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David C. Szostak

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## VERTICAL INTEGRATION IN HEALTHCARE: THE REGULATORY LANDSCAPE

*David C. Szostak*

"...innumerable regulatory actions are conclusive proof, not of effective regulation, but of the desire to regulate."<sup>1</sup>

### PREFACE

The U.S. health care system is hopelessly fragmented.<sup>2</sup> Health care providers offer services to patients in distinct venues – hospitals, outpatient surgery centers, physicians' offices, drugstores, and many other places. In a wholly separate industry, health insurance companies finance this care. This dysfunctional system arose over many decades, due to the combination of historical accident and government policy.<sup>3</sup> Not surprisingly, nobody knows what anything really costs – or should cost, at least, based on market value<sup>4</sup> – and financial incentives encourage all kinds of counterproductive behavior.

The purpose of this paper is neither to prove that the health care industry is fragmented and inefficient (which is obvious enough)<sup>5</sup> nor to discuss its history and evolution since the early twentieth century (which many authors have done already).<sup>6</sup> It is enough for our purposes to state upfront that the modern U.S. health care system is broken and its business models have thoroughly ossified. Imposing change across so many separate entities and industries, each with its own economic interests and moti-

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<sup>1</sup> George J. Stigler and Claire Friedland, *What Can Regulators Regulate? The Case of Electricity*, 5 J.L. & ECON 1, 1 (1962).

<sup>2</sup> See, e.g., David Hyman, *Follow the Money: Money Matters in Health Care, Just Like Everything Else*, 36 AM J.L. & MED 370, 371-372 (2010) (referring to the existing system as "a dysfunctional non-system that delivers uncoordinated care of widely varying quality at a high cost.").

<sup>3</sup> See generally e.g., Thomas Greaney, *Competition Policy and Organizational Fragmentation in Health Care*, 71 U. PITT. L. REV. 217 (2009-2010); Karen S. Palmer, Remarks at the Meeting of the Physicians for a National Health Program: *A Brief History: Universal Health Care Efforts in the US* (Spring 1999), at <http://www.pnhp.org/facts/a-brief-history-universal-health-care-efforts-in-the-us>.

<sup>4</sup> E.g., Steven Brill, *Bitter Pill: Why Medical Bills Are Killing Us*, TIME, Apr. 4, 2013.

<sup>5</sup> See note 2, *supra*.

<sup>6</sup> See note 3, *supra*.

vations, is increasingly difficult, and progress remains sclerotic.<sup>7</sup> The necessary and inevitable solution is for a major player in the health care industry to undertake dramatic, all-encompassing vertical integration; only such a completely vertically integrated entity can have the necessary system-wide perspective and sufficient scope to get its arms around the fragmentation and fix it, reshaping and optimizing everything from the ground up. Therefore, this paper generally assumes that vertical integration is desirable and explores the next logical questions: Is it feasible? What are the legal and regulatory obstacles to integration, and are these regulations appropriate in this novel context? What would the ideal regulatory landscape for an integrated system look like?

This paper will essentially consist of three large substantive sections, all found in Part II below. As a starting point, first, Part I will define the term, "vertical integration" and briefly discuss the concept, as this sets the stage for the rest of the discussion. This section will also lay out some of the reasons that vertical integration is beneficial. This is not necessarily the thrust of the paper's argument, but it is critical to understand before proceeding. Part I will make the case that an integrated payor-provider system, if implemented correctly, has the potential to dramatically reduce cost, increase quality, and increase access to care.

Part II will explore the legal framework in existence today that any health care entity wishing to undertake vertical integration would need to carefully consider. Generally, this means state and federal law, though quasi-legal business considerations may be equally important and bear examining.

Traditionally, states have regulated the health care industry as one of their fundamental "police powers."<sup>8</sup> State legislatures typically enact an insurance code as well as health maintenance organization laws, and states generally establish departments of insurance, administrative agencies that are responsible for regulating and overseeing insurers, including the health insurance industry.<sup>9</sup> States have myriad other laws governing institutions such as hospitals, nursing homes, ambulatory surgery centers, and other

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<sup>7</sup> See, e.g., Humphrey Taylor, *Why Is Health Care Reform So Difficult in the United States*, Health Care Blog, Dec. 22, 2009, at [http://www.thehealthcareblog.com/the\\_health\\_care\\_blog/2009/12/why-health-care-reform-is-so-difficult-in-the-united-states.html](http://www.thehealthcareblog.com/the_health_care_blog/2009/12/why-health-care-reform-is-so-difficult-in-the-united-states.html).

<sup>8</sup> See generally Glenn H. Reynolds and David B. Kopel, *The Evolving Police Power: Some Observations for a New Century*, 27 HASTINGS CONST. L.Q. 511 (1999-2000).

<sup>9</sup> See, "State regulation of the insurance industry is primarily accomplished by means of state statutes governing unfair insurance trade practices and by state departments of insurance that receive their regulatory authority from these statutes." Katie Cook Morgan, *Leaving the Management of "Managed Care" Up to the States: The Health Insurance Industry and the Need for Regulation of the Regulators*, 65 U. CIN. L. REV. 225, 235 (1996-1997).

facilities; in addition, states regulate and license individual practitioners.<sup>10</sup> A health care entity wishing to vertically integrate would need to consider state laws governing insurers, as well as those governing providers. The corporate practice of medicine doctrine<sup>11</sup> – depending on the state – might raise further barriers to employing physicians. States may also require regulatory notice or approval for certain corporate transactions, such as mergers or acquisitions.<sup>12</sup> In some states, a certificate of need is required to construct a new facility or even for a transfer of ownership of such a facility.<sup>13</sup> “Any willing provider” laws, too, could interfere with a vertically integrated entity that wants to directly employ health care providers and essentially create a closed system.<sup>14</sup> Innumerable other state insurance mandates would likely impede an integration strategy.

At the federal level, different but equally complex legal questions arise. The formation and operation of the vertically integrated entity could pose major antitrust concerns under the Sherman Act,<sup>15</sup> the Clayton Act,<sup>16</sup> and the Federal Trade Commission Act.<sup>17</sup> Taking formation first, parties should examine whether vertical integration (e.g., an insurer’s acquisition of hospital system) would violate section 7 of the Clayton Act, which prohibits mergers or acquisitions that would substantially foreclose competition.<sup>18</sup> Similarly, the formation of the vertically integrated entity may violate section 1 of the Sherman Act, which prohibits contracts that unreasonably restrain trade.<sup>19</sup> For both analyses, the key question is whether the effect of any acquisitions is to substantially lessen competition in the relevant market. A separate inquiry is operational: Would the vertically integrated entity, once created, monopolize the market in violation section 2 of the Sherman Act?<sup>20</sup> A monopoly in a given market is not per

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<sup>10</sup> See, e.g., Illinois laws such as the Hospital Licensing Act, 210 ILCS 85/1 et seq., Nursing Home Act, 210 ILCS 45/1-101 et seq., Ambulatory Surgical Treatment Center Act, 210 ILCS 5/1 et seq., Medical Practice Act of 1987, 225 ILCS 60/1 et seq., Nurse Practice Act, 225 ILCS 65/50-1 et seq.

<sup>11</sup> See, e.g., *Parker v. Bd. of Dental Examiners of State of Cal.*, 216 Cal. 285, 14 P.2d 67 (1932); *State v. Winneshiek Co-op. Burial Ass'n*, 237 Iowa 556, 22 N.W.2d 800 (1946).

<sup>12</sup> See, e.g., Wis. Stat. Ann. § 165.40 (requiring approval for certain acquisitions from the state attorney general, the insurance commissioner, and the department of health services).

<sup>13</sup> Mark E. Kaplan, Comment, *An Economic Analysis of Florida's Hospital Certificate of Need Program and Recommendations for Change*, 19 FLA. ST. U. L. REV. 475, 478 (1991-1992).

<sup>14</sup> James W. Childs, *You May Be Willing, But Are You Able? A Critical Analysis of "Any Willing Provider" Legislation*, 27 CUMB. L. REV. 199, 199 (1996-1997).

<sup>15</sup> Sherman Antitrust Act, 15 U.S.C.A. §§ 1-7 (1890) (“Sherman Act”).

<sup>16</sup> Clayton Act, 15 U.S.C.A. §§ 12-27 (1914) (“Clayton Act”).

<sup>17</sup> Federal Trade Commission Act, 15 USC §§ 41-58 (1914) (“FTC Act”).

<sup>18</sup> Clayton Act, *supra* note 16.

<sup>19</sup> Sherman Act, *supra* note 15.

<sup>20</sup> *Id.*

se unlawful, but it may be unlawful if acquired or maintained through unlawful (predatory or exclusionary) conduct.

Finally, there are numerous legal issues related to the business model and organization. What should the legal structure of the integrated system be? Is it permissible (or appropriate) to house an insurer, hospital systems, and physician practices in a single corporate entity, or should they be split into two or more distinct entities – but still closely interrelated and bound by mutually exclusive contracts – as in the Kaiser Permanente model?<sup>21</sup> The financial and capital requirements also pose difficulties: it may be more feasible to start on a smaller scale, integrating first in a single town or region of a state and then expanding, rather than attempting to integrate state-wide, all at once. It is also clear that whoever decides to step up and integrate would be taking on additional legal and financial risk. A large hospital system may be familiar with regulatory compliance for providers and well-acquainted with medical malpractice lawsuits, but if it acquired a smaller insurer, it would suddenly take on a very new and different kind of risk – health insurance underwriting risk – as well as needing to comply with a large number of new regulations that only pertain to the insurance industry. The same would be true for larger insurers looking to acquire a provider system.

Part II will also explore the policies behind these regulations and ask whether they are appropriate as applied to a vertically integrated health care entity. As noted above, the health care system is extraordinarily fragmented, and the regulatory regime governing various aspects of this system understandably mirrors its fragmentation.<sup>22</sup> Different state and federal statutes, regulations, and administrative agencies set standards for different health care entities. A vertically integrated system, which provides all levels of care in all types of health care facilities and handles payment and financing of care, has the potential to enhance quality and coordination of care, increase access, and dramatically reduce costs.<sup>23</sup> Yet it is subject to all of the same laws and regulations as all other separate en-

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<sup>21</sup> Douglas McCarthy, Kimberly Mueller, and Jennifer Wrenn, *Kaiser Permanente: Bridging the Quality Divide with Integrated Practice, Group Accountability, and Health Information Technology*, Case Study, The Commonwealth Fund (Jun. 2009), available at [http://www.commonwealthfund.org/~media/Files/Publications/Case%20Study/2009/Jun/1278\\_McCarthy\\_Kaiser\\_case\\_study\\_624\\_update.pdf](http://www.commonwealthfund.org/~media/Files/Publications/Case%20Study/2009/Jun/1278_McCarthy_Kaiser_case_study_624_update.pdf).

<sup>22</sup> Robert I. Field, *Why Is Health Care Regulation So Complex?*, 33 PHARMACY AND THERAPEUTICS 607, 607 (2008) ("...the present regulatory structure is neither uniform nor consistent. A broad range of regulatory bodies and programs apply in different ways to various aspects of the industry. Health care regulations are developed and enforced by all levels of government – federal, state, and local – and also by a large assortment of private organizations. At times, they operate without coordination.").

<sup>23</sup> See Part I of this paper (the case for vertical integration).

tities combined, a huge disincentive to companies considering this route. Public policy should encourage such innovation, not hamper it. Furthermore, the rationale behind many of these regulations may be perfectly sound as applied to a single, fragmented institution (e.g., a stand-alone hospital), but it may not make sense as applied to an integrated insurer-provider system.

The paper concludes in Part III with recommendations for the regulatory landscape of the health care system, particularly with respect to vertically integrated organizations. Health care laws and regulations should not discourage vertical integration, and their underlying purposes should be re-examined in light of the emergence of these entities. Is there an ideal landscape for such an integrated system?

### I. THE CASE FOR VERTICAL INTEGRATION

For purposes of this paper, “vertical integration” means a company’s expansion of its business into areas that are at different stages of production or distribution.<sup>24</sup> Companies often do this in order to ensure a steady supply of a particular input or to ensure that a reliable market exists for their output. A classic example of this is Henry Ford. Ford needed numerous raw materials and supplies for manufacturing automobiles, and he faced the continual problems of high costs, shortages of materials, and suppliers unable to keep up with demand. “The answer, he decided, was total control: owning the whole supply chain. By the 1920s his company ran coal and iron ore mines, timberlands, rubber plantations, a railroad, freighters, sawmills, blast furnaces, a glassworks, and more.”<sup>25</sup> Vertical integration – expansion up or down the supply chain in some capacity – is distinct from mere horizontal expansion, in which a company continues to do the same thing but expands into new regions, or it acquires a competitor in the same line of business.<sup>26</sup>

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<sup>24</sup> Friedrich Kessler and Richard H. Stern, *Competition, Contract, and Vertical Integration*, 69 Yale L. J. 1, 1 (1959-1960) available at <http://www.economist.com/node/13173671> (defining vertical integration as “the coordination of successive stages of production or distribution”).

<sup>25</sup> The Economist, *Moving on up: Is the recession heralding a return to Henry Ford's model?*, Mar. 27, 2009.

<sup>26</sup> John A. Cook et al., *Meeting Challenges of Health Care Reform: Vertically Integrated Health Care Delivery Systems*, 73 Mich. B.J. 170, 171 (1994) (describing vertical integration as the integration of “services of physicians and hospitals (and other providers), as contrasted with the horizontal integration created when hospitals affiliate among themselves, or when physicians become associated as POs [physician organizations], multi-specialty clinics or similar physician groups. An IDS can also include a third tier if an insurance company ... becomes a partner in financing health care coverage.”).

Integration in itself offers numerous benefits: “Cost reduction is the principal technological justification for vertical integration.”<sup>27</sup> This broad reason includes:

increased stability of operations that coordination affords. Consumer outlets, sources of supply, and uniformity of quality are made more secure, thus increasing the feasibility of long-range planning. Facilities can be fully utilized, overtime production or idle plant minimized, and inventory reduced. Moreover, vertical integration eliminates many costs incurred in the transfer of goods from one control to another.<sup>28</sup>

This description was written in 1959, but it remains just as powerful today. A modern exemplar of this strategy is Amazon, the online retailer, which has expanded and continues to expand into numerous seemingly unrelated markets over the past few years, from publishing digital books and manufacturing hardware (such as e-readers or television streaming devices) to offering streaming video content.<sup>29</sup> Most recently, the company announced plans to begin delivering packages to consumers directly, rather than relying on companies like FedEx and UPS to complete the last leg of the journey to people’s homes.<sup>30</sup> In particular, last winter, these shipping companies failed in some cases to deliver packages to consumers in time for Christmas, which had a serious negative impact on Amazon.<sup>31</sup> But as a non-integrated system, this was outside of Amazon’s immediate control. Delivering its own packages will give Amazon more power over the shipping process and will allow it to ensure more reliable and faster deliveries, including receiving items the same day they are ordered, continuing to deliver late at night, or delivering at more specific times.<sup>32</sup> Vertical integration, as noted previously, can help a company ensure more reliability in its supply chains, which are critical to its business. It also allows a greater degree of control over costs.

In health care, vertical integration can mean – in a more limited sense – one type of provider’s acquisition of a different type of provider. One example of this is a hospital acquisition of a physician practice, which

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<sup>27</sup> Kessler, *supra* note 24, at 2.

<sup>28</sup> *Id.* at 3.

<sup>29</sup> See, e.g., Puneet Sikka, *Why Kindle Fire TV will help Amazon expand its customer base*, MARKET REALIST, Apr. 14, 2014; Liz Gannes and Dawn Chmielewski, *Amazon’s Hard Sell: Gaining Developers for Its Coming Smartphones*, Re/code, Apr. 11, 2014.

<sup>30</sup> Greg Bensinger and Laura Stevens, *Amazon, in Threat to UPS, Tries Its Own Deliveries*, The Wall St J, Apr. 24, 2014.

<sup>31</sup> *Id.*

<sup>32</sup> *Id.*

is an increasingly common trend, and one that is actually accelerating under the Affordable Care Act.<sup>33</sup> Physicians generally control a certain volume of patients, and the hospital can benefit from this referral stream by acquiring the physician practice – though this may raise potential issues under the federal anti-kickback law and Stark law, as discussed later.<sup>34</sup> Vertical integration in health care could similarly mean a pharmacy opening up a line of retail clinics, employing nurse practitioners or other professionals. For purposes of this discussion, the terms “vertically integrated entity” and “integrated delivery system” are used interchangeably. One useful definition of this concept might be as follows:

“An integrated delivery system is an organization that furnishes patients with all levels and types of health care services from affiliated providers and coordinates case management and interprovider information flow. An integrated delivery system normally provides, at a minimum, hospital, physician, and ancillary health services.”<sup>35</sup>

In this paper, vertical integration is used in its Henry Ford sense – that is, its broadest possible sense – to mean a total integration of providers at every stage as well as a financing function. Such a completely integrated entity would include, at a minimum, an insurer, an inpatient hospital system, outpatient surgery facilities, traditional clinics and physician offices, retail clinics, home health care services, skilled nursing facilities, long-term care and rehabilitation facilities, running the gamut in providing all necessary levels of care. It would also need to include laboratories, pharmacies, pharmaceutical research and development, durable medical equipment (DME) developers and manufacturers, and even medical schools, which train the physicians that ultimately practice in this system. A patient covered under this plan could receive all types of care, from complex and acute to routine and preventive, without ever leaving the integrated system.

