Volume 24 | Issue 2
Spring 2015

LOYOLA UNIVERSITY CHICAGO
SCHOOL *of* LAW

BEAZLEY INSTITUTE FOR HEALTH LAW AND POLICY

Annals OF Health Law

ADVANCE DIRECTIVE

The Student Health Policy and Law Review of
LOYOLA UNIVERSITY CHICAGO SCHOOL *of* LAW

ANNALS OF HEALTH LAW

THE HEALTH POLICY AND LAW REVIEW OF LOYOLA UNIVERSITY CHICAGO SCHOOL OF LAW

BEAZLEY INSTITUTE FOR HEALTH LAW AND POLICY

VOLUME 24, ISSUE 2 SPRING 2015

ANNALS OF HEALTH LAW
Advance Directive

THE *STUDENT* HEALTH POLICY AND LAW REVIEW OF LOYOLA UNIVERSITY CHICAGO SCHOOL OF LAW

BRINGING YOU THE LATEST DEVELOPMENTS IN HEALTH LAW

Beazley Institute for Health Law and Policy

VOLUME 24, STUDENT ISSUE 2 Spring 2015

CONTENTS

ANNALS OF HEALTH LAW
Advance Directive

Editors' Note

The *Annals of Health Law* is proud to present the Fourteenth Issue of our online, student-written publication, *Advance Directive*. *Advance Directive* aims to support and encourage student scholarship in the area of health law and policy. In this vein, this issue explores the challenges and opportunities facing clinical integration within the health care industry. Clinical integration furthers the concept of value-based care by facilitating the coordination of patient care across various settings. The authors examine a variety of issues related to clinical integration, ranging from the legal concerns presented by physician owned distributorships to the opportunities of clinically integrated networks (CINs) to improve patient end-of-life care.

This Issue begins with a look at the federal regulatory issues involved with clinical integration in health care. First, we examine broad federal laws in the areas of fraud and abuse, and antitrust. Our authors advocate for the reformation of both the Stark Law and the antitrust laws governing mergers and acquisitions to facilitate clinical integration. Next, our authors discuss the need to reform reimbursement rules – specifically, those requirements pertaining to provider-based billing status and the Hospital Readmissions Reduction Program – for Medicare and Medicaid patients in CINs. Lastly, our authors analyze the regulatory risks associated with physician owned distributorships, which work against the goals of clinical integration.

Our Issue continues with an analysis of state law restraints on clinical integration. Specifically, our authors consider the corporate practice of medicine doctrine and how it functions to restrict the expansion of value-based care through clinical integration. Our authors argue that the doctrine should be codified and relaxed in Illinois to promote further clinical integration among providers.

Finally, this Issue concludes with a concentrated look at the delivery of care by CINs. First, our authors examine the primary characteristics of effective CINs, and propose necessary measures for future success. We also explore how CINs, such as accountable care organizations, can improve the delivery of patient end-of-life care.

We would like to thank Adrienne Saltz, our Technical Editor, because without her knowledge and commitment this Issue would not have been possible. We would like to give special thanks to our *Annals* Editor-in-Chief, Anne Compton-Brown, for her leadership and support. The *Annals* Executive Board Members, Leighanne Root, Jean Liu, Matthew Brothers, and Christopher Conway, provided invaluable editorial assistance with this Issue. The *Annals* members deserve special recognition for their thoughtful and topical articles, and for editing the work of their peers. Lastly, we must thank the Beazley Institute for Health Law and Policy and our faculty advisors, Professor Lawrence Singer, Professor John Blum, and Kristin Finn for their guidance and support.

We hope you enjoy our Fourteenth Issue of *Advance Directive.*

Sincerely,

Jessica J. Wolf
Advance Directive Editor
Annals of Health Law
Loyola University Chicago School of Law

Ashley Huntington
Advance Directive Editor
Annals of Health Law
Loyola University Chicago School of Law

ANNALS OF HEALTH LAW
Advance Directive

VOLUME 24 SPRING 2015 PAGES 1-11

Merging Hospitals: Balancing Clinical Integration and Competition

Jennifer Fenton[*]

I. INTRODUCTION

The United States healthcare system is the most expensive system in the world.[1] Nonetheless, the United States has the highest percentage of adults who report problems accessing health care out of all first-world countries.[2] In 2013, more than one-third of adults in the United States failed to receive health care because of cost-related barriers.[3] Concern has prompted many initiatives to change the landscape of health care in America because slowing the growth of these costs and providing access to care is critical to the country's long-term fiscal stability.[4] Clinical integration of healthcare organizations is one such initiative that has produced meaningful results by slowing the growth of costs and increasing access to care.[5] Most recently, calls for

[*] Juris Doctor Candidate, May 2016, Loyola University Chicago School of Law. Ms. Fenton is a staff member of Annals of Health Law.

1. Olga Khazan, *U.S. Healthcare: Most Expensive and Worst Performing*, ATLANTIC (June 16, 2014), *available at* http://www.theatlantic.com/health/archive/2014/06/us-healthcare-most-expensive-and-worst-performing/372828/.

