will be immediately terminated from the operation. A PSHP and its parent provider could even implement an employee monitoring software that would immediately notify the PSHP and provider if an employee viewed an individual's PHI which they should not have had access to.<sup>247</sup> If a system like this was put into place between a provider and a PSHP, it would safeguard PHI while still allowing PSHPs and providers to share data that could improve healthcare quality and efficiency.

Complying with HIPAA will become a continuing and evolving challenge for providers and PSHPs. If providers and PSHPs desire to continue to use their data to improve the care the provider offers to its patients and to lower the costs of the PSHP, then the provider and PSHP will have to constantly work to make sure their data transferring system is in compliance with the various rules of HIPAA. Luckily, if the provider and PSHP are able to set up a proper electronic system that only allows them to access patient data when it fits into the HIPAA regulation on disclosing PHI for treatment, payment, or healthcare operations, then it is likely the PSHP and provider can actively share data to receive the benefits of a PSHP without fear of HIPAA.

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245. See Mackin, *supra* note 41, at 13.

246. Conn, *supra* note 224.

247. Adnan Raja, *How Does Employee Monitoring Software Provide HIPAA Compliance*, ATLANTIC.NET (June 25, 2018), <https://www.atlantic.net/hipaa-compliant-hosting/how-does-employee-monitoring-software-provide-hipaa-compliance/> [perma.cc/Z22Q-CU8T].

## CONCLUSION

A PSHP is an innovative insurance design that has the potential to benefit both providers and consumers of healthcare.<sup>248</sup> Even though the first PSHP was invented in the early twentieth century, PSHPs are only now finding a healthcare environment in which they can find widespread success in light of recent massive legal changes affecting United States healthcare over the past decade. Although various state laws might affect PSHPs and further research should be conducted to analyze how PSHPs are affected by the various state legal landscapes, this Note addressed how recent changes in federal law have affected PSHP creation. For example, the ACA insurance exchanges have allowed more PSHPs to be able to adequately compete with large insurers for insurance members within their community.<sup>249</sup> Also, the federal government's push for value-based reimbursement through the ACA, MACRA, and CMS has forced providers to take on more patient risk and look to new programs, such as PSHPs, that can help improve the provider's quality of care given to patients.<sup>250</sup> However, providers should not haphazardly rush into creating a PSHP to take advantage of these federal legal changes without properly understanding the opposing federal legal risks. The Sherman Antitrust Act, the Anti-Kickback Statute, the Physician Self-Referral law, and HIPAA are all areas of federal law which can potentially negatively affect a provider because of their operation of a PSHP.<sup>251</sup> That being said, through proper planning and structuring of a PSHP's agreements with other providers and physicians, as well as proper structuring of a provider's data sharing plan with its PSHP, providers can mitigate the federal legal risks that come with operating a PSHP while maintaining their potential benefits.<sup>252</sup> In conclusion, given the current federal healthcare landscape and the vast number of providers looking to start PSHPs<sup>253</sup> if providers operate their PSHPs correctly to be resilient to potential federal pitfalls, in the near future health plans offered through a provider might become the norm rather than the exception.

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248. *See supra* section I.B.

249. Simer, *supra* note 113, at 9.

250. BAUMGARTEN, *supra* note 38, at 8.

251. *See supra* section III.

252. *See supra* section IV.

253. Thirteen percent of health systems in the U.S. have created PSHPs, and fifty percent more have applied, or are intending to apply, for a health insurance licenses so they can consider starting their own PSHP. Rickert, *supra* note 4.