Two features of this system are worth mentioning at the outset. First, nothing like this exists today. Even the most thoroughly integrated systems, such as Kaiser Permanente, do not come close to incorporating all

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<sup>33</sup> Robert Kocher and Nikhil R. Sahni, *Hospitals' Race to Employ Physicians — The Logic behind a Money-Losing Proposition*, 364 N. ENGL. J. MED. 1790 (May 12, 2011).

<sup>34</sup> 42 USC 1320a-7b(b); 42 USC 1395nn. (For example, a hospital paying a physician practice more than fair market value for its hard assets could run afoul of the anti-kickback law)

<sup>35</sup> Carl H. Hitchner et al., *Integrated Delivery Systems: A Survey of Organizational Models*, 29 Wake Forest L. Rev. 273, 274 (1994). See also Thomas L. Greaney, *Managed Competition, Integrated Delivery Systems and Antitrust*, 79 Cornell L. Rev. 1507 (1994).

of these functions.<sup>36</sup> Second, only an integrated provider on this grand scale could possess the sufficient vision and scope to rearrange the entire health care system and restructure the way care is provided.<sup>37</sup> In its current, highly splintered state, the health care system cannot fix itself, as no single entity has the clout or the financial incentive to overhaul everything and rebuild it from the ground up. An integrated system would at least have the potential to do so, even if it is a risky and daunting endeavor.

Several compelling reasons exist to undertake such dramatic vertical integration in health care. The reasons generally fall into two categories: the first is that, even if integration offered no substantial or obvious benefits as compared with the current business models, individual fragmented players in this system (whether insurers or providers) will increasingly face an uphill battle and will inevitably be driven out of business. In short, they must integrate simply to survive. The second reason is that vertical integration does, in fact, offer invaluable benefits. A brief discussion of each of these reasons follows.

As health insurance companies and health care providers increasingly enter each other's territories and the lines between their conventional business models begin to blur, competition will eventually undermine those who adhere to the old, inflexible regime. From an insurer's viewpoint, the danger is that large hospital systems are increasingly taking on risk, and these providers will find it advantageous to simply vertically integrate. Hospitals have already been acquiring physician practices; some are beginning to acquire small insurance companies as well, or they are hiring strategically and building the function in-house.<sup>38</sup> Either way, if successful, these larger providers may bypass 'middlemen' insurance companies and beat them at their own game.

A number of large hospital systems are already moving in this direction. Dr. Kenneth L. Davis, the CEO and President of Mount Sinai Health System – the largest health care provider in the state of New York – believes integrated payor-provider systems are the future: “Inevitably the

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<sup>36</sup> The Kaiser Permanente Medical Care Program consists of three separate entities that cooperate under mutually exclusive contracts: (1) a foundation that operates a health plan (a payor), (2) a foundation that operates a number of hospital systems and outpatient clinics, which include labs, radiology, and pharmacy, and (3) a medical group of multi-specialty physicians. Douglas McCarthy, Kimberly Mueller, and Jennifer Wrenn, *Kaiser Permanente: Bridging the Quality Divide with Integrated Practice, Group Accountability, and Health Information Technology*, Case Study, The Commonwealth Fund, June 2009.

<sup>37</sup> Alfred D. Chandler, *Scale and Scope: The Dynamics of Industrial Capitalism* (Belknap Press 1994) (1991). Chandler argues that at the beginning stages of every industry, it required businesses with sufficient scale and scope to assemble the value network or fundamentally change the architecture of the system.

<sup>38</sup> Melanie Evans, *Cutting out the middleman: Systems buying and developing insurance plans*, *Modern Healthcare*, Mar. 23, 2013.

large systems are going to move to take part of the premium dollar.”<sup>39</sup> Mount Sinai recently entered into a merger agreement with Continuum Health Partners in New York City, creating the largest private hospital system in the city.<sup>40</sup> Dr. Ezekiel Emanuel, chairman of the Department of Medical Ethics and Health Policy at the University of Pennsylvania and a former Obama administration official who helped draft the Affordable Care Act, seems to agree.<sup>41</sup> Dr. Emanuel puts it even more starkly: he states that we are witnessing “the end of insurance companies as we know them” and that if insurers want to survive, they “will have to get into the business of providing care.”<sup>42</sup> In fact, Dr. Emanuel argues that “the wave of the future is integrated delivery systems – integrating insurance with delivery function.”<sup>43</sup>

In a completely separate threat to the health insurance industry, large employers may cut out traditional insurance companies or third-party administrators and just take on certain functions themselves. A large employer could build on-site clinics and hire health care professionals (including physicians) directly, encouraging prevention and wellness to keep employees healthy and keep costs low.<sup>44</sup> The employer could also directly contract with hospitals and build its own network.<sup>45</sup> Some larger self-insured employers have already found this to be a beneficial strategy, and as medical costs and health insurance premiums continue their inexorable rise, more will likely pursue this path. In sum, insurers that cling to the traditional business of offering insurance policies and performing administrative services – but that refuse to take on responsibility for providing medical care – will be swept into the proverbial historical dustbin.<sup>46</sup>

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<sup>39</sup> Rob Garver, *Hospitals Plot the End of Insurance Companies*, The Fiscal Times, Mar. 27, 2014.

<sup>40</sup> Anemona Hartocollis, *2 Hospital Networks Agree to Merge, Raising Specter of Costlier Care*, N.Y. Times, Jul. 16, 2013, at A19.

<sup>41</sup> Brianna Ehley, *Obamacare Spells the End of Employer-Based Coverage*, The Fiscal Times, Mar. 24, 2014.

<sup>42</sup> Garver, *supra* note 39.

<sup>43</sup> *Id.*

<sup>44</sup> Chris Anderson, *More large employers adding on-site health clinics*, Healthcare Finance News, Mar. 13, 2013; David G. Knott, *Vertical Integration: 80's Fad or Health Care's Future?* Strategy+Business, Jul. 1, 1997 (describing six factors that will lead health plans to reconsider vertical integration, including that providers’ “ability to pursue ‘direct contracts’ with employers will raise the threat of ‘disintermediation’ for insurers -- leading some plans to buy them.”).

<sup>45</sup> Evans, *supra* note 38.

<sup>46</sup> “...nonintegrated providers with no disruptive business models will experience the financial crises and consolidations that befall all disrptees eventually. The major health assistance plans from traditional health insurance companies will struggle to remain viable, because the fee-for-service model will be relegated to a shrinking portion of the market.” Clayton Christensen, Jerome Grossman, and Jason Hwang, *The Innovator's Prescription: A Disruptive Solution for Healthcare* (McGraw-Hill 2008) at 216.

On the flip side, from a provider's perspective, the situation is just as perilous. One danger lies in competitors merging to become the "must-have" system in a particular geographic region,<sup>47</sup> increasing their bargaining power for higher reimbursement from payors and decreasing the bargaining power of any player that remains isolated as a result. An insurance company that acquires a competing provider system also poses a risk.<sup>48</sup> In either scenario, providers will have an increasingly difficult time obtaining more favorable rates. If entities maintain the status quo as fragmented, separate institutions, they will inevitably be out-competed by others whose integration gives them the upper hand.<sup>49</sup>

An isolated entity also lacks the ability and scope to truly control the underlying cost of providing medical care. For example, insurers negotiate reimbursement rates with providers in a zero-sum game – when one wins, the other loses. Both are already operating on thin margins, on average,<sup>50</sup> so neither can afford to give much. Health insurers had an average profit margin of 3.4 percent in 2008,<sup>51</sup> for example, and most hospitals barely break even: the median operating margin for hospitals with 200 or more beds in 2010 was slightly negative, averaging 0.7 percent.<sup>52</sup> Moreover, in the current fee-for-service ("FFS") reimbursement system, providers have an incentive to deliver (and bill for) as many services as possible.<sup>53</sup> The Affordable Care Act attempts to reform health care in certain ways, but it did not do much to address the cost of care – it mostly consists of insurance market reforms.<sup>54</sup> To the extent that the current trend is to move away from FFS and toward fee-for-value or something similar (shifting risk onto providers), this still leaves in place the zero-sum game between two distinct parties with clashing economic interests.

Insurers are also building so-called tiered or narrow networks, which have the potential to reduce costs, but they also reduce access for members and have attracted attention in the media<sup>55</sup> and among certain in-

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<sup>47</sup> See, e.g., Peter Frost, *Northwestern, Cadence reach merger deal*, Chicago Tribune, May 15, 2014; Anthe Mitrakos, *Hospital mergers build clout to hike fees*, Crain's Chicago Business, Jun. 11, 2012.

<sup>48</sup> *Highmark closes \$604 mln buyout of West Penn Allegheny bondholders*, Reuters, Apr. 29, 2013.

<sup>49</sup> According to Melinda Hatton, general counsel for the American Hospital Association, "hospitals may have no choice but to consolidate." Kate Pickert, *Fewer Hospitals May Lead to Higher Prices*, Time, Jul. 23, 2013.

<sup>50</sup> Rick Newman, *Why Health Insurers Make Lousy Villains*, US News & World Report, Aug. 25, 2009

<sup>51</sup> *Id.*

<sup>52</sup> David Whelan, *America's Most Profitable Hospitals*, Forbes, Aug. 31, 2010.

<sup>53</sup> David Hyman, *Follow the Money: Money Matters in Health Care, Just Like Everything Else*, 36 Am J Law Med 370 (2010).

<sup>54</sup> David C. Szostak, *What Lawyers Should Know About the Affordable Care Act*, Ill Bar J (Aug. 2012).

<sup>55</sup> See, e.g., Anna Wilde Mathews and Christopher Weaver, *Insurers Face New Pressure Over Limited Doctor Choice*, The Wall Street Journal, Feb. 6, 2014); Bob Herman, Reform Update: More providers, insurers

terest groups – most notably physicians.<sup>56</sup> Increased transparency in prices that providers charge would also help somewhat, but none of these ideas gets at the underlying cost of care – nor can they, since insurers lack the scope to truly control this. A hospital is just as powerless: its overarching financial incentive is to fill every inpatient bed to maximize revenue, but this would drive up the costs to the system as a whole. As medical technology improves, fewer hospital beds will be necessary.<sup>57</sup> No single entity today has a system-wide perspective. Vertical integration is the only way to overcome these otherwise insurmountable obstacles and fundamentally change the way care is provided.

Thus, the first compelling reason to undertake vertical integration is that those who refuse will find it increasingly difficult to compete with those who embrace it, and they will ultimately be driven from the market. If this were the only reason to integrate, it would be a sufficient one. However, vertical integration also offers significant benefits. Often, health care commentators point to the so-called iron triangle of cost, access, and quality.<sup>58</sup> Increasing any one of these in the current system will come at the cost of decreasing another. For example, in a “narrow network,” physicians and hospitals will accept lower reimbursement rates (in exchange for higher patient volume) but this obviously decreases access for patients, who now have fewer options. Similarly, a network could just focus on the highest-quality providers, measurable by standardized and agreed-upon metrics, but such a plan would be much more expensive. Once again, we are faced with a zero-sum game.

The reason for such high costs and such poor outcomes in the U.S. is the outdated and conflated business models in health care. Medical technology and expertise continue to grow increasingly sophisticated, but they are absorbed into business models that have solidified and – due to the fragmented nature of the system – cannot be changed. No single entity has the power or scope to implement new business models and rearrange the structure of the entire system. This is where a totally vertically inte-

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showing appetite for narrow networks *Modern Healthcare*, Oct. 16, 2014, available at <http://www.modernhealthcare.com/article/20141016/NEWS/310169963>.

<sup>56</sup> American College of Physicians, Annual Report on the State of the Nation’s Health Care, Feb. 11, 2014.

<sup>57</sup> See, e.g., Molly Gamble, *The Future of the American Hospital: Role and Relevancy in the Next Decade*, 2012 *Becker’s Hospital Review* 1, 8, May 7, 2012 (stating that the “growth of outpatient service utilization is going to present the largest change to hospitals’ strategic plans in the next decade... A simultaneous decline in hospital inpatient services is expected.”).

<sup>58</sup> See, e.g. Kirsten Rabe Smolensky, *Telemedicine Reimbursement: Raising the Iron Triangle to a New Plateau*, 13 *Health Matrix* 371 n.63 (2003) (“Ideally, a health care system will be low cost, high quality and accessible to all who need its services. Cost, quality and access are referred to as ‘the iron triangle’ because all three of these goals can never be met.”).

grated system offers a *deus ex machina* – it alone can get its arms around the entire system and impose a whole new order, allowing it to provide better care at a much lower cost and, therefore, capture enormous savings. How, exactly, this payor-provider entity should reorganize the way that care is provided could be the subject of a whole paper – indeed, it is the subject of an excellent and highly recommended book<sup>59</sup> – but the crux of the reason vertical integration is so critical is as follows.

Care is currently trapped in inappropriate business models. On the one hand, complex, difficult, high-risk, and uncertain diagnoses and treatments are appropriately performed by highly trained experts with extensive training and education, such as physicians. At the other end of the spectrum, routine, straightforward, predictable diagnoses and treatments can be safely and effectively performed in lower-cost venues by lower-cost professionals. The hallmark of this end of the spectrum is that the diagnosis and solution are not unique, but are instead common and predictable.<sup>60</sup> It is the medical equivalent of the assembly line that mass produces a product, as opposed to crafting highly individualized and unique products by hand. Neither business model is appropriate for all customers in all situations.

Today's hospitals and physicians attempt to do everything for everyone, combining two separate business models under one roof.<sup>61</sup> This is extraordinarily inefficient and results in nobody really knowing what anything should cost.<sup>62</sup> The high costs of complex, uncertain, unique care inappropriately inflate the low costs of routine, precise, predictable care. If properly separated into two different business models, most health care services would cost significantly less than they do today because predictable diagnoses and treatments can be streamlined and replicated at low cost.<sup>63</sup> The power to orchestrate this degree of change in the health care system – separating care out into different business models and even creating new venues of care where they do not exist – requires nothing less than vertical integration.

As noted above, the primary purpose of this paper is not to convince the reader of the benefits of vertically integrating. This introduction

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<sup>59</sup> Christensen, *supra* note 46.

<sup>60</sup> *Id.* at 20-27.

<sup>61</sup> Christensen, *supra* at 75 (“...hospitals [have] commingled value-adding process and solution shop activities within the same institution – resulting in some of the most managerially intractable institutions in the annals of capitalism.”).

<sup>62</sup> Steven Brill, *Bitter Pill: Why Medical Bills Are Killing Us*, Time, Apr. 4, 2013.

<sup>63</sup> Christensen, *supra* note 46, at 26 (arguing that this type of disruption to health care has the potential to ultimately reduce costs by 20 to 60 percent while simultaneously improving the quality and efficacy of care received).

to the concept hopefully provides a sufficient overview. However, having considered why health care entities would want to integrate, we next turn to the laws and regulations that would obstruct such a strategy.

## II. THE FRAGMENTED REGULATORY FRAMEWORK

A jungle of health care laws and regulations accurately reflects the splintered health care system that it governs. These laws are, in part, the product of the push-and-pull of different levels of government with different spheres of influence, as well as the product of numerous private actors locked in perpetual business struggles, each lobbying for its own self-serving legislative agenda.<sup>64</sup> Many of these laws were developed in another era, when the health care system was scarcely recognizable when compared with the system today – antitrust laws were written a full century ago, and they were never written for the peculiarities of the health care industry. The Stark and anti-kickback laws were passed in an era of independent physicians, in part due to the concern that hospitals could be buying a referral stream. Today, though, physician employment in hospitals is more prevalent than ever and steadily increasing.<sup>65</sup> These statutes, and others that constitute the overarching regulatory framework in health care, are not even entirely appropriate to the current health care system. But even if they were conceded to be appropriate today, a vertically integrated entity is another matter altogether, and the same framework cannot logically apply.

### A. Federal Legal Issues

#### 1. Antitrust

##### a. Formation of the Vertically Integrated Entity

One of the biggest legal issues that may interfere with vertical integration is inevitably antitrust. Conceptually, any antitrust analysis might best be split into two categories: the formation of the vertically integrated entity (e.g., potential merger and acquisition issues), and the operation of

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<sup>64</sup> See, e.g., Robert I. Field, *Why Is Health Care Regulation So Complex?*, 33 *Pharmacy and Therapeutics* 607 (2008).