2. Comilla Sasson et al., The Changing Landscape of America's Health Care System and the Value of Emergency Medicine, 19 ACAD. EMERGENCY MED. 1204, 1205 (2012).

3. Cathy Schoen et al., *Access, Affordability, And Insurance Complexity Are Often Worse In the United States Compared To Ten Other Countries*, 32 HEALTH AFF. 2205, 2207 (2013).

4. Anna D. Sinaiko & Meredith B. Rosenthal, *Increased Price Transparency in Health Care – Challenges and Potential Effects*, 364 N. ENGL. J. MED, 891, 891 (2011).

5. Sara Rosenbaum et al., *Assessing and Addressing Legal Barriers to the Clinical Integration of Community Health Centers and Other Community Providers*, THE COMMONWEALTH FUND (Feb. 20, 2015, 8:07 PM), http://www.commonwealthfund.org/~/media/Files/Publications/Fund%20Report/2011/Jul/1525_Rosenbaum_assessing_barriers_clinical_integration_CHCs.pdf.

collaboration among healthcare organizations have materialized into the biggest surge of hospital mergers since the 1990s.[6] This surge threatens the cost and quality of health care and federal regulators have responded by blocking a number of recent mergers.[7] By examining the relationship between clinical integration and the market-based system of health care in the United States, this article first argues how the recent surge of hospital mergers threatens healthcare reform and then moves to discuss how recent court decisions serve as useful guidance for providers considering a merger. Critics who oppose these recent decisions and argue that hospital mergers should be subject to relaxed standards of antitrust law misunderstand the market-based system of health care in the United States. Part II of this article examines the relationship between clinical integration and the United States' market-based healthcare system. Part III discusses why efforts to coordinate cannot be made at the expense of competition. Part IV provides an overview of the recent surge in hospital mergers and examines the Federal Trade Commission's reaction and Part V concludes that achieving the goals of clinical integration does not require relaxation of antitrust law within the healthcare sector.

II. CLINICAL INTEGRATION AND THE UNITED STATES MARKET-BASED SYSTEM

As clinical integration gains traction, hospital systems in the United States are reacting by consolidating into larger systems.[8] While the goals of clinical integration encourage coordination among providers, regulators must ensure such coordination achieves the goals of healthcare reform: higher quality and more efficient patient services.[9] At a definitional level, clinical

6. Julie Creswell & Reed Abelson, *New Laws and Rising Costs Create a Surge of Supersizing Hospitals*, N.Y. TIMES, Aug. 12, 2013, *available at* http://www.nytimes.com/2013/08/13/business/bigger-hospitals-may-lead-to-bigger-bills-for-patients.html?pagewanted=all.

7. Because the United States healthcare system operates in the private sector, decreased competition risks both cost and quality. *Id.*

8. CHRISTOPHER M. POPE, THE HERITAGE FOUNDATION BACKGROUNDER, HOW THE AFFORDABLE CARE ACT FUELS HEALTH CARE MARKET CONSOLIDATION 1 (No. 2928, 2014).

9. U.S. Dep't of Health & Human Servs., *HHS Strategic Plan*, (Mar. 20, 2015), http://

integration denotes the extent to which patient services are coordinated across institutions, disciplines, and time.[10] In practice, clinical integration rejects reactive medicine and focuses on keeping each individual patient healthy.[11] By coordinating the care of individual patients across disciplines and institutions, clinical integration results in a more efficient healthcare system.[12] While some attempts to coordinate healthcare organizations demonstrate potential for success, others threaten the health care reform movement.[13]

Although approximately half of health care spending in the United States is financed by public money, the beneficiaries of those public funds obtain care from the private sector.[14] Thus, the United States healthcare system is a market-based system – consumers obtain care in the private sector, where prices are fixed by the laws of supply and demand. In order to ensure that consumers benefit from health care reform, the market-based system must function properly.[15] As with any market-based system, competition encourages investment and innovation, which leads to lower costs and higher-quality services.[16] When hospitals merge to create a dominant system, decreased competition results in higher costs and fewer options for consumers.[17] In order to achieve the benefits of clinical integration, hospital systems

---

www.hhs.gov/strategic-plan/goal1.html. (In 2010, President Barack Obama signed into law the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010. Both laws are the culmination of immense efforts to reshape health care in the United States by increasing access to care, making health insurance more affordable, and strengthening Medicare).

10. Pim P. Valentijn et al., *Understanding Integrated Care: A Comprehensive Conceptual Framework Based on the Integrative Functions of Primary Care*, 13 INT'L J. OF INTEGRATED CARE 1, 7 (2013).

11. *Id.*

12. *Id*.

13. Martin Gaynor, *Competition Policy in Health Care Markets: Navigating the Enforcement and Policy Maze*, 33 HEALTH AFF.1088, 1088 (2014); *See generally* Anne Sharamitaro, *Retail Clinics and Health Systems Coordinate Care*, 7 HEALTH CAPITAL TOPICS 1 (2014) (demonstrating the success of retail clinics in coordinating healthcare services).

14. Gaynor, *supra* note 13, at 1089.

15. Edith Ramirez, *Antitrust Enforcement in Health Care – Controlling Costs, Improving Quality*, 371 N. ENG. J. MED., 2245, 2245 (2014).