<sup>65</sup> About 25 percent of specialist physicians were employed by hospitals in 2013, compared with only 5 percent in 2000. Bob Herman, *7 Trends in Hospital-Employed Physician Compensation*, *Becker's Hospital Review*, Jan. 25, 2013. For primary care physicians, the number employed by hospitals has increased from about 20 percent to 40 percent during this time period. Molly Gamble, *Are Hospital-Employed Physicians Synonymous With Higher Prices?* *Becker's Hospital Review*, Aug. 27, 2012.

the entity after it is created (e.g., potential monopolization issues). These will be discussed separately below.

Antitrust analysis generally only involves a few major statutes – the Sherman Act,<sup>66</sup> the Clayton Act,<sup>67</sup> and the Federal Trade Commission (“FTC”) Act<sup>68</sup> – but it can become extraordinarily complex and depend heavily on facts and circumstances. The formation of a vertically integrated entity might trigger scrutiny under two provisions, in particular. First, section 7 of the Clayton Act states:

"No person engaged in commerce or in any activity affecting commerce shall acquire, directly or indirectly, the whole or any part of the stock or other share capital and no person subject to the jurisdiction of the Federal Trade Commission shall acquire the whole or any part of the assets of another person engaged also in commerce or in any activity affecting commerce, where in any line of commerce or in any activity affecting commerce in any section of the country, the effect of such acquisition may be substantially to lessen competition, or to tend to create a monopoly."<sup>69</sup>

The key question here is whether the effect of any merger or acquisition is to substantially lessen competition in the relevant product and geographic market. If so, the transaction might violate section 7 of the Clayton Act.

The other major relevant provision that such a transaction implicates is section 1 of the Sherman Act, which states: “Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal.”<sup>70</sup> Despite this absolute language, not literally every contract that restrains trade is unlawful. The key question is whether it *unreasonably* restrains trade.<sup>71</sup> In one of the early leading cases, Justice Brandeis explained:

“Every agreement concerning trade, every regulation of trade, restrains. To bind, to restrain, is of their very essence. The true test of legality is whether the restraint im-

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<sup>66</sup> Sherman Act, *supra* note 15.

<sup>67</sup> Clayton Act, *supra* note 16.

<sup>68</sup> FTC Act, *supra* note 17.

<sup>69</sup> Clayton Act, *supra* note 16.

<sup>70</sup> Sherman Act, *supra* note 15.

<sup>71</sup> Board of Trade of the City of Chicago v. United States, 246 U.S. 231, 244 (1918).

posed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition. To determine that question, the court must ordinarily consider the facts peculiar to the business to which the restraint is applied, its condition before and after the restraint was imposed, the nature of the restraint, and its effect, actual or probable.”<sup>72</sup>

Under either antitrust statute, a court would perform the traditional “rule of reason” analysis, which would require properly identifying the relevant product market and geographic market at issue, and then weighing the pro-competitive benefits of the transaction against its anti-competitive effects.<sup>73</sup> The standard depends heavily upon the circumstances in a particular situation and is necessarily somewhat subjective; in fact, the entire rule of reason analytical framework is arguably problematic and flawed.<sup>74</sup>

Nevertheless, each step, each corporate transaction in the formation of a vertically integrated entity would need to be analyzed separately and undergo a thorough rule of reason analysis. More frequently, a horizontal merger or acquisition takes place and the analysis is more straightforward, because everything is happening in the same market. For example, if a particular region has three large hospital systems, and two of them decide to merge, there may be a significant reduction in competition for the services that they provide, and the deal might violate section 7 of the Clayton Act.<sup>75</sup> With vertical integration, however, the parties to the transaction may not be competing against each other – rather, each competes with others in two or more different markets. As a result, two separate analyses would be required, involving the effect on competition in each relevant market.<sup>76</sup>

To help clarify this point, as an example, a health insurance company might propose to acquire a hospital system in Chicago, Illinois. In this case, the relevant product market might be “general acute care inpatient services” because the hospital is competing against other hospitals in providing these services to patients. The antitrust question is: to what ex-

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<sup>72</sup> Board of Trade of the City of Chicago v. United States, 246 U.S. 231, 244 (1918).

<sup>73</sup> Standard Oil Co. of NJ v. United States, 221 US 1 (1911) (establishing rule of reason analysis).

<sup>74</sup> Maurice E. Stucke, *Does the Rule of Reason Violate the Rule of Law?* 42 UC DAVIS L.Rev. 1375, 1421 (2009) (arguing that the rule of reason has been criticized for its inaccuracy, its poor administrability, its subjectivity, its lack of transparency, and its inconsistent results).

<sup>75</sup> Clayton Act (prohibiting any corporation from acquiring another corporation where the effect of such acquisition may be to substantially lessen competition between them, or to restrain commerce, or to tend to create a monopoly).

<sup>76</sup> Oliver Hart and Jean Tirole, *Vertical Integration and Market Foreclosure*, 1990 Brookings Papers on Economic Activity 205 (1990).

tent does this acquisition substantially lessen or foreclose competition in the relevant product and geographic market? (Alternatively, the product market might be outpatient services if the hospital also provides them, or health insurance products because that is the market in which the insurer competes.) The relevant geographic market might depend on how large an area the hospital serves – how far do patients typically travel who use the hospital’s services?<sup>77</sup> – but for simplicity, let us say the geographic market is the city of Chicago. Looking solely at inpatient services in Chicago, then, other health insurance companies that contract with hospitals in the city would now potentially have one less hospital from which to purchase these services. In this case, other hospitals might now enjoy better bargaining power with other insurers, allowing them to obtain higher reimbursement and therefore driving up prices for consumers. Or, now that the insurer owns the hospital, it may attempt to inappropriately require its enrollees to use its own hospital and prevent them from using others, which could be an unlawful tying arrangement (discussed further below). Chicago happens to have quite a few hospital systems, but in more rural areas there may be fewer competitors and this could cause much greater relative harm to consumers and a more substantial loss of competition. These are some of the types of anti-competitive effects that the antitrust laws seek to avoid.

A rule of reason analysis would then involve looking in-depth at the competitors (here, hospital systems offering inpatient services) in the relevant market and determining market share and market concentration. Courts have suggested that antitrust concerns typically arise with at least 30-40 percent market foreclosure.<sup>78</sup> In an early leading case dealing with vertical integration, *Brown Shoe Co. v. United States*, the Supreme Court held that the merger of two manufacturers and sellers of shoes violated section 7 of the Clayton Act.<sup>79</sup> The Court explained that “[i]f the share of the market foreclosed is so large that it approaches monopoly proportions,” then it would violate both the Clayton Act and the Sherman Act.<sup>80</sup> On the other hand, a *de minimis* amount of market foreclosure would not trigger a violation. Between these two extremes, the percentage alone is

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<sup>77</sup> The Department of Justice and the Federal Trade Commission may look at supplier location or customer location in order to define a geographic market. See U.S. Department of Justice and Federal Trade Commission, Horizontal Merger Guidelines, sec. 4.2 (2010).

<sup>78</sup> See, e.g., Jonathan M. Jacobson, *Exclusive Dealing, “Foreclosure,” and Consumer Harm*, 70 Antitrust L J 311, at 324 (2002) (“Post-Beltone decisions routinely sustained the legality of exclusive dealing arrangements with foreclosure percentages of 40 percent or less.”).

<sup>79</sup> *Brown Shoe Co. v. United States*, 370 U.S. 294 (1962).

<sup>80</sup> *Id.* at 328.

not decisive – other factors, like the nature and purpose of the transaction or the trend toward concentration in the industry, must be considered.<sup>81</sup> In general, the fewer the competitors and the higher the market concentration, the more suspect a merger or acquisition in that market.

Finally, having defined the relevant product and geographic markets and having reviewed the competitors' market share and market concentration, a court would determine the likelihood that the transaction would, on balance, be anti-competitive. Market concentration is important and, if sufficiently high, it may lead to a presumption that the transaction would be unlawful. However, other factors merit consideration, as well: generally speaking, the extent to which a transaction forecloses competition in the relevant market is critical.<sup>82</sup>

If an Insurer A were to acquire Hospital B, one factor in the analysis would be whether the contract is exclusive in either direction, or even mutually exclusive. In other words, would members enrolled in one of Insurer A's plans be required to use Hospital B (and would then any other hospital be considered out-of-network for that enrollee)? Likewise, would Hospital B only accept as in-network patients who had insurance coverage through Insurer A? Imagine a hospital system with an inpatient admissions market share of 20 percent. If this hospital system were acquired by an insurer and could not contract with any other commercial insurer (at least, as an in-network provider), then competitors in the health insurance market in Chicago would potentially be foreclosed from 20 percent of business in the market for general acute care inpatient services. This is a fairly large amount of the market, and depending on circumstances and other factors, it could trigger a problem under antitrust laws.

If the transaction were presumed anti-competitive, then pro-competitive benefits might be offered to rebut this presumption.<sup>83</sup> However, this is a difficult hurdle to overcome. Courts look at barriers to entry in the industry and efficiencies that would result<sup>84</sup> – although any efficiencies must be real and verifiable, not speculative.<sup>85</sup> For example, in the formation of a vertically integrated entity, the parties might demonstrate that

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<sup>81</sup> *Brown Shoe Co. v. United States*, 370 U.S. at 329.

<sup>82</sup> See Jonathan M. Jacobson, *Exclusive Dealing, "Foreclosure," and Consumer Harm*, 70 Antitrust L J 311 (2002).

<sup>83</sup> *FTC v. Butterworth Health Corp.*, 946 F. Supp. 1285, at 1302 (1996).

<sup>84</sup> See, e.g., *Federal Trade Comm'n v. University Health Inc.*, 938 F.2d 1206, 1222 (11th Cir.1991) (“[E]vidence that a proposed acquisition would create significant efficiencies benefitting consumers is useful in evaluating the ultimate issue – the acquisition's overall effect on competition.”).

<sup>85</sup> See U.S. Department of Justice and Federal Trade Commission, *Horizontal Merger Guidelines*, sec. 10 (2010) (“Efficiency claims will not be considered if they are vague, speculative, or otherwise cannot be verified by reasonable means.”).

that an increase in the quality of care would result, as well as a dramatic reduction in costs of providing medical care, resulting in much lower prices for consumers. Generally, though, courts are skeptical without concrete evidence – ideally, historical evidence that the defendants engaged in similar transactions in the past and real efficiencies were documented. In addition, any savings must have been passed on to consumers.

The foregoing analysis, and in particular the decision in *Brown Shoe*, demonstrates how perilous the antitrust laws can be, and how hostile an attitude the judiciary can establish, for businesses that decide to vertically integrate. According to Herbert Hovenkamp, a law professor and antitrust expert, with the Court's decision in *Brown Shoe*, “. . . antitrust policy set out on a counterproductive, decade-long enterprise of condemning efficient mergers that would have benefitted consumers, simply because they made it more difficult for smaller rivals to compete.”<sup>86</sup> The whole rule of reason analysis is complicated but also inherently subjective and to some extent arbitrary. For example, in another landmark antitrust case, *United States v. Paramount Pictures*, Justice Douglas wrote for the majority that vertical integration violates antitrust laws “if it was a calculated scheme to gain control over an appreciable segment of the market and to restrain or suppress competition, rather than an expansion to meet legitimate business needs.”<sup>87</sup> But what assurance is there that integration for legitimate business purposes would not be viewed by a court as an unlawful anti-competitive scheme?

Professor Hovenkamp also notes that the government's “arguments against vertical integration became increasingly fantastic”<sup>88</sup> as the twentieth century progressed, and that the “truly extraordinary thing about vertical integration of all kinds is how robustly it developed through the twentieth century in the face of a legal regime that was rarely accommodating and often hostile.”<sup>89</sup> This does not bode well for an entity looking to integrate.

In sum, the effect of such a merger or acquisition on competition in a particular market is uncertain, and it could trigger a violation of the antitrust statutes. Yet the concern behind these laws is misplaced when it comes to the formation of a vertically integrated entity in health care. A thoroughly integrated system would lower costs and create much better

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<sup>86</sup> Herbert Hovenkamp, *The Law of Vertical Integration and the Business Firm: 1880-1960*, 95 IOWA L. REV. 863, 910 (2010).

<sup>87</sup> *United States v. Paramount Pictures, Inc.*, 334 U.S. 131, 174 (1948).

<sup>88</sup> Hovenkamp, *supra* note 86, at 915.

<sup>89</sup> *Id.* at 917 (citing *United States v. Yellow Cab Co.*, 332 U.S. 218, 226-27 (1947); *United States v. N.Y. Great Atl. & Pac. Tea Co.*, 173 F.2d 79, 85 (7th Cir. 1949)).

quality of care, both of which would be beneficial to consumers. Antitrust laws that block such outcomes, in this context, do a disservice to their intended purpose.

b. Operation of the Vertically Integrated Entity

As mentioned above, the antitrust analysis is conceptually best split into two clusters of issues: those related to the formation of the entity, and those related to its operation once it is formed. The operation of the vertically-integrated entity might trigger potential monopolization issues. Namely, section 2 of the Sherman Act provides:

“Every 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>90</sup>

Courts have interpreted this to mean that monopoly (i.e., a sufficiently large market share and degree of market power) is not per se unlawful, but that monopolization (i.e., acquiring or maintaining monopoly power through predatory or exclusionary conduct) is unlawful.<sup>91</sup> Here, the key questions would therefore be: once the integrated system is formed and has begun operating, does it possess sufficient market power in an appropriately defined market? And if so, is it wielding this market power in a prohibited way?

A monopolist can engage in unlawful predatory conduct in a variety of ways. For example, it can establish a tying arrangement, in which a seller with sufficient market power basically says, “if you want to buy the very popular Product A [called the ‘tying product’], then you also must buy the less popular Product B [called the ‘tied product’].”<sup>92</sup> Regarding this arrangement, courts have stated that:

The essential characteristic of an invalid tying arrangement lies in the seller’s exploitation of its control over the tying product to force the buyer into the purchase of a tied product that the buyer either did not want at all, or might have preferred to purchase elsewhere on different terms. When

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<sup>90</sup> 15 USC § 2.

<sup>91</sup> *US v. Grinnell Corp*, 384 US 563, 570-71 (1966) (“The offense of monopoly under §2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident.”).

<sup>92</sup> *Jefferson Parish Hosp District No. 2 v. Hyde*, 466 US 2, 2 (1984).

such ‘forcing’ is present, competition on the merits in the market for the tied item is restrained and the Sherman Act is violated.<sup>93</sup>

In *Jefferson Parish*, the case from which the above quote is taken, the Supreme Court found that despite the existence of a tying arrangement, the Sherman Act was not violated because the hospital only had 30 percent market share, which was insufficient to establish the element of forcing.

Another way monopolists can wield their power unlawfully is through an exclusive dealing contract. These contracts can be unlawful; they operate to prevent a distributor from selling the products of a competitor. For example, in *United States v. Dentsply International*, a dominant manufacturer of artificial teeth used in dentures had a practice of dropping dealers who took on competitors’ products.<sup>94</sup> Since Dentsply had such a large market share – 75 to 80 percent of the market, based on revenue, and 15 times larger than the next largest competitor – dealers had to choose between offering only Dentsply’s products or offering others but losing Dentsply (and therefore losing the majority of their sales).<sup>95</sup> Predictably, no dealers chose to drop Dentsply products. The court found that this practice constituted an unlawful exclusionary dealing arrangement and violated the Sherman Act and Clayton Act.<sup>96</sup>

Anticompetitive leveraging, too, is a danger that monopolists may pose. Similar to a tying arrangement, anticompetitive leveraging is the use of monopoly power in one market to amplify or leverage power in another, more competitive market. In *White and White, Inc. v. American Hospital Supply Corp.* (“AHSC”), a national distributor of hospital supplies entered into a purchase agreement with a group of hospitals that offered the hospitals volume discounts and a price increase limit in return for a high volume of purchases by the group from AHSC’s full range of hospital supply products.<sup>97</sup> White and White, Inc. and other local distributors of surgical supplies sued, arguing that AHSC violated sections 1 and 2 of the Sherman Act. In this case, the Sixth Circuit held that AHSC did not actually have the requisite monopoly power to violate the antitrust laws, but it laid out the basis for anticompetitive leveraging as a prohibited business practice.

The operation of a completely integrated health care system raises special antitrust concerns because it would be a colossal organization, in-

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<sup>93</sup> *Jefferson Parish Hosp District No. 2 v. Hyde*, 466 US at 13.

<sup>94</sup> *US v. Dentsply Int’l*, 399 F.3d 181 (3rd Cir. 2005).

<sup>95</sup> *Id* at 185.

<sup>96</sup> *Id* at 196.

<sup>97</sup> *White and White, Inc. v. Am Hosp Supply Corp.*, 723 F.2d 495 (6th Cir. 1983).

corporating everything from an insurance function to large hospital systems, numerous retail clinics, pharmacies, laboratories, medical device and drug manufacturers, and much more. Each of these businesses would normally operate in one or more distinct product markets, but the danger in this context would be that the fully integrated system exercises its market power in an unlawful or exclusionary way. As with the prior section discussing formation of the entity, a rule of reason analysis is necessary to weigh the procompetitive benefits against the anti-competitive effects.

For example, if the insurer arm of the organization enjoyed a very large market share, then it would need to be careful about requiring its enrollees to use its medical facilities (a potential tying arrangement). In such a large organization offering so many different products and services, potential tying arrangements could occur. Similarly, exclusive dealing contracts would probably be in place: numerous vendor and supplier contracts would be required, and the entity must take care not to wield any market power to unlawfully exclude competitors from any markets.

The concern behind these laws and their interpretation and enforcement over the past century has been that two or more competitors may be tempted to agree on prices, or a single firm might unfairly corner the market. In either case, the businesses involved may raise prices above competitive levels, harming competition and consumers. In health care, competing hospitals, physicians, or insurers could potentially collude in this way. Collusion or monopolization could also take place at different levels in the supply chain: a sufficiently large hospital system could wield its market power unlawfully by telling insurers that if they contract with any other hospitals in the region, the insurer will receive a much lower discount. If the hospital is a large “must-have” facility, then most or all insurers may decide to contract exclusively with it, to the detriment of competing hospitals. One Texas hospital system did just this,<sup>98</sup> and it is a classic example of monopolization through exclusionary conduct.

In the normal, highly fragmented health care world, these concerns are valid and the antitrust laws may be necessary to prevent such evils. However, these same laws deter and unnecessarily complicate vertical integration. In a relatively simple merger between a hospital and an insurer, things would get complicated and expensive quickly. Both entities would need to hire legal counsel that specialize in antitrust as well as economic experts to perform costly analyses, determining market share in their respective markets and the competitive impacts of the transaction. Depend-

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<sup>98</sup>US v. United Reg'l Health Care System, U.S. Dept. of Justice Final Judgment (Sept. 29, 2011), available at <http://www.justice.gov/atr/cases/t276000/276027.pdf>.

ing on whether certain dollar thresholds are met, the parties may need to file a pre-merger notification with federal authorities and pay a filing fee.<sup>99</sup> Regulators may make a second request for additional information, dwarfing the first filing in terms of resources needed to properly respond: this can take months or even years and require a tremendous output of legal effort in negotiations and due diligence.<sup>100</sup> The administrative agency could challenge the deal, seeking to stop it by filing for a preliminary injunction in court. Either the agency or a court could find the transaction violates antitrust laws and it will be blocked from proceeding.<sup>101</sup> Finally, private litigation by other affected parties (such as a rival hospital or insurer) based on the antitrust laws could erect similar obstacles. The outcome at every stage is uncertain, and even if the transaction is ultimately allowed to proceed, the laws will have exacted a serious toll on all participants. This also creates a serious chilling effect on attempts at vertical integration – entities that were otherwise considering the strategy might decide it is not worth the cost and risk.

If the public policy goal is to align the financial incentives of all parties and reduce overall costs in the health care system – as decades of Congressional and state legislation seem to imply is the case – then vertical integration should be seen as a desirable strategy, generating tremendous efficiencies that benefit consumers in the form of much lower prices and higher quality health care, while also increasing access to care. Such broader policy goals should not be obstructed by myopic and antiquated antitrust concerns.

## 2. Anti-kickback and Stark

While antitrust law might present the largest and most complex set of issues, other federal laws would also impede vertical integration. Among the most prominent of these are the federal anti-kickback statute<sup>102</sup> and physician self-referral (“Stark”) law.<sup>103</sup>

<sup>99</sup> 15 USC § 18a.

<sup>100</sup> *Can Your Second Request Vendor Make the Impossible Possible?* Kiersted/Systems White Paper (2011), available at [http://www.kiersted.com/public/products/white-papers/kiersted\\_ftc\\_2nd\\_request\\_whitepaper.pdf](http://www.kiersted.com/public/products/white-papers/kiersted_ftc_2nd_request_whitepaper.pdf) (“Few legal events are as all-consuming as the M&A second request. In recent years, complying with this most difficult of legal challenges has become more costly and complex...”).

<sup>101</sup> *Premerger Notification and the Merger Review Process*, Federal Trade Commission, available at <http://www.ftc.gov/tips-advice/competition-guidance/guide-antitrust-laws/mergers/premerger-notification-and-merger>.

<sup>102</sup> Anti-kickback Statute, 42 USC 1320a-7b(b) (2014) (“AKS”).

<sup>103</sup> The Ethics in Patient Referral Act of 1989, 42 USC 1395nn (2010) (“Stark”). This law is named for its initial sponsor, U.S. Congressman Pete Stark.

The federal anti-kickback statute prohibits the exchange of remuneration with the intent to induce referrals of patients for Medicare or Medicaid services.<sup>104</sup> The law provides for penalties against anyone who:

knowingly and willfully solicits, receives, offers, or pays remuneration, in cash or in kind, to induce or in return for: (1) referring an individual to a person for the furnishing or arranging for the furnishing of any item or service payable under the Medicaid or Medicaid programs, or (2) purchasing, leasing, or ordering or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item payable under the Medicare or Medicaid programs.<sup>105</sup>

The statute also contains a number of exceptions or safe harbors for certain specified remuneration or compensation arrangements that will not violate the otherwise broad prohibition.<sup>106</sup> For example, any amount paid by an employer to an employee who has a bona fide employment relationship with the employer for employment in the provision of covered services is exempt (“employment exception”).<sup>107</sup>

The Office of Inspector General (“OIG”) in the U.S. Department of Health and Human Services is one of several agencies responsible for overseeing and enforcing the Medicare and Medicaid programs, including the anti-kickback statute. Particularly relevant in the context of vertical integration, the OIG has stated that when a hospital acquires a physician practice – or another entity acquires both – any upfront payment must be only for the hard assets of the practice, and any subsequent payments to the physicians must be for services rendered.<sup>108</sup> Anything in excess of this is suspect as potentially paying for a referral stream, which would violate the anti-kickback statute.<sup>109</sup> Intent is also required to demonstrate a violation, so it is important to clarify in any acquisition of a physician practice that the intent is not to induce referrals: parties must demonstrate that the consideration paid is consistent with fair market value.<sup>110</sup>

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<sup>104</sup> AKS, *supra* note 102.

<sup>105</sup> *Id.*

<sup>106</sup> 42 USC 1320a-7b(b)(3).

<sup>107</sup> 42 USC 1320a-7b(b)(3)(B).

<sup>108</sup> D. McCarty Thornton, *Letter concerning the application of the Medicare and Medicaid anti-kickback statute to the acquisition of physician practices*, Office of the Inspector General, U.S. Department of Health & Human Services, Dec. 22, 1992, available at <https://oig.hhs.gov/fraud/docs/safeharborregulations/acquisition122292.htm>

<sup>109</sup> *Id.*

<sup>110</sup> Barton C. Walker, Kristian A. Werling, & Anna M. Timmerman, *Physician Practice Acquisitions: Key Legal Concerns for Hospital Boards and Executives*, BoardRoomPress, Apr. 2011.

The OIG has issued numerous advisory opinions under the anti-kickback statute, providing its interpretation of what specific practices are prohibited.<sup>111</sup> These opinions depend heavily on the particular facts and circumstances and cannot be relied on for other parties, but they are nevertheless instructive. Courts have also been called on to decide whether certain arrangements violate the anti-kickback statute.

The anti-kickback statute is an impediment to vertical integration because a hospital or other entity would need to acquire physician practices or hire individual physicians as employees. When this happens, there may be a possibility that the compensation paid to the physicians or their practice group would be in excess of fair market value and would be perceived instead as paying for the value of a referral stream of patients to the hospital or other entity. The integrated system could therefore find itself in violation of the anti-kickback provisions, even despite the employment exception.

Interpretations of the anti-kickback law “reach conduct far beyond the traditional, straightforward kickback or bribe, and now affect the healthcare community's conduct in a broad spectrum of ordinary business transactions.”<sup>112</sup> Arguably, this law overreaches and overregulates even in the modern health care system. Furthermore, it subjects providers to a great deal of uncertainty: “Despite the abundance of administrative interpretations, judicial decisions, and the promulgation of the safe harbor regulations, it is still unclear precisely which business arrangements the law prohibits and which business arrangements the law protects. Moreover, the reach of the Anti-Kickback Statute appears to be extending, rather than narrowing.”<sup>113</sup> A strong argument can be made that this law is not appropriate in the current fragmented system. But it is certainly inappropriate as applied to an integrated delivery system, where the same financial incentives and the same policy concerns no longer exist.

The federal physician self-referral law (commonly known as the Stark law, or just “Stark”) prohibits physician referrals for certain “designated health services” if there is a financial relationship between the physician and the entity to which the referral is made.<sup>114</sup> It is a strict liability statute, so a physician can violate it regardless of intent.<sup>115</sup> “Designated health services” is a defined term that includes clinical lab services, radiology and

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<sup>111</sup> 42 USC 1320-7d(b) and 42 CFR part 1008 (authority for OIG advisory opinions).

<sup>112</sup> David E. Matyas, Carrie Valiant, et al., *Legal Issues in Healthcare Fraud and Abuse: Navigating the Uncertainties* 21 (American Health Lawyers Association 2012, 4th ed.).

<sup>113</sup> *Id.* at 24.

<sup>114</sup> 42 USC 1395nn.

<sup>115</sup> *Id.*

imaging services, physical therapy, durable medical equipment, and inpatient and outpatient hospital services.<sup>116</sup>

Stark applies to Medicare and, indirectly, to Medicaid as well. The law does not prohibit the referral of Medicaid patients, but rather authorizes the federal government to deny state programs the federal matching funds for any Medicaid services pursuant to a referral which would have been prohibited if the patient had been a Medicare beneficiary.<sup>117</sup> For practical purposes, therefore, Stark is applicable to both Medicare and Medicaid. Frequently, physicians in practices that are being acquired make referrals to the hospital that is acquiring them, so entities and physicians need to comply with a Stark exception if they want to ensure the transaction is not illegal.<sup>118</sup>

As with the anti-kickback statute, Stark contains a number of exceptions to its otherwise broad prohibition on compensation arrangements. Under Stark, for example, hospitals may pay physicians as employees as long as the amount paid is: (i) for identifiable services, (ii) consistent with fair market value, (iii) not determined by taking into account the volume or value or referrals by the physician to the hospital, and (iv) commercially reasonable.<sup>119</sup>

The United States government has taken parties to court when it believes certain practices violate Stark. In *United States v. Halifax Hospital Medical Center*, a federal district court held that a hospital's compensation of physicians can violate Stark, even if the hospital employs the physicians and the pool of compensation is distributed proportionally based on the services each physician performs.<sup>120</sup> In *Halifax*, the hospital employed six medical oncologists and set up a compensation structure that included a bonus for the physicians' Medicare referrals to the hospital.<sup>121</sup> The hospital set aside a certain pool of money as an incentive payment that was to be divided between the six physicians based on each physician's share of their total billing for professional services.<sup>122</sup> The hospital argued that the arrangement fell within the bona fide employment exception to Stark because the bonus payment was based on services personally performed by

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<sup>116</sup> 42 USC 1395nn(h)(6).

<sup>117</sup> Robert G. Homchick, *Top 10 Lessons Learned from the Physician Practice Acquisition Wars: Stark and Anti-kickback Issues in Physician Compensation*, Davis Wright Tremaine LLP, June 2010.

<sup>118</sup> Barton C. Walker, Kristian A. Werling, & Anna M. Timmerman, *Physician Practice Acquisitions: Key Legal Concerns for Hospital Boards and Executives*, BoardRoomPress, Apr. 2011.

<sup>119</sup> § 1395nn(e)(2).

<sup>120</sup> *United States v. Halifax Hosp Med Ctr*, 2013 WL 6017329 (M.D. Fla. 2013).

<sup>121</sup> *Id.* at 1.

<sup>122</sup> *Id.* at 2-3.

the oncologists.<sup>123</sup> However, the court held that this is insufficient to bring the payment within the employment exception: the bonus was divided up based on services that the oncologists personally performed, but the total size of the bonus was based on other facts as well, including revenue from referrals that the oncologists made for designated health services.<sup>124</sup>

Another recent court case involving a Stark violation is *United States v. Tuomey Healthcare System*.<sup>125</sup> In that case, a number of specialist physicians informed Tuomey that they were considering performing outpatient surgical procedures in their offices, rather than at Tuomey Hospital, which would mean a significant loss of revenue for the hospital.<sup>126</sup> In order to prevent this, Tuomey entered into agreements with the physicians to perform outpatient procedures exclusively at Tuomey Hospital.<sup>127</sup> As part of the agreements, the hospital agreed to pay each physician an annual base salary that depended on the hospital's total revenue for the outpatient procedures, as well as a bonus.<sup>128</sup> A physician who did not reach such an agreement with the hospital filed suit under the qui tam provisions of the False Claims Act and the United States intervened, asserting a violation of the Stark law, among several other counts.<sup>129</sup>

The Fourth Circuit held that the facility component of the physicians' personally performed services constitutes a referral, and that the physicians were therefore making referrals to Tuomey, for purposes of Stark.<sup>130</sup> Furthermore, the court held that the compensation received by the physicians that takes into account the volume or value of *anticipated* referrals falls within the prohibition, and it remanded to the district court to determine whether the contracts, on their face, took into account the value or volume of anticipated referrals.<sup>131</sup>

*Halifax* and *Tuomey* illustrate the complexity of establishing a compensation package for a health care system that directly employs physicians without violating Stark. The employer, or integrated health system, needs to ensure that the compensation for any physicians that it employs is not based, even in part, on the system's profits or revenues related to any

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<sup>123</sup> *United States v. Halifax Hosp Med Ctr*, at 8.

<sup>124</sup> *Id.* at 9.

<sup>125</sup> *United States v. Tuomey Healthcare System*, 675 F.3d 394 (4th Cir.2012).

<sup>126</sup> *Id.* at 399.

<sup>127</sup> *Id.*

<sup>128</sup> *Id.*

<sup>129</sup> *Id.* at 400.

<sup>130</sup> *United States v. Tuomey Healthcare System*, 675 F.3d at 407.

<sup>131</sup> *Id.* at 409.

referrals.<sup>132</sup> And even where the physician's salary or bonus seems independent of the value of referrals, Stark may nevertheless be violated if the compensation greatly exceeds the fair market value of the physician's services.<sup>133</sup>

In the context of vertical integration, the Stark and anti-kickback laws are inappropriate and antiquated. Health care entities undertaking integration are provided assurances under the employee exception, for example, yet case law has significantly restricted the exception and placed these entities in a very uncertain regulatory environment.<sup>134</sup> The broad prohibitions and their respective exceptions can become extraordinarily difficult to navigate on a practical level; these laws may pose serious obstacles to comprehensive vertical integration and must be carefully considered in its planning and execution.

The anti-kickback statute's purpose is "to protect patients and the federal healthcare programs from fraud and abuse by curtailing the corrupting influence of money on health care decisions."<sup>135</sup> Stark's purpose, similarly, is:

to prevent overutilization by prohibiting a physician from making a referral for certain services to an entity with whom the physician has a compensation arrangement or ownership interest except in certain situations, and to ensure that physicians' medical judgments are not compromised by improper financial incentives and are based solely on the best interests of the patient.<sup>136</sup>

The concern underlying both of these laws is generally that physicians may refer patients for unnecessary services (driving up costs to the federal government and to the health care system as a whole) or they may refer to certain providers or facilities for self-interested financial reasons,

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<sup>132</sup> Peter W. Chatfield and Timothy P. McCormack, *The lurking risks of hospital-employed physicians: Stark, Anti-Kickback and False Claims Act compliance*, Healthcare Finance News, Mar. 25, 2014 available at <http://www.healthcarefinancenews.com/blog/lurking-risks-hospital-employed-physicians-stark-anti-kickback-and-false-claims-act-compliance>.

<sup>133</sup> *Id.*

<sup>134</sup> Susan O. Scheutzow and Steven A. Eisenberg, *The Employee Exceptions to the Anti-Kickback and Stark Laws After Tuomey: What's a Physician's Employer to Do?*, 4 J. of Health & Life Sci. L. 146, 148, Feb. 2011 ("...recent interpretations of the Employee Exceptions in *Tuomey* and other cases and settlements may limit the traditional applicability of these Exceptions severely, placing healthcare providers and their counsel in the precarious position of not knowing the extent of protection the Employee Exception offers. ... The uncertainty not only creates concern for past arrangements, but also may impact the development of innovative healthcare delivery models...").

<sup>135</sup> Office of Inspector Gen., *Fact Sheet: Federal Anti-Kickback Law and Regulatory Safe Harbors* (Nov. 1999).

<sup>136</sup> Scheutzow *supra* note 134 at 160, n.21.

as opposed to making decisions solely based on the best interest of the patient.