16. *Id.*

17. Promedica Health System, Inc. v. F.T.C., 749 F.3d 559, 563 (6th Cir. 2014).

must strike a balance between collaborative activity and maintenance of competitive markets.[18]

III. GUIDING COORDINATION WITHOUT OFFENDING COMPETITION

Critics contend that rigid enforcement of antitrust law in the health care arena threatens provider efforts to collaborate and is thus at odds with the goals of health care reform.[19] This argument not only misinterprets the role that market forces play in the healthcare sector, but also the analysis regulators such as the Federal Trade Commission (FTC) undertake when reviewing a proposed hospital merger.[20] To start, market forces have a significant impact on the cost of health care.[21] Relaxing antitrust laws for the healthcare industry ignores evidence that dominant systems lead to substantial price increases.[22] When hospitals merge in concentrated markets, prices tend to increase by at least twenty percent.[23] Moreover, substantial evidence supports a conclusion that competition in hospital markets enhances quality.[24] Thus, both quantitative and qualitative evidence supports the notion that enforcement of antitrust laws in the healthcare sector should not be treated any differently than in other private industries.

Those who argue that the FTC's enforcement of antitrust law is at odds with health care reform also misunderstand the process by which a proposed merger is challenged. Contrary to much of the literature that criticizes FTC

18. Ramirez, *supra* note 15, at 2247.

19. *Id.* at 2246. ("The FTC intervenes when there is strong evidence that a merger between health care providers is likely to result in market power that will lead to an increase in prices – through higher insurance premiums and copayments – without corresponding quality improvements.").

20. *Id.*

21. *See* Gene J. O'Dell, *Take a Look at How Market Forces Will Impact Health Care*, HOSPITALS & HEALTH NETWORKS, (Feb. 20, 2015, 10:00am), http://www.hhnmag.com/display/HHN-news-article.dhtml?dcrPath=/templatedata/HF_Common/NewsArticle/data/HHN/Magazine/2014/Sep/gate-aha-environment-scan-2015.

22. Gaynor, *supra* note 13, at 1089.

23. Pope, *supra* note 8, at 4.

24. Gaynor, *supra* note 13, at 1089.

merger analysis, review is not limited to quantitative determinations.[25] Under traditional horizontal-merger analysis (mergers between two companies that offer similar services or products), the FTC will identify competitors and determine the post-merger market share and concentration levels.[26] If the figures reach a certain threshold, a presumption of unlawfulness arises.[27] Put more simply, the analysis determines how much of the market the merged entity would control and if a certain percentage of enhanced market power is attained, the merger is presumed to be unlawful.[28]

However, the defending provider can rebut the presumption by presenting evidence related to: low entry or expansion barriers to demonstrate new competitors could easily challenge the merged entity's market share post-merger; efficiencies from the transaction such as demonstrated consumer benefits from the merger; and/or evidence that one of the providers is currently a weakened competitor unable to survive absent the merger.[29] Thus, the analysis is not limited to quantitative assessments of cost – providers are able to rebut a presumption of illegality by showing that the merger will result in qualitative improvements for consumers.[30] Because increased efficiencies is a goal of clinical integration, the FTC's requirement that providers present qualitative evidence that the merger will result in more efficient care is in line with the goals of health care reform.[31] Absent demonstrable proof that consumers will benefit in a post-merger environment, regulators cannot be expected to blindly trust that the merger's stated improvements are both likely and attainable.[32]

---

25. Ramirez, *supra* note 15, at 2246.
26. 2 Health Care and Antitrust L. § 12:1 (West 2014).
27. *Id.*
28. *Id.*
29. *Id.*
30. *Id*.
31. Rosenbaum et al., *supra* note 5.
32. 2 Health Care and Antitrust L. § 12:1 (West 2014).

IV. THE SURGE

In 2009, fifty hospitals merged in the United States.[33] By 2012, that number more than doubled.[34] Moreover, Booz & Company, a consulting firm, predicts that 1,000 of the country's 5,000 hospitals could merge in the next five to seven years.[35] Consequently, regulators and consumers have cause for concern. The last wave of hospital mergers ended in the late 1990s and resulted in substantial price increases with virtually no benefits to consumers.[36] However, analysts of the latest wave say motivations for the recent surge are much broader.[37] Some hospitals contend that consolidation is needed in order to survive in an environment of lower reimbursement.[38] Others are less candid, citing desires for increased bargaining clout with private insurers as motivation to merge.[39] Regardless of the motivations, independent hospitals may be unable to compete against bigger, leaner systems if the surge continues.[40]

A. Recent FTC Challenges

Beginning in 2007 and spanning to the present, the FTC has played an active role in challenging hospital mergers.[41] Although health care reform works through public programs to ensure all Americans have coverage, the providers still remain in the private sector.[42] As such, regardless of the mo-