These are genuine concerns in the present, fragmented health care system. A physician could have a financial interest in a laboratory that provides certain services, and she could then refer patients to that lab for services even when not medically necessary. Or a hospital could purchase a physician practice to obtain its referrals of patients and increase its revenue, rather than for purposes of better clinical integration or improved coordination of patient care and outcomes. These laws help protect against such overutilization, fraud, and abuse, and they might arguably serve an important role in the present disjointed system of care.

But in light of vertical integration, the Stark and anti-kickback laws no longer make sense. As noted above, both of these laws contain an exception for employment arrangements, including a health care system's employment of physicians. But the narrow interpretation of these exceptions leaves much uncertainty for providers.<sup>137</sup> The difficulty here is that part of the reason for vertical integration is to put in place novel and radically different compensation and care arrangements; to fundamentally change and restructure who is providing what care.

A vertically integrated system, taking a holistic approach, needs the flexibility to reimburse different entities providing care based on very different business models. The integrated system might employ physicians and provide them with a base salary, but also put in place certain incentive or bonus payments for achieving quality measures. The physicians might refer patients to the integrated system's own hospital for inpatient or outpatient services, or to other facilities, such as for physical therapy or laboratory services. As discussed above, some of these arrangements may violate the Stark and anti-kickback laws. However, these restrictions should not be applicable – the same concerns are simply not present in a vertically integrated entity. The physician and the employing entity have the aligned economic interests; there is no reason to think that a salaried physician would not be making decisions in the best interests of her patients, even with additional incentive payments for quality.

To explain this point another way: in the current fee-for-service system, a physician is reimbursed more for providing more services; a provider has no incentive to control utilization. The Stark and anti-kickback laws may play a legitimate role here. In a vertically integrated

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<sup>137</sup> Scheutzow *supra* at 166 (The government's position "that a healthcare provider cannot even consider ancillary service revenue when determining whether to employ a physician ... is ridiculous in the realities of modern healthcare delivery.").

system, in contrast, an individual physician has no financial incentive to refer for unnecessary services. Further, the system as a whole receives a set amount of payment to provide all the care its members need – essentially a capitation arrangement – and has an economic incentive to control utilization. The fraud and abuse laws do not serve any purpose here.

Stark and anti-kickback were designed for an era of independent physicians with ownership interests in certain facilities and services, and out of a concern that hospitals might be buying referrals – concerns and facts that are absent with vertical integration. In general, laws that seriously restrict innovative compensation arrangements will reduce the incentive to vertically integrate and will reduce the benefits for any entity that undertakes it. As with antitrust, these laws may make sense in the current fragmented context, but not necessarily in an integrated system.

### *B. State Legal Issues*

#### **1. Powers of HMOs**

Some of the federal legal issues can be the most complex and unclear, and they may also contain the most serious consequences if not handled appropriately throughout a transaction. However, with certain exceptions like those discussed above, states have traditionally played the primary role in regulating the health care industry. State laws and regulations may introduce an additional layer of complexity because every state's regulatory framework is different.

A plethora of state regulations that govern the practice of medicine and various aspects of the health care industry might be implicated in studying vertical integration. A few, however, are particularly important to entities considering this business strategy. A logical starting point might be any laws that expressly permit or at least facilitate such integration.

Most states have a Health Maintenance Organization (“HMO”) Act,<sup>138</sup> passed several decades ago when HMOs were rising in popularity as a way to control medical costs. State HMO laws proliferated after Congress passed the HMO Act of 1973 to encourage the development of HMOs.<sup>139</sup> The original idea, at least with a staff-model HMO, was that the same entity would provide insurance and also operate hospitals and employ physicians, thereby giving the entity the power and scope to align

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<sup>138</sup> P.P. Cooper and K. Green, *The impact of state laws on managed care*, 10 Health Affairs no.4, 161 (1991).

<sup>139</sup> 42 U.S.C. § 300e.

everyone's financial incentives and curb rising medical costs. This is a more limited version of the vertical integration discussed throughout this paper, but it is an initial step in the same direction. For a variety of reasons, it did not quite work as planned,<sup>140</sup> but these laws are generally still in place<sup>141</sup> and payors need to obtain an HMO license if they want to offer an HMO product (distinct from an insurance license to offer an insurance product). Illinois, for example, has an HMO Act that is representative of the law in many states. This Act grants specific powers to HMOs, including the power to purchase or operate hospitals and to furnish health care services, and the power to directly employ providers.<sup>142</sup>

HMOs have changed dramatically in concept over the past few decades. As noted above, the initial idea was the "pure" staff-model HMO, which would serve as a single all-encompassing entity: it would provide medical care and it would assume complete financial risk. But over the years, the concept of an HMO became much more watered down as it was absorbed into the fragmented universe of modern health care.<sup>143</sup> Even by the close of the century, less than 1 percent of HMO enrollees in the US were in staff-model plans, and only 8 HMOs (just 1.2 percent) out of several hundred in the United States were staff-model plans.<sup>144</sup>

Instead of offering a fundamentally different business and risk model and a chance to curb rising medical costs, HMOs have become a simple variation on traditional networks. An insurance company will typically offer an HMO as an alternative to a PPO or other product, but in either case it has to contract with external providers and does not employ them directly. Some of the major differences are that an HMO plan (1) generally has a narrower network of physicians; (2) often structures the reimbursement as capitation rather than fee-for-service; (3) imposes little to no cost-sharing on an enrollee if she receives services in-network, but provides no benefits at all if the enrollee receives services out of network; and (4) requires an enrollee to designate a primary care physician (who acts as gatekeeper) and to receive a referral from this primary care physician to

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<sup>140</sup> See, e.g., Jan Gregoire Coombs, *The Rise and Fall of HMOs: An American Health Care Revolution* (Madison: University of Wisconsin Press 2005).

<sup>141</sup> *Managed Care State Laws and Regulations, Including Consumer and Provider Protections*, National Conference of State Legislatures, Sept. 2011, available at <http://www.ncsl.org/research/health/managed-care-state-laws.aspx>.

<sup>142</sup> 215 ILCS 125/2-3.

<sup>143</sup> Karen L. Trespacz, *Staff-Model HMOs: Don't Blink or You'll Miss Them!*, *Managed Care*, July 1999 ("The staff model used to define the HMO. Now it's almost gone.").

<sup>144</sup> *The Interstudy Competitive Edge: HMO Industry Report 9.1*, Interstudy Publications, Minneapolis, 1999.

see any specialists.<sup>145</sup> These factors separate HMOs from PPOs as product offerings and contracted networks, but they are worlds apart from the original staff-model concept.

HMO laws are a critical starting point in the analysis because they enable any entity with an HMO license to undertake full-scale vertical integration. In some cases, a health insurance issuer may already have an HMO license and could therefore begin acquiring hospitals and other health care facilities, and could similarly begin hiring physicians and other professionals. On the flip side, a large provider system might acquire an HMO license and begin offering plans under this license. In either case, such laws should be analyzed in the relevant state, as they could help to provide a solid foundation for integration efforts. The regulatory framework in health care is nearly an unnavigable labyrinth for any entity that vertically integrates, but the HMO laws may at least provide a small but serendipitous shortcut.

## 2. Corporate Practice of Medicine

While an HMO law, if wielded properly, may help facilitate vertical integration, a number of state laws pose daunting obstacles. One such obstacle could be a state's corporate practice of medicine ("CPM") doctrine. The CPM doctrine prohibits a corporation from practicing medicine or employing a physician to provide professional medical services. Some states, including Illinois, have carved out certain corporate employers as exceptions to the CPM prohibition, such as hospitals, health maintenance organizations, and professional corporations.<sup>146</sup> The rationale behind the CPM is based on public policy considerations: if corporations were to employ physicians, the concern is that the relationship "tends to the commercialization and debasement" of the profession,<sup>147</sup> undermines the physician-patient relationship and the physician's exercise of independent medical judgment,<sup>148</sup> and causes corporations to inappropriately intrude into the practice of medicine because they are not licensed and not subject to the same professional standards and regulations as licensed entities.<sup>149</sup>

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<sup>145</sup> See 21 Ill. Prac., The Law of Medical Practice in Illinois § 13:2, 13:5 (3d ed.) (2014).

<sup>146</sup> *Corporate Practice of Medicine*, American Health Lawyers Association, Aug. 10, 2012, available at [http://www.healthlawyers.org/hlresources/Health Law Wiki/Corporate Practice of Medicine.aspx](http://www.healthlawyers.org/hlresources/Health%20Law%20Wiki/Corporate%20Practice%20of%20Medicine.aspx); *Berlin v. Sarah Bush Lincoln Health Ctr.*, 179 Ill.2d 1 (Ill. 1997).

<sup>147</sup> *Barton v. Codington Country*, 2 N.W. 2d 337, 346 (S.D. 1942).

<sup>148</sup> See *Garcia v. Texas State Bd. of Med. Exam'rs*, 384 F. Supp. 434, 438-39 (W.D. Tex. 1974).

<sup>149</sup> See *State v. Boren*, 219 P.2d 566, 570 (Wash. 1950).

Since states may take very different approaches to the CPM doctrine – from strictly enforcing it to completely disregarding it – it may be more helpful here to study a single state’s approach in a bit more detail. Illinois, for example, may serve as a representative middle ground: it has a statutory and common law prohibition against CPM, but it also has several exceptions, and the Illinois Supreme Court has recently weighed in on the extent to which this doctrine should apply.

The statutory basis for the doctrine in Illinois is the Medical Practice Act of 1987 (“Medical Practice Act”), which prohibits the practice of medicine by an individual without a license.<sup>150</sup> Since a corporation or other entity may not obtain a medical license, Illinois courts have determined that it logically follows that a corporation cannot practice medicine – which also means the corporation cannot employ anyone who practices medicine, as it would exercise control over the physician’s decisions. In one of the early leading cases, the Illinois Supreme Court explained: “The qualifications [to practice a profession] include personal characteristics, such as honesty, guided by an upright conscience and a sense of loyalty to clients or patients, even to the extent of sacrificing pecuniary profit, if necessary... No corporation can qualify.”<sup>151</sup> However, the Medical Practice Act specifically allows four business forms to directly employ physicians: (1) partnerships, (2) medical or professional service corporations, (3) limited liability companies, and (4) professional associations.<sup>152</sup>

The CPM doctrine in Illinois (as in most states) is judicially-created, and its courts have carved out four practice arrangements that do not violate the prohibition against CPM: (1) HMOs, (2) limited health service place, (3) voluntary health service plans, and (4) employment by a hospital. For example, in *Berlin v. Sarah Bush Lincoln Health Center*, the Illinois Supreme Court held that the state’s Hospital Licensing Act implicitly allowed licensed hospitals to employ physicians. The Court declared in its explanation:

“The Medical Practice Act contains no express prohibition on the corporate employment of physicians. Rather, the corporate practice of medicine doctrine was inferred from the general policies behind the Medical Practice Act. ... Such a prohibition is entirely appropriate to a general corporation possessing no licensed authority to offer medical services to the public. ... However, when a corporation has

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<sup>150</sup> 225 ILCS 60/3 and 60/3.5.

<sup>151</sup> *Dr. Allison, Dentist, Inc. v. Allison*, 360 Ill. 638, 196 NE 799 (Ill. 1935).

<sup>152</sup> 225 ILCS 60/54.

been sanctioned by the laws of this state to operate a hospital, such a prohibition is inapplicable... The foregoing statutes clearly authorize, and at all times mandate, licensed hospital corporations to provide medical services. We believe that the authority to employ duly-licensed physicians for that purpose is reasonably implied from these legislative enactments.”<sup>153</sup>

Thus, if an entity wanted to vertically integrate in Illinois, it might be able to do so without violating the CPM doctrine. In that state, hospitals and HMOs can directly employ physicians. In other states, the CPM doctrine may be more strictly applied.<sup>154</sup> Various strategies may allow an entity to achieve the same goal through other means. In California, for example, hospitals may establish medical foundations – which are grounded in state law – to buy the assets of physician practices. The foundation contracts with the physician group and holds the health plan contracts, while a professional services agreement ties each party to the other. The medical group provides the employment relationship.<sup>155</sup> Thus, where the CPM doctrine is applicable, alternative approaches may provide a viable path to integration.

However, regardless of whether an entity can take advantage of a straightforward exception – or circumnavigate the doctrine through various creative and increasingly burdensome schemes – the CPM doctrine is a relic of another era. To put it in more colorful terms, the doctrine “is a remnant of a time when doctors with black bags made house calls, and hospitals were a place where people went to be ‘bled’ and to die.”<sup>156</sup> Many commentators have argued that the prohibition against CPM no

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<sup>153</sup>Berlin v. Sarah Bush Lincoln Health Ctr., 179 Ill.2d 1, 16-17 (Ill. 1997).

<sup>154</sup>See, e.g., Cal.Bus. & Prof.Code § 2400 (“Corporations and other artificial legal entities shall have no professional rights, privileges or powers.”) and *People v. Cole*, 135 P.3d 669, 672 (Cal. 2006) (“In general, under California’s long-standing ‘policy ... against [the] corporate practice of the learned professions,’ for-profit corporations ‘may not engage in the practice of ... medicine’ [citation omitted]. The ban on the corporate practice of medicine generally precludes for-profit corporations – other than licensed medical corporations – from providing medical care through either salaried employees or independent contractors.”); NY Educ. Law § 6522 (“Only a person licensed or otherwise authorized under this article shall practice medicine.”) and *People v. John H. Woodbury Dermatological Inst.*, 85 N.E. 697 (N.Y. 1908) (The use of the word “person” in the physician licensing statute means that a corporation may not practice medicine. Corporations may not employ licensed professionals to practice medicine.); *Gupta v. E. Idaho Tumor Inst., Inc.*, 140 S.W.3d 747, 752 (Tex. App. 2004) (“Under the Medical Practice Act, when a corporation comprised of lay persons employs licensed physicians to treat patients and the corporation receives the fee, the corporation is unlawfully engaged in the practice of medicine.”).

<sup>155</sup>Debra A. Draper, Robert A. Berenson, et al., *A Tighter Bond: California Hospitals Seek Stronger Ties with Physicians*, Issue Brief, California Health Care Almanac, Dec. 2009.

<sup>156</sup>Nicole Huberfeld, *Be Not Afraid of Change: Time to Eliminate the Corporate Practice of Medicine Doctrine*, 14 Health Matrix 243, 244 (2004).

longer makes sense even in today's health care construct;<sup>157</sup> the doctrine certainly should not be applicable to the innovative operations of a vertically integrated system.

By prohibiting corporations from employing physicians, the doctrine was designed to protect the physician-patient relationship and ensure that the corporation does not inappropriately influence or restrict the physician's judgment. But the doctrine "reaches much farther than delivery of medical care; it also relates to payment for medical services, management of medical practices, employment and engagement of physicians, patient relations, and more."<sup>158</sup> This could seriously interfere with the operations of a thoroughly integrated system. And as some states have recognized, the CPM doctrine does not make sense as a blanket prohibition. The most straightforward argument against CPM is the existence of a hospital, an institution licensed and even required by law to provide medical care for patients – what sense does it make to prohibit a hospital from employing physicians? In more novel arrangements that may result from vertical integration, the CPM doctrine could require entities to set up burdensome and complex business structures, adding a tremendous amount of unnecessary cost and imposing constraints that make it more difficult to achieve integration and related goals.

### 3. State Regulatory Approval of Transactions

Another potential obstacle at the state level to vertical integration is required regulatory consent or approval of certain corporate transactions. Most states have requirements that the attorney general be notified of a proposed transfer of a non-profit corporation's assets,<sup>159</sup> for example, and certain types of transactions require approval of the state attorney general or another regulatory agency.<sup>160</sup> States may also require the attorney general to work with the state's Department of Insurance, Department of Health, or other administrative agency to grant formal approval to a pro-

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<sup>157</sup> See, e.g., Huberfeld, *supra* note 156; see also Jeffrey F. Chase-Lubitz, *The Corporate Practice of Medicine Doctrine: An Anachronism in the Modern Health Care Industry*, 40 Vand L Rev 445 (1987); Adam M. Freiman, *The Abandonment of the Antiquated Corporate Practice of Medicine Doctrine: Injecting a Dose of Efficiency Into the Modern Health Care Environment*, 47 Emory LJ 697 (1998); Sara Mars, *The Corporate Practice of Medicine: A Call For Action*, 7 Health Matrix 241 (1997).

<sup>158</sup> Huberfeld, *supra* note 156, at 244-45 ("In increasingly integrated health care delivery systems, the corporate practice of medicine doctrine does nothing to improve quality, efficiency, or accountability.").

<sup>159</sup> See, e.g., Cal Corp Code § 5914 (2003) (California); Gen Laws 1956, § 23-17.14-7 (2013) (Rhode Island); RC § 109.34 (2014) (Ohio).

<sup>160</sup> *Id.*

posed deal, or else it cannot proceed.<sup>161</sup> One state even requires approval from all three regulators.<sup>162</sup> Obtaining state regulatory approval can delay a transaction for months; it can even ultimately derail it, even in the absence of any official denial of permission to proceed.<sup>163</sup>

Even if a state grants approval to a transaction, it may require the parties seeking approval to meet an onerous list of conditions. For example, in Rhode Island, Prime Healthcare Services – which acquires and turns around financially struggling community hospitals – recently sought and received approval from the state’s Department of Health to purchase facilities on the verge of bankruptcy.<sup>164</sup> The Department of Health, however, imposed a number of conditions on Prime in its acquisition, from financial commitments to quality benchmarks.<sup>165</sup> According to an M&A consultant involved in that sale, “it’s not unusual for attorneys general to attach conditions to a deal” – and the consultant described Rhode Island’s conditions as ‘tame,’ in contrast to the terms imposed in some other states, such as New Jersey.<sup>166</sup>

In addition, states may have entirely separate requirements to provide notice to agencies. Under the Illinois Insurance Code, for example, if an insurer proposes the acquisition of a non-insurance entity, such as a health care provider, the insurer would not need to seek approval from a regulatory agency, but it would be required to notify the DOI at least 30 days in advance whenever it acquires an ownership interest that exceeds a certain threshold.<sup>167</sup> Specifically:

“The Director shall be notified within 30 days of any investment of the domestic insurer in any one corporation if the total investment in that corporation by the insurance holding company system exceeds 10% of that corporation’s voting securities.”<sup>168</sup>

<sup>161</sup> See, e.g., Cal Corp Code § 5914 (2003) (California); Gen Laws 1956, § 23-17.14-7 (2013) (Rhode Island); RC § 109.34 (2014) (Ohio).

<sup>162</sup> In Wisconsin, parties must obtain approval from the attorney general, the Commissioner of Insurance, and the Department of Health and Family Services. Wis. Stat. Ann. § 165.40.

<sup>163</sup> See, e.g., Lindsay Tice, *Central Maine Healthcare halts effort to take over Parkview medical center in Brunswick*, Sun Journal, Oct. 1, 2013 (“Central Maine Healthcare has withdrawn its application ... saying state regulators aren’t playing fair and are ‘inexplicably but undeniably committed to denying this application.’”).

<sup>164</sup> Beth Kutscher, *R.I. slaps conditions on Prime acquisition amid Calif. controversy*, MODERN HEALTHCARE, Dec. 27, 2013, available at <http://www.modernhealthcare.com/article/20131227/NEWS/312279965/%7B%7BbuttonURL%7D%7D>

<sup>165</sup> *Id.*

<sup>166</sup> *Id.*  
<sup>167</sup> 215 ILCS 5/131.20a.

<sup>168</sup> 215 ILCS 5/131.20a(e).

Moreover, if the insurer were acquiring a non-profit hospital, it would need to obtain approval from the attorney general, as noted previously.<sup>169</sup> Other states may have additional or unique notice or approval requirements.

Some states may specifically require a party to obtain a certificate of need (“CON”) to build a new health care facility, or even to effect a transfer of ownership of such a facility. A CON is an official document that a state regulatory agency issues to affirm that there is a legitimate need to build or expand a health care facility; the purpose of requiring a CON is to eliminate unnecessary duplication of services.<sup>170</sup> These legal constructs began to arise in the 1960s, when New York was the first state to institute such a process,<sup>171</sup> and then became mandatory when Congress passed a federal law in 1974 requiring all states to have CON processes in place.<sup>172</sup> States followed suit, and the federal law was repealed in 1987 – as a result, a number of states repealed their own CON statutes.<sup>173</sup> A total of 36 states still have some form of CON law in place.<sup>174</sup>

In Illinois, for example, the Health Facilities Planning Act requires parties to obtain a CON to build or expand a health care facility or to acquire certain equipment.<sup>175</sup> The statute states: “No person shall construct, modify or establish a health care facility or acquire major medical equipment without first obtaining a permit or exemption from the State Board.”<sup>176</sup> The State Board referred to here is the Health Facilities and Service Review Board, created under the Illinois Department of Public Health.<sup>177</sup>

A large company undertaking a dramatic program of vertical integration could elect to either acquire an existing hospital or health system or build one from scratch. An insurance company, a retail store (e.g., Walgreens, CVS, or Wal-Mart), or any other large corporation going down this path, for example, might choose to purchase an existing hospital, since it would be entering a new and somewhat unfamiliar line of business. Alternatively, the company may have sufficient capital (and be sufficiently

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<sup>169</sup> 760 ILCS 55/15.5(a).

<sup>170</sup> 41 CJS Hospitals § 8.

<sup>171</sup> *Certificate of Need: State Health Laws and Programs*, National Conference of State Legislatures, Nov. 2013, available at <http://www.ncsl.org/research/health/con-certificate-of-need-state-laws.aspx> (hereinafter “NCSL CON laws”).

<sup>172</sup> National Health Planning and Resources Development Act of 1974, 88 Stat. 2225.

<sup>173</sup> NCSL CON laws, *supra* note 172.

<sup>174</sup> *Id.*

<sup>175</sup> 20 ILCS 3960/1 (2012). et seq.

<sup>176</sup> 20 ILCS 3960/5 (2012).

<sup>177</sup> 20 ILCS 3960/3 (2012).

bold) to build an attractive and modern brand new facility. In the same vein, a large hospital system may want to acquire additional facilities, an ambulatory surgery center, or retail clinics to integrate further, or it may simply build or expand.

An acquisition or transfer of ownership might appear to be a more straightforward regulatory proposal: the State Board in Illinois is required to approve an exemption when the requisite information is submitted.<sup>178</sup> A change in ownership of a health care facility is expressly listed as a “project eligible for an exemption” (as opposed to a project requiring a permit).<sup>179</sup> In other states, however, even a simple change of ownership could face regulatory hurdles. In New York, the CON application may need to receive a recommendation from local health systems agencies (if applicable), and it must receive a recommendation from the Department of Health Staff and the Public Health and Health Planning Council Establishment and Project Review Committee.<sup>180</sup> After this, the Public Health and Health Planning Committee makes a final decision to approve or deny the CON.<sup>181</sup> To construct a new facility in New York, the company would have to proceed through all the prior regulatory bodies, and also receive approval from the Commissioner of Health.<sup>182</sup> These are a lot of hoops through which the entity must successfully jump – a costly process for an ultimately uncertain outcome.

One additional question in states that have CON restrictions is that of scope: which health care facilities are subject to the requirements? Illinois, for example, requires a CON permit or exemption for ambulatory surgical centers and hospitals, though not for a retail clinic or physician’s office.<sup>183</sup> Other states may have more regulatory oversight and require even entities like retail clinics to satisfy the CON process.<sup>184</sup> In states that do subject retail clinics to CON scrutiny, they may fail because they do not

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<sup>178</sup> 20 ILCS 3960/6(b) (2012).

<sup>179</sup> *Id.*; see also 77 Ill. Adm. Code 1130.410.

<sup>180</sup> *The CON Process*, Department of Health, New York State, May 2009, available at [http://www.health.ny.gov/facilities/cons/more\\_information/process.htm](http://www.health.ny.gov/facilities/cons/more_information/process.htm).

<sup>181</sup> *Id.*

<sup>182</sup> *Id.*

<sup>183</sup> 20 ILCS 3960/3 (2012).

<sup>184</sup> Kentucky, for example, requires a certificate of need for limited service clinics, including retail clinics. KRS § 216B.065. Other states similarly impose CON requirements on outpatient facilities; see, e.g., *State Health Planning & Dev Agency v. Baptist Health System, Inc.*, 766 So. 2d 176 (Ala. Civ. App. 1999) (rural health clinic); *Auburn Med Ctr, Inc. v. East Ala Health Care Auth.*, 847 So. 2d 942 (Ala. Civ. App. 2001) (ambulatory surgical center).

provide new services as much as they offer simple existing services in a lower-cost venue.<sup>185</sup>

Many have argued that CON laws are inappropriate even in our current fragmented health care system, another regulatory relic of a bygone era.<sup>186</sup> The CON approval process is inevitably subjective and heavily political,<sup>187</sup> as some projects get approved even when applicants do not fully satisfy the CON review criteria or the community still has excess unused capacity,<sup>188</sup> while other projects get denied even when the CON review criteria are fully met or the community genuinely needs additional health care services.<sup>189</sup> Even the Department of Justice and Federal Trade Commission have criticized some states' CON laws, alleging that they "undercut consumer choice, stifle innovation and generally have failed to keep health care costs down."<sup>190</sup> State and federal governments are working at cross-purposes.

Regardless of whether CON laws were ever appropriate in a fragmented system of care, they are entirely inappropriate as applied to a verti-

<sup>185</sup> Kaj Rozga, *Retail Health Clinics: How the Next Innovation in Market-Driven Health Care is Testing State and Federal Law*, 35 Am. J.L. & Med. 205, 216 (2009).

<sup>186</sup> See, e.g., Grant D. Bosse, *Irrational: Do Certificate of Need laws reduce costs or hurt patients?* Policy Matters, Feb. 2012 (arguing that experience has shown that CON laws do not control costs but provide a significant barrier to entry to innovative health care facilities and limit competition); Patrick John McGinley, *Beyond Health Care Reform: Reconsidering Certificate of Need Laws in a "Managed Competition" System*, 23 FLA. ST. U. L. REV. 141 (1995) (arguing that the reasons and rationale justifying CON laws no longer exists, and that these laws should be repealed); Lowell M. Zeta, *Fundamental First Steps Along the Road to Health Care Reform: Eliminating the Bureaucratic Burdens of Certificate of Need Programs and Embracing Market Competition to Improve State Health Care Systems*, 41 CREIGHTON L. REV. 727 (2008) (arguing states should abandon CON regulations because they have failed to control costs and stifled quality improvements to health care).

<sup>187</sup> "In its nearly 40-year history, the board has seen more than its share of corruption and political scandal ... critics blast the facilities board as a relic of a bygone health care environment that has outlived its usefulness." Andrew L. Wang, *State decisions on Mercy, Centegra renew questions on certificates of need*, Crain's Chicago Business, Sept. 13, 2012, available at <http://www.chicagobusiness.com/article/20120913/NEWS03/120919878/state-decisions-on-mercy-centegra-renew-questions-on-certificates-of-need>.

<sup>188</sup> McGuireWoods, *Illinois Certificate of Need: A New Majority of Five*, at <http://www.mcguirewoods.com/Client-Resources/Alerts/2010/6/Illinois-Certificate-of-Need-A-New-Majority-of-Five.aspx> (last updated June 2, 2010) ("Board members often approve projects even though the applicants fail to fully satisfy the CON review criteria. This outcome occurs when enough Board members make a subjective analysis of a project, and for reasons independent of the CON review criteria, decide that a project is necessary."). See also *Provena Health v. Ill Health Facilities Planning Bd*, 382 Ill App 3d 34, 42 (Ill App 2008) (holding that Board had the authority to issue the CON even though the hospital application did not conform to all of the pertinent review criteria).

<sup>189</sup> See, e.g., *Access Ctr for Health, Ltd. v. Ill Health Facilities Planning Bd*, 283 Ill App 3d 227 (1996) (holding that the Board's denial of a CON application was not arbitrary and capricious even when it relied on a factor which the legislature had not intended the Board to consider, when the record lacked required documentation, or when it went against the recommendation of the Department of Public Health).

<sup>190</sup> Amy Lynn Sorrel, *Certificate-of-need law in Illinois slammed by feds, AMA*, American Medical News, Oct. 6, 2008, at <http://www.amednews.com/article/20081006/government/310069982/6/> (last updated Oct. 6, 2008.).

cally integrated system. The purpose behind vertical integration as proposed in this paper is not merely to mash together a payor, a hospital system, and physicians into an amalgamated corporate entity where nothing changes other than the ownership – though even if nothing more than this took place, it would still be enormously advantageous in aligning financial incentives and coordinating better care. Rather, the deeper purpose is once these parties (along with many more, such as labs, retail clinics, medical device manufacturers, and pharmacies) are joined under a single roof, the organization can then (and only then) fundamentally restructure way health care is provided and delivered. Patients with different types of diagnostic and treatment needs can be steered into very different types of care that operate through entirely different businessmodels.

The implications of this are that overly simplistic analyses of the number of hospital beds in a geographic area are completely irrelevant in evaluating the usefulness of a vertically integrated system. Under a CON regime, such a system might be blocked from strategic acquisitions or from building new facilities because the community has unused “beds” or a small group of people, subject to political pressures if not corruption, determines the community’s needs to be sufficiently met. Yet the benefits of vertical integration are incalculable and go far beyond merely providing additional services that are essentially more of the same – it would involve providing these services in a new way, and providing new and unprecedented services that did not previously exist.

#### 4. State Insurance Laws

State regulators impose benefit mandates on health insurance issuers, requiring them to cover either specific services or certain underlying conditions or diagnoses. For example, Illinois requires coverage for the inpatient treatment of alcoholism,<sup>191</sup> the diagnosis and treatment of autism spectrum disorders for individuals under age 21,<sup>192</sup> and all outpatient contraceptive services, drugs and devices approved by the Food and Drug Administration.<sup>193</sup> Illinois has several dozen such benefit mandates, and it is far from atypical in this regard.<sup>194</sup> In all 50 states, there may be more

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<sup>191</sup> 215 ILCS 5/367(7) (2012).

<sup>192</sup> 215 ILCS 5/356z.14 (2012).

<sup>193</sup> 215 ILCS 5/356z.4; 215 ILCS 125/5-3 (2012).

<sup>194</sup> *Mandated Benefits, Offers, and Coverages for Accident & Health Insurance and HMOs*, Illinois Department of Insurance, at [http://insurance.illinois.gov/HealthInsurance/Mandated\\_benefits.asp](http://insurance.illinois.gov/HealthInsurance/Mandated_benefits.asp) (last updated Jan. 2012).

than 2,200 such statutory benefit mandates.<sup>195</sup> The federal government, too, has established minimum requirements for a more comprehensive health insurance product in certain market segments. The Affordable Care Act sets forth ten mandatory categories in its “essential health benefits” requirements;<sup>196</sup> the relevant regulations establish a baseline but defer to states to create an essential health benefits package, for which all non-grandfathered individual and small group policies must provide coverage.<sup>197</sup>

Furthermore, under both state and federal laws, insurers must provide myriad notices and explanations of benefits to consumers,<sup>198</sup> offer adequate provider networks,<sup>199</sup> provide rebates when their medical loss ratio is below a certain threshold,<sup>200</sup> establish processes governing internal claims and appeals and external review,<sup>201</sup> and so forth. Implicit assumptions and policy goals underlie these laws: legislators’ and regulators’ concerns include ensuring consumers receive due process in appealing claims, accurate claim adjudication, an expansive and liberal view of benefit determinations, ensuring consumers have sufficient information to make informed decisions, limiting corporate profits, insolvency, and keeping insurance premiums low, among other things. The overarching theme seems to be protecting consumers.

To take health insurance benefit mandates as a particular example of a problematic regulation: the difficulty is that they are set in stone and frozen in place, while technology and business models are fluid. This is a problem even in the disjointed health care system we have today – but it is less of a problem, because the system’s patchwork nature assures that business models will generally be static and will not change rapidly. An integrated system, on the other hand, has the power and scope to scrap older technology and outdated business models and to implement brand new ones, and benefit mandates are therefore a weighty albatross.

A more concrete example may help clarify this point: today, stand-alone hospitals provide inpatient care, but they are monumental and ex-

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<sup>195</sup> *State Health Insurance Mandates and the ACA Essential Benefits Provisions*, National Conference of State Legislatures, at <http://www.ncsl.org/research/health/state-ins-mandates-and-aca-essential-benefits.aspx> (last updated Jan. 2, 2014).

<sup>196</sup> 42 USC § 300gg-6(a) (2006).

<sup>197</sup> 45 CFR § 156.100 (2013) et seq.

<sup>198</sup> See, e.g., 26 USC § 4980B and 26 CFR § 54.4980B-1 to B-8 (requirements to provide COBRA notices of continuation of coverage); 42 USC 300gg-15 and 45 CFR 147.200 (requirements to provide summaries of benefits and coverage under the Affordable Care Act); 29 USC § 1133(1) and 29 CFR § 2560.503-1(g)(1) (requirements to provide explanations of benefits for any adverse benefit determination).

<sup>199</sup> 50 Ill. Adm. Code 2051.310.

<sup>200</sup> 42 USC 300gg-18 (2006); 45 CFR Part 158 (2013).

<sup>201</sup> 42 USC 300gg-19 (2006); 45 CFR § 147.136 (2013).

traordinarily expensive physical structures with enormous inertia. They have a business model that is dependent on filling beds to the greatest extent possible and maximizing their reimbursement for doing so. To the extent new technology allows for a shift away from inpatient beds to outpatient care, or to a physician's office, the hospital would naturally resist; this fragment of the system has ossified. Similarly, new technology could ensure greater reliability and safer results for a given procedure, allowing for a shift away from highly trained expert physicians to health care professionals with less extensive training, or even to patient self-care at home (e.g., blood glucose monitoring equipment and insulin injections, which patients with diabetes self-administer). When technology permits bypassing physicians, physicians would naturally resist. Laws that require a patient to continue receiving care through an expensive venue mean that new, innovative, less expensive technology will wither or be absorbed into the more expensive venue.