33. Creswell & Abelson, *supra* note 6.
34. *Id*.
35. *Id*.
36. Leemore Dafny, *Hospital Industry Consolidation – Still More to Come?*, 370 N. ENG. J. MED., 198, 198 (2014).
37. Creswell & Abelson, *supra* note 6.
38. 2 Health Care and Antitrust L. § 12:1 (West 2014).
39. 2 Health Care and Antitrust L. § 12:1 (West 2014); Promedica Health System, Inc. v. F.T.C., 749 F.3d 559, 563 (2014).
40. Creswell & Abelson, *supra* note 6.
41. 2 Health Care and Antitrust L. § 12:1 (West 2014).
42. Gaynor, *supra* note 13, at 1089.

tivation to merge, hospitals must be able to demonstrate that a proposed merger will benefit consumers, not harm through anticompetitive practices.[43] Over the last year, the Ninth and Sixth Circuits have affirmed FTC determinations that blocked proposed mergers.[44] The proponents for the mergers in each case cited different motivations for the merger and advanced different defenses in order to rebut a presumption of illegality.[45] The dicta from the courts in each of these decisions is crucial for understanding how these mergers threaten the goals of clinical integration.[46]

1. St. Alphonsus Med. Ctr. – Nampa Inc. v. St. Luke's Health System, Ltd.

The most recent decision came out of the Ninth Circuit earlier this year and blocked a hospital-physician group merger in Idaho.[47] The challenge was the FTC's first involving a hospital and physician group that proceeded to trial.[48] Attempting to rebut a presumption of illegality, St. Luke's Hospital advanced a defense of claimed post-merger efficiencies.[49] In particular, St. Luke's contended the merger would permit a move toward integrated care.[50] While the Court was notably skeptical of whether the efficiencies defense could be used within the context of antitrust law, the Court allowed rebuttal evidence that the proposed merger would create a more efficient combined

43. Ramirez, *supra* note 16, at 2246.

44. St. Alphonsus Med. Ctr. – Nampa Inc. v. St. Luke's Health Sys., Ltd., No. 14-35173 1, 32 (9th Cir. filed Feb. 10, 2015); Promedica Health System, Inc. v. F.T.C., 749 F.3d 559, 573 (2014).

45. *See St. Alphonsus Med. Ctr. – Nampa Inc*., No. 14-35173; *Promedica Health System, Inc.*, 749 F.3d at 559.

46. *See St. Alphonsus Med. Ctr. – Nampa Inc.*, No. 14-35173; *Promedica Health System, Inc*., 749 F.3d at 559.

47. *St. Alphonsus Med. Ctr. – Nampa Inc*., No. 14-35173 at 7.

48. David R. Garcia & Helen Cho Eckert, *In Highly-Anticipated Decision, Ninth Circuit Affirms That Hospital-Physician Group Merger in St. Luke's Violated Section 7 And Casts Serious Doubt on Viability of Efficiencies Defense*, NAT'L L. REV. (Feb. 18, 2015), http://www.natlawreview.com/article/highly-anticipated-decision-ninth-circuit-affirms-hospital-physician-group-merger-st.

49. *Id.*

50. *St. Alphonsus Med. Ctr. – Nampa Inc*., No. 14-35173 at 22.

entity resulting in increased competition.[51] Specifically, St. Luke's argued the merger would permit more patients to have access to Epic, an electronic medical records system.[52] Ultimately, the Court held that St. Luke's argument – the merger would allow the hospital to better serve patients - was not sufficient.[53] Instead, St. Luke's needed to show that the predicted anticompetitive effects of the merger were inaccurate.[54]

The decision serves as strong precedent for the FTC and sets a high burden for any provider who is faced with rebutting a presumption of illegality. St. Luke's highlights the fact that providers will not be able to bury anticompetitive effects by stressing ancillary patient benefits.[55] While increased use of electronic medical records will benefit patients in line with the goals of clinical integration, it does not address the fact that a shrunken market will result in higher prices for consumers.[56] If successful, the St. Luke's merger would have led to higher costs for both consumers and employers.[57] Clinical integration does not require such a result.

2. ProMedica Health System, Inc. v. F.T.C.

In another recent opinion, the Sixth Circuit expounded on the troubling effects of mergers motivated by bargaining clout.[58] The case involved the FTC's challenge to a proposed merger of two of the four hospital systems in Lucas County, Ohio.[59] In holding that the FTC did not abuse its discretion in ordering divestiture of the two systems, the Court highlighted testimony by witnesses employed by managed care organizations (MCOs) in Lucas

51. *Id.* at 25-26.
52. *Id.* at 27.
53. *Id.* at 28.
54. *Id.*
55. Garcia & Eckert, *supra* note 48, at 2.
56. Gaynor, *supra* note 13, at 1089.
57. Press Release, Fed. Trade Comm'n, Statement by FTC Chairwoman Edith Ramirez on Appellate Ruling in the St. Luke's Hospital Matter (Feb. 10, 2015).
58. Promedica Health System, Inc. v. F.T.C., 749 F.3d 559, 571 (2014).
59. *Id.* at 561.