Insurance benefit mandates require coverage for specific services, sometimes in specific settings by specific professionals. In a fragmented system, requiring insurance coverage for expensive inpatient hospital care when a patient could otherwise be safely and effectively treated in an outpatient setting – or requiring a physician provide care when a nurse practitioner or trained technician could safely and effectively do the same thing – increases overall costs and slows down or destroys innovation. But these mandates at least make some sense when a lot of isolated players are defending the status quo and preventing business model innovation anyway. In an integrated system, such mandates constitute shackles on the ability to restructure the way care is provided, which could otherwise lower costs, while improving both access and quality. The vertically integrated system – consisting of large hospitals, outpatient surgery centers, physician offices, retail clinics, pharmacies, and so forth – is free to steer patients away from more expensive venues of care and towards less expensive venues whenever it is clinically justifiable and rational to do so. The entity has no bias toward filling hospital beds or maximizing physician services. Such regulations impose an undue burden on the integrated entity, diluting its potential consumer benefits.

Other laws that govern insurers specifically exist to protect or benefit providers. States often have prompt pay laws, for example, which require that when a provider submits a 'clean claim' to a health insurance company, the insurer must pay the provider within a specified amount of

time, such as 30 or 45 days.<sup>202</sup> If an insurer fails to pay in a timely manner, it is subject to penalties, which are generally paid either to the provider or to the state.<sup>203</sup> The underlying policy goal here is to protect providers and ensure quick and full payment of claims. Several instances of delayed payments from insurers arguably make the case that these requirements are necessary.<sup>204</sup> What's unusual about these laws is that this is a straightforward arms-length transaction, and laws mandating a buyer (of any goods or services) pay a seller within a certain period of time are rare or nonexistent in almost any other industry. This is generally a contractual issue that private parties negotiate and agree to. Insurers are a special case who apparently cannot be trusted to pay in a reasonable period of time without an additional legal obligation.

Prompt pay requirements do not necessarily make sense even in the current system; there is no reason to treat insurers differently from any other business that purchases services. And even proponents of these laws concede that they are inadequate and largely ineffective.<sup>205,206</sup> But they almost inevitably must exist in our fragmented regulatory landscape; prompt pay is one of many attempts to referee the ongoing game between insurers and providers.

However, in a closed and vertically integrated system, the payor and all relevant providers are housed under one roof. Any physicians or other health care professionals are simply on staff as employees and are paid an hourly wage or an annual salary, or some other typical compensation structure. The concern behind prompt pay laws – insurers refusing to pay or delaying payment to providers, pending claims, etc. – simply evaporates.

Unfortunately, the situation is not quite this simple; it is not the case that prompt pay laws are simply inapplicable to an integrated payor-provider system, i.e., that they are merely superfluous but do no real harm. Rather, these laws could actively interfere with the operations and benefits of such a system. No matter how closed and integrated the system is, “leakage” will always exist. Members would still occasionally need to

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<sup>202</sup> 215 ILCS 5/368a. (2012).

<sup>203</sup> *Id.*

<sup>204</sup> *See, e.g.*, Susan Laccetti Meyers, *Insurers Fined \$400,000 for Tardy Pay*, Atlanta J. & Const., Jan. 25, 2002, at 1F.

<sup>205</sup> Michael Flynn, *The Check Isn't In the Mail: The Inadequacy of State Prompt Pay Statutes*, 10 DEPAUL J HEALTH CARE L 397, 407. 411 (2007) (“[T]his legislative solution [prompt pay statutes] is far from perfect. In fact, Prompt Pay statutes and regulations spawn more squabbles, pitting doctors against HMOs who quickly blame trial lawyers...”)

<sup>206</sup> *Id.* at 411 (“...[S]tatistics continue to show that health care providers are still not paid in a timely manner.”).

visit providers that are outside of the closed system, such as in an emergency or when the system lacks a particularly appropriate specialist, and it would then need to reimburse the provider. To this extent, prompt pay laws would still apply. Yet we are no longer dealing with the same entity; the game has changed, and it is not an isolated insurer but rather a thoroughly integrated health care delivery system making these payments. The concerns behind insurers' perceived tactics are not present, yet the restrictions would apply and the vertically integrated system would have to comply with antiquated and burdensome regulations or face steep financial penalties.<sup>207</sup>

One final example of state insurance regulation is "any willing provider" laws, which require managed care organizations and insurers to grant network participation to health care providers willing to join and meet network requirements.<sup>208</sup> From the perspective of the insurer, these laws restrict the insurers' ability to use a closed panel of physicians, hospitals, or other providers. Proponents of any willing provider laws – including many physicians – argue that these laws prevent discrimination against particular providers, and they protect the patient-physician relationship by safeguarding the patient's freedom of choice.<sup>209</sup> Opponents of these laws – including many HMOs and insurers – argue that these laws restrict their ability to freely contract, and that they therefore are prevented from lowering cost or improving quality.<sup>210</sup>

Illinois, for example, has two such laws; one is applicable to non-institutional health care providers, and the other is applicable to pharmacies.<sup>211, 212</sup> In either case, a health insurance issuer or third party administrator may not refuse to contract with any provider or pharmacy that meets the plan's terms and conditions. Several considerations follow from these laws in Illinois. First, they do not require contracting with institutional providers, such as hospitals. Second, even where the any willing provider laws do apply, the insurer or third party administrator may offer different levels of reimbursement as an incentive or disincentive for individual pro-

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<sup>207</sup> Some would even argue that payors should be subject to additional risk and liability: *see, e.g.*, Monica E. Nussbaum, *Prompt Pay Statutes Should Be Interpreted to Grant Providers a Private Right of Action to Seek Enforcement Against Payors*, 15 HEALTH MATRIX 205 (2005).

<sup>208</sup> Ashley Noble, *Any Willing or Authorized Providers*, National Conference of State Legislatures, *available at* <http://www.ncsl.org/research/health/any-willing-or-authorized-providers.aspx> (last updated Nov. 5, 2014).

<sup>209</sup> William J. Bahr, *Although Offering More Freedom to Choose, "Any Willing Provider" Legislation is the Wrong Choice*, 45 U.KAN.L.REV 557, 570 (1997).

<sup>210</sup> *Id.*

<sup>211</sup> 215 ILCS 5/370h (2014).

<sup>212</sup> 215 ILCS 134/72(a) (2014).

viders or pharmacies. This allows the health plan to maintain some degree of control over its networks.

In many ways, the any willing provider laws are similar to prompt pay laws discussed above: in the context of a vertically integrated system, neither of these regulatory constructs makes sense. A closed, integrated system would generally acquire and employ individual health care professionals, from physicians to pharmacists, as opposed to contracting with providers – yet the any willing provider laws speak only of contracting. To a large extent these laws would have no meaning. Again, however, the analysis does not end here.

The payor-provider system could not become thoroughly integrated and completely closed overnight – it would need to go about a strategic series of acquisitions and mergers that would take many years, if not decades. In the meantime, it may still need to contract with a number of different types of providers. Furthermore, to the extent that there is “leakage” and the system cannot be 100 percent closed, it would need to continue contracting with certain providers to ensure all of its members’ health care needs are fully met. However, any willing provider laws stem from the assumption that the way care is delivered currently is optimal, and the problem to be solved is simply eliminating potential discrimination among providers and ensuring freedom of choice for patients. The difficulty is that one of the main reasons for vertically integrating is to restructure and optimize the way care is provided. The ideal delivery system might consist of very few hospitals and a large number of retail clinics, for example. Requiring this type of innovative system to contract with every willing provider is troublesome and unhelpful.

These laws and many others in this regulatory framework are illogical with respect to a vertically integrated entity. An integrated payor-provider system is fundamentally different from two parties dealing at arm’s length. There is no more reason to think such a system would withhold or delay payment to its employees (whether physicians or any other individual health care professional) than any other business would. Likewise, there would be no reason to assume it might pay providers too little or provide too few services for enrollees. The policy concerns behind many of the existing laws and ‘protections’ – even if arguably rational and necessary in the gloom of the current fragmented health care environment – vanish in the light of a completely integrated system.

*C. Business Considerations***1. Legal Corporate Structure**

Beyond state and federal laws and regulations, vertical integration raises a host of quasi-legal business considerations. The most obvious and immediate consideration is that of legal structure: what form should the organization take? Should it ultimately be a single colossal corporate entity with a single board of directors overseeing everything? Or would it function better as separate interrelated and mutually dependent entities, each with its own board of directors? If separate, should the board of directors partially or completely overlap?

These are not just academic or theoretical questions. Other health care systems that have taken steps toward integration have faced these issues, and to a great extent state law may constrain their ultimate corporate form – and with it, their potential to integrate and achieve efficiencies.

For example, the Kaiser Permanente Medical Care Program (“Kaiser”) is one of the most well-known payor-provider systems. Upon closer inspection, Kaiser actually consists of three separate entities that cooperate under mutually exclusive contracts.<sup>213</sup> The Kaiser Foundation Health Plan, a nonprofit corporation, contracts with individual, group, and public purchasers of coverage to finance care, effectively operating as an insurer or payor.<sup>214</sup> Kaiser Foundation Hospitals, another nonprofit corporation, arranges for inpatient, extended, and home health care for health plan members in owned or contracted facilities.<sup>215</sup> It owns and operates 35 medical centers (hospitals with multi-specialty outpatient and ancillary services) in several states, as well as 431 outpatient medical office buildings to provide primary care, lab, radiology, and pharmacy services.<sup>216</sup> The health plan and the hospital system share a common board of directors,<sup>217</sup> which may give it a stronger and more cohesive governance structure for unified operations and decision-making authority.<sup>218</sup> Finally, the Permanente Medical Group consists of multi-specialty groups of physi-

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<sup>213</sup> Douglas McCarthy, Kimberly Mueller, and Jennifer Wrenn, *Kaiser Permanente: Bridging the Quality Divide with Integrated Practice, Group Accountability, and Health Information Technology*, Case Study, The Commonwealth Fund, Jun. 2009.

<sup>214</sup> *Id.*

<sup>215</sup> *Id.*

<sup>216</sup> *Id.*

<sup>217</sup> *Id.*

<sup>218</sup> See L R Burns, J Cacciamani, et al., *The Fall of the House of AHERF: The Allegheny Bankruptcy*, 19 HEALTH AFFAIRS 7, 21 (2000) (“[A]HERF suffered from a weak governance structure. ... it had a network of ten different boards responsible for its various operations (fifty-five different corporate entities) which had little overlap in their membership. Consequently, directors on one board reportedly were never sure what was happening elsewhere in the AHERF empire, thus making effective oversight impossible.”).

cians who accept a fixed payment to provide medical care exclusively for Kaiser health plan members in Kaiser facilities.<sup>219</sup> The reason for this tripartite organizational structure is that California follows the corporate practice of medicine doctrine and prohibits the direct employment of physicians. In order to achieve some degree of integration, Kaiser therefore set up foundations, which contract with the separate medical group.

Another example of California law impacting a corporate structure is the United Health Care acquisition of a physician group in recent years. United Optum, a division of United Health Care, purchased the management arm of Monarch HealthCare, an association in southern California of approximately 2,300 physicians practicing in a range of specialties.<sup>220</sup> Optum could not purchase and employ the physician group, again because of the corporate practice of medicine doctrine: rules in California prevent most entities from directly employing physicians.<sup>221</sup> Instead, a company like this “might buy non-clinical assets and sign a long-term management agreement with an independent practice association of physicians such as Monarch.”<sup>222</sup> It is important to note, for purposes of this paper, that this is far from complete vertical integration – it is not even an exclusive contract. The physicians that Optum acquired “will not work exclusively with United's health plan, and will continue to contract with an array of insurers.”<sup>223</sup> However, this demonstrates the unnecessary restrictions that state law can impose on an entity wishing to undergo even a relatively simple acquisition.

One of the few parties taking steps toward vertical integration at this time is Highmark, a health insurance company in Pennsylvania. In a recent transaction, Highmark acquired West Penn Allegheny Health System (“West Penn”), a troubled hospital system, for just over \$600 million.<sup>224</sup> Highmark additionally invested about \$475 million in the system, bringing the total cost closer to \$1.1 billion.<sup>225</sup> This is a relatively large transaction and represents an initial step toward integration, even if only between a single insurer and hospital system. The corporate structure of the new entity will consist of a parent company called Highmark and subsidiaries that include an insurance company and Allegheny Health Net-

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<sup>219</sup> *Supra*, note 213.

<sup>220</sup> Anna Wilde Mathews, *UnitedHealth Buys California Group of 2,300 Doctors*, WALL ST. J., Sept. 1, 2011.

<sup>221</sup> *Id.*

<sup>222</sup> *Id.*

<sup>223</sup> *Id.*

<sup>224</sup> *Highmark closes \$604 mln buyout of West Penn Allegheny bondholders*, Reuters, Apr. 29, 2013.

<sup>225</sup> *Id.*

work (consisting of numerous providers, including West Penn).<sup>226</sup> Unlike in some other states, Pennsylvania law may allow for more flexibility in employment of physicians.<sup>227</sup> However, the Pennsylvania insurance department imposed conditions on the acquisition, including a clause limiting contracts between Highmark and hospitals (including West Penn) to five years; a prohibition on exclusive contracts that would benefit West Penn; and a firewall to prevent Highmark and West Penn from sharing rivals' pricing information.<sup>228</sup>

A vertically integrated payor-provider system could be structured in myriad ways. Depending on the jurisdiction, however, state laws may seriously constrain the permissible corporate forms and restrict the system's options. The result of this can be a loosely knit organization requiring foundations, parent companies or holding companies, or other incorporeal inventions solely to comply with laws and regulations that no longer make sense.

If this were all, it might be a distinction without a difference. But more critically, such a cumbersome and disjointed structure may not allow for genuine integration of the payor, the hospital and other health care facilities, the medical groups, and other types of providers in a way that achieves maximum efficiencies and optimizes cost, quality of care, and access. For example, when an insurer or a hospital enters into a management agreement with a physician group, such as Optum did with Monarch in California, the physician group is generally paid a lump sum and an incentive payment or bonus that depends on meeting certain quality and patient satisfaction metrics.<sup>229</sup> These remain two isolated parties entering into a contractual arrangement; it is no different than the agreement insurers frequently establish with physician groups (e.g., independent practice associations or IPAs) on a capitated basis. No real integration has occurred with this type of setup. Similarly, by structuring the new health system as separate corporate entities (parent and subsidiaries), Highmark has created an entity that may appear to be "integrated" superficially, but is really an extension of the old fragmented system and will be regulated as such. In the state regulators' view, West Penn appears to be just one

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<sup>226</sup> Melanie Evans, *Highmark completes West Penn deal, announces new system*, Modern Healthcare, Apr. 29, 2013.

<sup>227</sup> 35 PA. CONS. STAT. § 448.817a (2014). ("A health care practitioner may practice the healing arts as an employee or independent contractor of a health care facility or health care provider or an affiliate of a health care facility or health care provider established to provide health care.")

<sup>228</sup> *Highmark forms one of the nation's largest integrated health systems*, The Advisory Board Co., Apr. 30, 2013.

<sup>229</sup> Heather Punke, *Hospital-Physician Co-Management Agreements: How to Avoid a Major Pitfall*, Becker's Hospital Review, Nov. 1, 2013.

more hospital with whom Highmark (as a payor) contracts. This will restrict the system's ability to restructure the way care is provided.

## 2. The Costly Consequences of Fragmentation

The highly fragmented nature of the current health care system – in particular, the schism between insurance companies and health care providers – creates a problem of “moral hazard.” Generally, moral hazard is the tendency of an individual to behave differently based on the presence of insurance.<sup>230</sup> The principle of moral hazard in health care means individuals tend to increase utilization of medical services that their insurance pays for – in other words, as insurance coverage increases, demand for covered services increases.<sup>231</sup>

Moral hazard manifests itself in a fragmented health care system in the following way: public demand for the newest, sleekest hospitals with private rooms, luxurious accommodations, and the most advanced technology fuels providers to spend great sums of money building these facilities to attract patients. In a typical example, in 2009, the Children's Hospital of Pittsburgh moved from an older downtown facility to a 10-acre site just a few miles away.<sup>232</sup> The new hospital and adjacent research center exceeded expected costs, reaching \$625 million. The nonprofit parent, University of Pittsburgh Medical Center, complained that Children's spending plans were too lavish.<sup>233</sup> One hospital executive boasted, “We went from a Yugo to a Ferrari.”<sup>234</sup> In Illinois, a new tower for the Rehabilitation Institute of Chicago will cost an estimated \$523 million, as of Feb. 2012, up ten percent from estimates just one month prior.<sup>235</sup>

Similarly, in the southwest suburbs of Chicago, Silver Cross Hospital recently moved its operations from its aging facilities in Joliet (originally built in 1919) to a brand new sprawling complex in New Lenox,

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<sup>230</sup> Douglass Farnsworth, *Moral Hazard in Health Insurance: Are Consumer-Directed Plans the Answer?* 15 ANNALS HEALTHL. 251, 253 (2006).