County.[60] The MCO witnesses testified that if St. Luke's and ProMedica Health System, Inc. (ProMedica) merged, the MCOs would have little ability to resist ProMedica's demands for higher rates because MCOs would not be able to offer health care plans without including the newly merged ProMedica.[61] Moreover, the Chief Executive Officer of St. Luke's Hospital stated himself that an affiliation with ProMedica could "harm the community by forcing higher hospital rates on them."[62] Such a result is clearly at odds with the goals of clinical integration. Coordinating institutions, disciplines, and time in order to achieve a more efficient system does not require that consumers pay higher prices for fewer options. While such explicit motivations to merge are not possessed by all providers, the goals of reform in a market-based healthcare system are best achieved in an environment that fosters healthy competition.[63]

V. WHERE THESE DECISIONS LEAVE HOSPITALS

The above decisions serve as useful guidance for providers considering a merger. Moreover, ProMedica recently filed a Petition for a Writ of Certiorari to the United States Court of Appeals for the Sixth Circuit.[64] If the Supreme Court decides to hear the case, providers may receive more detailed guidance of what must be shown in order to accomplish successful mergers. In the meantime, the FTC has provided guidance for accomplishing the goals of clinical integration.[65] In 2011, the FTC issued a policy statement of antitrust guidance for providers looking to form accountable care organizations

60. *Id.* at 571.
61. *Id.*
62. *Id.* at 563.
63. Ramirez, *supra* note 15, at 2247.
64. Promedica Health System, Inc. v. F.T.C, 749 F.3d 559 (6th Cir. 2014), *petition for cert. filed*, (U.S. Dec. 22, 2014) (No. 14-762).
65. Ramirez, *supra* note 15, at 2246.

(ACOs).[66] The Final Policy Statement assisted health care providers in forming pro-competitive ACOs that benefited patients with private health insurance and Medicare beneficiaries while also protecting consumers from increased prices and decreased quality.[67] Moreover, the FTC and the United States Department of Justice (DOJ) also agreed to offer voluntary expedited ninety-day reviews for newly formed ACOs that seek additional antitrust guidance.[68] Although regulators such as the FTC and DOJ are charged with preventing anticompetitive behavior, their enforcement of antitrust laws is not intended to obstruct health care reform.[69]

The Congressional Budget Office projects that federal health spending will increase from twenty-five percent to approximately forty percent of total federal spending by 2037.[70] In order to prevent health costs from swallowing up a significant portion of the federal budget, growth of healthcare costs must be controlled. While reform efforts such as the Patient Protection and Affordable Care Act will reduce Medicare spending over the next decade, the threat of rising health costs remains, and it is in the interest of the federal agencies to help combat rising costs.[71] Variation in medical prices within the United States is already extreme.[72] Vigilant monitoring of anticompetitive practices in the healthcare market must resume in order to lower costs and discrepancies between hospitals for the same procedures. Moreover, although it is beyond the scope of this article, anticompetitive effect may also have negative implications on hospital services. For example, the merging

66. *Id.*

67. Press Release, Fed. Trade Comm'n, Department of Justice Issue Final Statement of Antitrust Policy Enforcement Regarding Accountable Care Organizations (Oct. 20, 2011).

68. *Id.*

69. Ramirez, *supra* note 15, at 2247.

70. Ezekiel Emanuel et al., *A Systemic Approach to Containing Health Care Spending*, 367 N. ENGL. J. MED., 949, 949 (2012).

71. *Id.*

72. Jennifer Brown, *Price for Hip Replacement Highly Variable, Hard to Obtain*, IOWANOW, (Feb. 17, 2015), http://now.uiowa.edu/2013/02/price-hip-replacement-highly-variable-hard-obtain. (A recent study looked at routine hip replacements and found that the quoted hospital charge could range from $11,100 to $125,798).

of Catholic hospitals may have implications on a woman's access to reproductive health services.

VI. CONCLUSION

The healthcare market in the United States is undergoing the most drastic reforms since 1965 when Medicare and Medicaid were enacted.[73] While coordination across institutions, disciplines, and time create potential benefits for consumers, the nature of our market-based health care system cannot be ignored. While some hospital mergers could conceivably improve quality and control costs, the threat of dominant systems is undisputed. Research shows that dominant hospital systems have potential to increase prices as high as forty to fifty percent.[74] Relaxing antitrust laws in the healthcare arena ignores proven market outcomes. Providers who cannot produce demonstrable qualitative evidence to overcome the assumed anticompetitive effects will not and should not be permitted to merge.

73. Cathy Schoen et al., *supra* note 3, at 2205.
74. Gaynor, *supra* note 13, at 1089.

ANNALS OF HEALTH LAW
Advance Directive

VOLUME 24 SPRING 2015 PAGES 12-25

The Unintended Effects of the Stark Law: Regulating Clinical Integration

Maria Elena Martinez[*]

I. INTRODUCTION

The Patient Protection and Affordable Care Act (ACA)[1] has heavily and favorably impacted the delivery and payment of health care, thereby enabling greater access to care for those who were previously unable to attain it.[2] Despite these positive changes, many individuals still lack adequate access to care.[3] Historically, health care has been a fragmented industry without coordination between providers, payment methods, patients, and regulations.[4] Accordingly, a main goal of healthcare reform through the ACA is to improve the quality of care while minimizing the cost of care.[5] Consequently,

[*] Juris Doctor Candidate, May 2016, Loyola University Chicago School of Law. Ms. Martinez is a staff member of Annals of Health Law.

1. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 141 (2010) (codified as amended in scattered sections of 42 U.S.C.) [hereinafter ACA].

2. *See generally* Jason Furman, *Six Economic Benefits of the Affordable Care Act*, WHITEHOUSE.GOV (Feb. 6, 2014, 12:47 PM), http://www.whitehouse.gov/blog/2014/02/06/six-economic-benefits-affordable-care-act (discussing additional benefits of the ACA such as reduction of unemployment, laying the foundation for future growth, and improving financial security in the face of illness); Margot Sanger-Katz et al., *Is the Affordable Care Act Working?*, N.Y. TIMES (Oct. 26, 2014), http://www.nytimes.com/interactive/2014/10/27/us/is-the-affordable-care-act-working.html?_r=0#/.

3. Rachel Garfield et al., *The Coverage Gap: Uninsured Poor Adults in States That Do Not Expand Medicaid—An Update*, KAISER FAM. FOUND. (Nov. 12, 2014), http://kff.org/health-reform/issue-brief/the-coverage-gap-uninsured-poor-adults-in-states-that-do-not-expand-medicaid-an-update/.

4. *See* Amy L. Woodhall, *Integrated Delivery Systems: Reforming the Conflicts Among Federal Referral, Tax Exemption, and Antitrust Laws*, 5 HEALTH MATRIX 181, 183 (1995) ("Historically, health care has been a fragmented industry characterized by legally separate provider entities and separate payor and provider organization.").

5. *See generally* ACA § 1101, Pub. L. No. 111-148, 124 Stat. 136 (codified at 42 U.S.C. § 300gg-18 (2012)) (describing the health care reform). *See also* Edward Matto & Claire Turcotte, *Legal Challenges and Concerns with Clinical Integration*, BRICKER & ECKLER LLP

the ACA promotes clinical integration, which furthers value-based care by facilitating the coordination of patient care across providers and payors.[6] Thus, health care is moving from a fee-for-service industry that incentivizes providers to deliver additional, unnecessary services that are more profitable[7] to a value-based, integrated system that furthers the goal of the ACA.[8] This Article will specifically discuss the implications of the Ethics in Patient Referral Act (Stark Law),[9] which prohibits referrals for certain health services of Medicare patients by physicians to entities with which the physician has a financial relationship,[10] thereby impeding integration.

The federal government has been strict about prosecuting providers under the Stark Law and other fraud and abuse laws.[11] While these laws do help in preventing fraud,[12] they are also extremely limiting for clinical integration

---

1, https://www.healthlawyers.org/Events/Programs/Materials/Documents/IHC13/legalresources/BricklerEckler_materials.pdf (last visited Apr. 29, 2015) ("A clear goal of health reform is to foster greater integration and collaboration among health care providers to achieve the Centers for Medicare & Medicaid Services' (CMS) triple aim: better care, better health and reduced health care costs.").

6. Matto & Turcotte, *supra* note 5.

7. *See* Timothy Stoltzfus Jost & Sharon L. Davies, *The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement*, 51 ALA. L. REV. 239, 251 (1999) (explaining the incentives created by fee-for-service payment).

8. *See* Corbin Santo, Note, *Walking a Tightrope: Regulating Medicare Fraud and Abuse and the Transition to Value-Based Payment*, 64 CASE W. RES. L. REV. 1377, 1394 (2014) (discussing the trend toward value-based payments); AM. HOSP. ASS'N, TRENDWATCH: CLINICAL INTEGRATION—THE KEY TO REAL REFORM 1 (2010) (explaining how greater clinical integration is essential to achieve the goals of the ACA).

9. Social Security Act of 1935 § 1877, 42 U.S.C. § 1395nn (2010). The Stark Law is also known as the Physician Self-Referral Law. The article will focus only on this specific fraud and abuse law due to page constraints, but also because of the strict liability imposed by the law and lack of scienter, making it a harsh law against integration.

10. *See* 42 U.S.C. § 1395nn (setting forth the language of the law); *Physician Self Referral*, CMS.GOV, http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/ (last modified Jan. 5, 2015, 10:59 AM) (summarizing the law).

11. *See* James Swann, *Anti-Fraud Funding Would Get a Boost from President's Budget*, BLOOMBERG BNA (Feb. 4, 2015), http://www.bna.com/antifraud-funding-boost-b17179922765/ (noting how the government has increased funding for fraud and abuse control).