<sup>231</sup> *Id.* at 254.

<sup>232</sup> See At, Gilbert M. Gaul, *Pittsburgh: Price of New Hospital Soared to \$625 Million Amid Dispute Over How Much To Spend*, KAISER HEALTH NEWS (Sept. 26, 2011), at <http://kaiserhealthnews.org/news/childrens-hospitals-pittsburgh/>.

<sup>233</sup> See Gaul, *supra* note 232.

<sup>234</sup> *Id.*

<sup>235</sup> See Andrew L. Wang, *Rehab Institute ups cost of new hospital to more than \$500 million*, CRAIN'S CHICAGO BUSINESS (Nov. 15, 2012), available at <http://www.chicagobusiness.com/article/20121115/NEWS03/121119869/rehab-institute-ups-cost-of-new-hospital-to-more-than-500-million..>

where the hospital alone covers 560,000 square feet.<sup>236</sup> The total price tag was \$395 million, but “officials said that it would have cost more to update the old building than to simply build the new facility.”<sup>237</sup> The new hospital is only three miles away from the old one, but the location will likely make a huge difference in terms of the payer mix that the hospital sees. The old facility was located in an area of Joliet with a lower socioeconomic status, a higher rate of poverty, and more patients who are uninsured or on Medicaid. The new Silver Cross complex is in a more affluent area where more people have commercial insurance coverage. Furthermore, it sits at the junction of two large expressways that will make the hospital easily accessible from surrounding, more affluent suburbs. Thus, it may be true that building a new facility was less expensive than updating the old hospital, but its new location serves the purpose of increasing profit as well.

Hospitals or other facilities built nearly a century ago certainly need to eventually be updated, if not completely replaced, and the expense in doing so may be justifiably high. But more hospitals are not necessarily what patients need today. Moreover, increasingly luxurious environments are constructed in order to attract more customers. For example, Silver Cross officials emphasized its hospital’s latest amenities, “such as private rooms with large windows and flat-screen TVs.”<sup>238</sup> The hospital is also equipped with wi-fi and other technology; each private room has its own temperature controls and sleeper sofas for family. The hospital’s vice president of operations commented that the “rooms are so nice that people are going to find it hard to go home.”<sup>239</sup> While statements like this contain some degree of hyperbole, they also offer a glimpse into the real reasons behind health care spending today.

Whether for-profit or non-profit, health care providers of all types are businesses operating in a capitalist economy, and they must make more money than they spend in order to keep the doors open and the lights on. To have positive revenue, they need to attract more patients, particularly those with private health insurance coverage, which pays them the highest in reimbursement. And in order to attract such patients, these facilities need to be state of the art with luxurious accommodations. Yet this is where the problem of moral hazard takes its grievous toll – from a pa-

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<sup>236</sup> See Mary Owen, *Silver Cross Hospital to open February 2012 in New Lenox*, TRIBLOCAL - JOLIET (Aug. 3, 2011, 5:34 PM) at <http://www.triblocal.com/joliet/2011/08/03/silver-cross-hospital-to-open-february-2012-in-new-lenox/>.

<sup>237</sup> *Id.*

<sup>238</sup> Owen, *supra* note 237..

<sup>239</sup> *Id.*

tient's perspective, as long as she has already paid her insurance premiums, some or all of the cost of the medical services will be covered, and she will be cushioned against bearing the full expense. Health care providers are generally catering to customers who are largely or completely immune to cost.

Hospitals are only one part of our deeply fragmented health care system, but they are a useful microcosm of its problems. The regulatory framework in health care continually reinforces the system's structure. The more that regulators define the players in the system (insurer, hospital, ambulatory surgery center, pharmacy, etc.) and draw sharp distinctions between them – the more they precisely delineate the scope of what each can and cannot do – the further regulators cement these categories as permanent and create incentives to maximize income within each category. Insurers try to reduce costs and negotiate more favorable reimbursement rates with providers. Providers in turn try to do the same thing and end up at loggerheads with insurers. The regulatory framework evolved over time to mirror the fragmented system, but it has had the unintended effect of crystallizing the system's disintegration. Each isolated entity in this environment lacks the financial incentives to do anything but maximize its own profits and lacks the clout to reinvent the entire structure.

A vertically integrated system has the potential to circumnavigate this problem. There is no third party payor in such a system. One entity both finances and delivers care; the financial incentives of all parties are aligned. This is not to say that any integrated system would automatically reorganize the entire health care system's architecture; it could simply continue operating as if nothing changed other than ownership. For example, Intermountain Health Care, a large integrated health care delivery system in Utah, recently constructed an enormously expensive brand new hospital.<sup>240</sup> Intermountain did not restructure anything, but rather, continued down the same path as other non-integrated entities. Integration is no guarantee of disruption to the existing system. However, complete vertical integration is a prerequisite and only such a system would have the ability to undertake this dramatic shakeup.

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<sup>240</sup> See *Intermountain Medical Center, About Intermountain Health Care*, <http://intermountainhealthcare.org/hospitals/imed/about/Pages/AboutIntermountainMedicalCenter.aspx> (last visited Apr. 20, 2014).

### III. CONCLUSION & RECOMMENDATIONS

The laws and regulations discussed in this paper, along with numerous others, would need to be carefully considered in the planning and implementation of any health care vertical integration strategy. Individually, these laws may make sense and address valid concerns in the present disjointed health care system (although in many cases, even that is debatable). In the aggregate, however, they clearly represent a byzantine regulatory framework that may be extraordinarily difficult for a single entity to successfully navigate. More importantly, this framework is entirely inappropriate as applied to a vertically integrated entity.

It is often said that if the only tool you have is a hammer, everything looks like a nail.<sup>241</sup> Likewise, to a legislator or regulator, all problems appear to have a solution in additional legislation or regulation. To be clear, this paper is not making the case that all regulation is inherently bad. In certain situations, governmental intervention is absolutely necessary and serves an important role where the market would otherwise fail or leave a gap. And as noted above, some of the regulations in the current fragmented health care system may be appropriate or even essential to such a system. However, a thoroughly integrated payor-provider system has the potential to change the health care landscape and transform the way care is provided. The financial incentives of all parties in such a system are internally coherent and aligned, a situation that is completely different from the disparate and conflicting incentives that isolated entities experience. In the bright light of such a new system, many of the concerns underlying health care laws melt away. A regulatory framework erected decades ago in a very different era unnecessarily sets up major obstacles to vertical integration, discouraging the very policy goals that policymakers were at one time trying to achieve.

At the outset, this paper suggested that it would propose what the ideal regulatory framework might look like, as it relates to an integrated delivery system. In short, the answer is that such a system would be subject to far less health care- or health insurance- specific regulation. Legislators and regulators should carve out and exempt an integrated payor-provider system from the most burdensome and inappropriate pieces of the regulatory framework, for at least two reasons.

First, even in the absence of healthcare-specific regulation, an abundance of employment laws would already govern the integrated sys-

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<sup>241</sup> Abraham H. Maslow, *THE PSYCHOLOGY OF SCIENCE* 15 (1966). This quote has been attributed to several original sources, most popularly to Maslow, and is therefore also sometimes called Maslow's hammer.

tem and would be sufficient to appropriately address most policy concerns. The payor-provider system must comply with wage and hour laws under the Fair Labor Standards Act<sup>242</sup> and its regulations; workplace safety requirements under the Occupational Safety and Health Act<sup>243</sup> and its regulations; workplace discrimination and harassment statutes including Title VII of the Civil Rights Act,<sup>244</sup> the Family and Medical Leave Act,<sup>245</sup> and legal or professional standards involving everything from workplace torts to medical staff issues like credentialing and privileges.<sup>246</sup> To the extent the business offers any employee benefit plans, such as pension or health benefit plans, it must comply with the Employee Retirement Income Security Act (“ERISA”)<sup>247</sup> and its regulations, as well as the Internal Revenue Code (“IRC”)<sup>248</sup> and its regulations – at least, to the extent ERISA and the IRC are generally applicable to most businesses or plans, since they too contain health care regulation. Social Security Act rules would also still apply.<sup>249</sup> Many state laws govern employers, as well.<sup>250</sup> This is not an exhaustive list of laws applicable to employers, but just a few examples.

The absence of healthcare-specific regulation would not mean the absence of any regulation: employment law, well-developed over many decades and equally applicable to most employers, would suffice to govern

<sup>242</sup> Fair Labor Standards Act of 1938, Pub. L. No. 75-718, 52 Stat. 1060 (codified as amended at 29 U.S.C. §§ 201-19, §557)(2012).

<sup>243</sup> Occupational Safety and Health Act of 1970, Pub. L. No. 91-596, 84 Stat. 1590 (codified as amended at 29 U.S.C. et seq.)(2012).

<sup>244</sup> Title VII of the Civil Rights Act of 1964, Pub. L. No. 83-352, 78 Stat. 241 (codified as amended at sections of 42 U.S.C.)(2012).

<sup>245</sup> Family and Medical Leave Act of 1993, Pub. L. No. 103-3, 107 Stat. 6 (codified as amended in scattered sections of 29 U.S.C. and 5 U.S.C.)(2012).

<sup>246</sup> Each hospital’s governing body must establish medical staff privileges, and various regulatory agencies or professional organizations set standards or requirements for this process. *See, e.g.*, 42 C.F.R. § 482.12 (2014) (conditioning participation for hospitals in the Medicare program); Am. Med. Assoc., A.M.A. Code of Medical Ethics, Op. 4.07 – Staff Privileges (1994), *available at* <http://www.ama-assn.org/ama/pub/physician-resources/medical-ethics/code-medical-ethics/opinion407.page?> (establishing standards of conduct related to granting and using privileges). Lawsuits may arise over the unfair or unreasonable denial or termination of staff privileges.

<sup>247</sup> Employee Retirement Income Security Act of 1974, Pub. L. No. 93-406, 88 Stat. 829 (codified as amended in scattered sections of 26 U.S.C. and 29 U.S.C.)(2012). Church plans and governmental plans are generally exempt from ERISA, but presumably an integrated delivery system would not fall into either of these categories and would therefore be subject to ERISA. 29 U.S.C. § 1003(b) (2012).

<sup>248</sup> Internal Revenue Code of 1986, Pub. L. No. 88-272, 68A Stat. 3 (codified as amended at 26 USC § 1 et seq.)(2012).

<sup>249</sup> Social Security Act, Pub. L. No. 74-271, 49 Stat. 620 (1935) (codified as amended in scattered sections of 42 U.S.C.)(2012).

<sup>250</sup> *See, e.g.*, 820 ILL. COMP. STAT. 105/4 (2012) *available at* <http://www.ilga.gov/legislation/ilcs/fulltext.asp?DocName=082001050K4> (Illinois law regarding minimum wage); 820 ILL. COMP. STAT. 140/2 (2012) *available at* <http://www.ilga.gov/legislation/ilcs/ilcs3.asp?ActID=2407&ChapterID=68> (Illinois law requiring minimum days of rest).

the entity and its operations. As one illustration, wage and hour laws are unquestionably appropriate for a system that employs physicians, nurses, and other health care professionals as common law employees. To the extent any concerns arise, they would typically be concerns common to employment generally. Many convoluted and antiquated healthcare-specific laws like Stark or anti-kickback, or doctrines such as the corporate practice of medicine, are inapplicable to an integrated system at best and are serious hindrances to it at worst.

Antitrust laws are a special case, for purposes of this argument. They are the only regulatory framework discussed in this paper that are generally applicable to any industry and that do not exclusively target health care entities. However, for the reasons outlined above, these laws could nevertheless pose major obstacles to integration in the health care arena. Regulators should therefore grant a safe harbor or exemption to an integrated payor-provider system and to entities attempting to create one.

This would not be without precedent. The Affordable Care Act included a health care delivery system reform, the Medicare Shared Savings Program, which promotes the formation and operation of Accountable Care Organizations (“ACOs”).<sup>251</sup> ACOs are groups of providers that work together to coordinate care, in this case for Medicare beneficiaries. In general, a payor provides the ACO with a lump sum payment and the parties in the ACO figure out how to divide it up among themselves; to the extent they can provide care more efficiently and save money, the ACO shares in the savings. The Department of Justice (“DOJ”) and the Federal Trade Commission (“FTC”) are the agencies responsible for enforcing antitrust laws, and since ACOs might otherwise trigger violations of these laws, the DOJ and FTC have issued a policy statement providing an antitrust safety zone for ACOs that meet certain criteria.<sup>252</sup> The DOJ and FTC assert in this statement that absent extraordinary circumstances, they will not challenge ACOs that fall into this safety zone.<sup>253</sup> Interestingly, the policy statement specifically does not apply to “single, fully integrated entities.”<sup>254</sup> Clearly, it is within the agencies’ discretion and power to carve out certain entities whose effect on competition is likely to be beneficial, particularly when there are demonstrable and significant benefits to con-

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<sup>251</sup> Patient Protection and Affordable Care Act § 3022, (codified as amended in 42 U.S.C. § 1395 et seq.) (2012).

<sup>252</sup> Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67025, 67026 (Oct. 28, 2011).

<sup>253</sup> *Id.* at 67028.

<sup>254</sup> *Id.* at 67027.

sumers. The agencies can and should create a broader safe harbor for fully integrated entities, as well.<sup>255</sup>

Policymakers should mirror this approach for fully integrated health care systems in certain other areas of the law. Such a system could be given an exemption or safe harbor from both Stark and anti-kickback. It could also be exempted from the corporate practice of medicine doctrine and certificate of need requirements. These laws and regulations were never developed for a thoroughly integrated entity; they arose out of concerns inherent in a fragmented health care delivery system. A number of state health care or health insurance laws and regulations, such as prompt pay requirements, should also be considered inapplicable to such an entity. As explained above, many of these mandates are understandable when providers and payors are two separate entities with distinct, sometimes conflicting economic interests. But when applied to an economically and managerially integrated system, these requirements are puzzling, as the policy concerns that formed their foundation suddenly disappear. Why would an integrated delivery system that employs health care professionals need special laws ordering them to pay their employees in a timely manner? Similar arguments could be advanced about numerous other regulations.

Thus, employment law would be sufficient in most cases to govern the integrated system, and additional regulation would be unnecessary. But second, and perhaps more importantly, health care entities today need room to maneuver and to begin preparations to vertically integrate. They need some degree of freedom to act without encountering intense and burdensome regulatory scrutiny every step of the way. And once formed and operating as a cohesive whole, the system needs room to breathe, expand, innovate, and experiment. If it hits up against a regulatory obstacle at every turn, its ability to transform health care delivery will be seriously constrained, and the benefits of such a system will be limited. In short, an integrated system needs some elbow room.

This is not to say that an overarching regulatory framework would be unnecessary. To the extent one is needed, though, it should be constructed around existing businesses and industries, after they come into existence – not before. It does not make sense to erect a rigid framework of regulation before the industry it governs exists or while it is in an embryonic stage. Nor does it make sense to erect it based on one existing industry and then expect a brand new disruptive business model to neatly fit and

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<sup>255</sup> More generally, ACOs are also an example of a situation in which policymakers saw a new health care delivery model emerging and changed their regulatory approach accordingly.

operate successfully within it. A colossal, thoroughly integrated health care financing and delivery system may pose special or unique problems that actually do require innovative regulatory solutions; this remains to be seen. But any such concerns are merely speculative at this point because such a system does not exist.

That any optimal solutions will even lie in legislation is far from clear. Clark Havighurst, law professor and an expert on health care law and policy, provides the most suitable concluding thoughts for this paper:

Regulation will frequently seem advantageous because it is measured only against the alternative of doing nothing, not against other promising policies that might have been, but were not, tried. Indeed, when adopted at the national level, regulation forecloses experimentation, not only making success or failure hard to recognize but also making the optimum strategy undiscoverable.<sup>256</sup>

If a genuinely integrated system poses any novel problems, there may be a fair and extensive debate about whether additional regulation is the best solution. But even if the answers do ultimately reside in regulation, the current framework is singularly inappropriate. It was built piecemeal and in a haphazard fashion over many decades and with many different purposes in mind. The current regulatory landscape includes some awkward and circuitous rivers, misguided and overgrown branches, petrified trees, occasional patches of quicksand, and massively obstructive mountains. With the emergence of an innovative integrated system, this landscape must be cleared away and transformed.

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<sup>256</sup> Clark C. Havighurst, *Health Care Cost-Containment Regulation: Prospects and an Alternative*, 3 AM. J.L. & MED. 309, 315 (1977).