12. *See Florida Hospital System Agrees to Pay the Government $85 Million to Settle Allegations of Improper Financial Relationships with Referring Physicians*, U.S. DEP'T OF

arrangements.[13] As health care moves toward an integrated system, it would benefit from a law that is not subjective, ambiguous, and non-uniformly applied. Moreover, it is worthy to note that Stark applies only to providers who treat Medicare patients,[14] essentially creating different standards for such providers and those who solely treat privately insured patients. This gap caused by the status of the Stark Law will not allow full integration. However, consolidation and integration brought by the ACA are here to stay.[15] Without truly integrated networks, some of the ACA's goals cannot be met, and little changes in the cost and quality of care will be observed.[16]

This Article will argue that the Stark Law's strict liability and narrow exceptions hinder the goals of the ACA by preventing the creation and operation of integrated networks. This Article will further propose alternatives to the strict application of the Stark Law to prevent fraud and abuse in light of healthcare reform. Part II will provide a brief history of the Stark Law, its language, scope, prohibitions, and enforcement.[17] Part III will explore the Stark Law's negative impact on the goals of clinical integration.[18] Finally, Part IV advocates for alternatives and solutions to the strict prosecution under

JUSTICE (Mar. 11, 2014), http://www.justice.gov/opa/pr/florida-hospital-system-agrees-pay-government-85-million-settle-allegations-improper (discussing hospital's settlement for violating Stark); Lindsey Dunn, *Federal Jury Rules South Carolina's Tuomey Hospital Violated Stark Law but Not False Claims Act*, BECKER'S HOSP. REV. (Apr. 19, 2010), http://www.beckershospitalreview.com/news-analysis/federal-jury-rules-south-carolinas-tuomey-hospital-violated-stark-law-but-not-false-claims-act.html (discussing Tuomey's violation of Stark).

13. *See* AM. HOSP. ASS'N, *supra* note 8, at 10 ("Some have proceeded despite legal and regulatory barriers that have made it more difficult for hospitals and physicians to collaborate. The AHA and others have urged that steps be taken to reduce these barriers.").

14. 42 U.S.C. § 1395nn (2010).

15. Matto & Turcotte, *supra* note 5, at 5.

16. AM. HOSP. ASS'N, *supra* note 8, at 1 (stating that "achieving greater clinical integration in care delivery is essential to the system change needed to achieve [the health care reform's] goals.").

17. *See infra* Part II (summarizing the policies underlying the law and its demands).

18. *See infra* Part III (discussing how the prohibitions of Stark Law hinder integration).

Stark that will allow the government to regulate fraud and abuse while allowing providers to integrate and achieve the goals of the ACA.[19]

II. BACKGROUND

Managed care emerged in the 1980s and changed the Medicare payment system by allowing physicians to bill for each service provided.[20] Over time, incentivization of abuse in providing services resulted.[21] Managed care enabled providers to acquire and administer in-office ancillary services, have ownership or a financial interest, of other facilities providing medical services, refer patients to them, and remunerate with each referral.[22] To curb these unethical practices, California's Democrat Representative Pete Stark proposed legislation in 1988 that would bar Medicare and Medicaid patient referrals by any physician to a facility providing designated health services in which the physician or a member of her family had an investment interest or a compensation arrangement.[23] The underlying policy was that the law would prevent the provision of unnecessary services because a referral would have no value to the referring physician.[24] The law became effective in 1992, with a revision going into effect in 1995, and later was codified in Title 42 of the United States Code.[25] It presumed illegality of any referral to a provider

19. *See infra* Part IV (proposing alternatives to the current regulation).

20. Santo, *supra* note 8, at 1379.

21. S*ee* Patrick A. Sutton, *The Stark Law in Retrospect*, 20 ANNALS HEALTH L. 15, 16–17 (2011) (discussing different physician practices).

22. *Id.* at 16–17; Santo, *supra* note 8, at 1379.

23. Santo, *supra* note 8, at 1380; *What Is the Stark Law*, BUTTACI & LEARDI LLC (Nov. 22, 2013), http://www.buttacilaw.com/blog/what-is-the-stark-law/.

24. *See* Santo, *supra* note 8, at 1385 ("The statutes . . . have attempted to counteract the natural response of providers to provide more care because each additional service can be billed with little or no scrutiny as to its value.").

25. BUTTACI & LEARDI LLC, *supra* note 23.

in which the physician had an ownership interest or a compensation arrangement, unless a listed exception was met.[26]

Since 1995, the Stark Law has been amended, but still retained its roots.[27] In its current form, the Stark Law prohibits referrals of Medicare patients by physicians for twelve "designated health services" to entities and/or providers with which the physician or his immediate family member has a financial relationship—i.e., ownership or a compensation arrangement—unless a listed exception applies.[28] It also prohibits the entity from presenting claims to Medicare or billing another individual for the referred services.[29] In addition to the statutory exceptions, the law grants the Secretary of the Department of Health and Human Services (HHS) the authority to create regulatory

---

26. Santo, *supra* note 8, at 1380. The listed exceptions include ownership exceptions and compensation exceptions. *See* 42 U.S.C. § 1395nn (describing the exceptions).

27. *Compare* Santo, *supra* note 8, at 1380, *with* 42 U.S.C. § 1395nn. The major changes were the repeal of the prohibitions based on compensation arrangements and the reduction of services subject to the ban. BUTTACI & LEARDI LLC, *supra* note 23.

28. 42 U.S.C. § 1395nn (discussing limits on physician referrals); *see also* AM. HOSP. ASS'N, *supra* note 8, at 11 tbl.5 (describing the prohibitions of Stark). The full language of the Stark Law reads:

§ 1395nn. Limitation on certain physician referrals

(a) Prohibition of certain referrals

(1) In general Except as provided in subsection (b) of this section, if a physician (or an immediate family member of such physician) has a financial relationship with an entity specified in paragraph (2), then—

(A) the physician may not make a referral to the entity for the furnishing of designated health services for which payment otherwise may be made under this subchapter, and

(B) the entity may not present or cause to be presented a claim under this subchapter or bill to any individual, third party payor, or other entity for designated health services furnished pursuant to a referral prohibited under subparagraph (A).

42 U.S.C. § 1395nn. The services classified as designated health services are: (1) clinical laboratory services; (2) physical therapy services; (3) occupational therapy services; (4) outpatient speech-language pathology services; (5) radiology and certain other imaging services; (6) radiation therapy services and supplies; (7) durable medical equipment and supplies; (8) parenteral and enteral nutrients, equipment, and supplies; (9) prosthetics, orthotics, and prosthetic devices and supplies; (10) home health services; (11) outpatient prescription drugs; and (12) inpatient and outpatient hospital services. 42 U.S.C. § 1395nn(h)(6).

29. 42 U.S.C. § 1395nn(a)(1)(B); *Physician Self-Referral*, *supra* note 10.

exceptions for financial relationships that are not at risk of abuse.[30] The statutory exceptions are divided into three major categories: (1) general exceptions (both ownership and compensation interests at issue); (2) ownership exceptions; and (3) compensation exceptions.[31] Additionally, the prohibition does not require physicians to act with intent.[32]

Physicians who violate the law are subject to penalties. These penalties include fines, repayment of claims, potential exclusion from participation in Medicare, and occasionally a finding of a violation of the False Claims Act, which increases the monetary penalty by three times.[33] If a physician is excluded from Medicare, he or she may not bill Medicare for any service performed or ordered to his or her Medicare patients.[34]

The ACA's shift toward a value-based system has enabled the wide-reaching scope of integration—from initiatives to achieve greater coordination around a patient's single condition to fully-integrated systems with their own staffs.[35] Clinical integration focuses on the tight collaboration among provid-

30. 42 U.S.C. § 1395nn(b); *Physician Self-Referral*, *supra* note 10.

31. 42 U.S.C. § 1395nn(b)–(d). For example, the in-office ancillary services exception is categorized under a general exception and applies to designated health services provided by the physician's practice, requiring those services to be provided in: (1) the same building in which the physician provides some services unrelated to the designated health services; or (2) if a group practice, in a "centralized building." 42 U.S.C § 1395nn(b)(2).

32. Santo, *supra* note 8, at 1390; *see also* 42 U.S.C. § 1395nn. The law does not have a scienter requirement—it does not provide for the physician to act with a particular mental state, or with the intent or knowledge of wrongdoing prior to committing an act.

33. *Medicare Fraud & Abuse: Prevention, Detection, and Reporting*, CTRS. FOR MEDICARE & MEDICAID SERVS. 6 (Aug. 2014), http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/MLNProducts/downloads/Fraud_and_Abuse.pdf [hereinafter CMS]; Carrie Valiant, *Stark Law Implications for ACOs: Fitting a Square Peg into a Round Hole*, 2 ACCOUNTABLE CARE NEWS, Jan. 2011, at 7, *available at* http://www.ebglaw.com/content/uploads/2014/06/42796_Valiant-Accountable-Care-News-Stark-Law.pdf.

34. CMS *supra* note 33, at 6. The physician is excluded for a period of time at the end of which reinstatement is not automatic; rather, such physician must ask for reinstatement and wait for approval.

35. AM. HOSP. ASS'N, *supra* note 8, at 1.

ers and care sites to further higher quality, more efficient, coordinated services.[36] The collaboration involves working together to establish a mechanism to monitor and control the utilization and administration of services.[37] This will naturally involve procedures such as referrals and compensation arrangements within the integrated system.[38]

However, the existence of federal fraud and abuse laws inherently hamper clinical integration by prohibiting certain compensation arrangements among providers and present legal challenges in structuring integrated networks.[39] These laws are at odds with the goals and policies underlying the ACA.[40] It is in an integrated network's best interest—and in the advancement of quality of care—to allow certain rewards for administering only the necessary services instead of wasting resources and money.[41]

III. STARK'S BARRIERS TO INTEGRATION

The Stark Law poses many obstacles to clinical integration that make the transition to a value-based system impossible. The rise in and stringent prosecution under Stark, and the strict liability imposed by the law have many physicians refusing to restructure their practices.[42]

---

36. *Id.* At 2.

37. *Id.* At 3.

38. *See id.* At 11 tbl.5 (discussing unintended consequences of clinical integration).

39. Matto & Turcotte, *supra* note 5, at 5; *see also* Jost & Davies, *supra* note 7, at 318 ("Though fraud and abuse enforcement receives nearly unanimous support in principle, it has proved increasingly controversial in practice."); AM. HOSP. ASS'N, *supra* note 8, at 1 (stating that hospital and providers "first need to overcome the legal hurdles presented by the . . . Stark . . . law[] . . . ."); *HHS IG Seeks Creative Ways to Shield ACOs from Fraud Laws*, 13 INSIDE CMS, Oct. 14, 2010, *available at* 2010 WLNR 20536630 (discussing how the fraud and abuse laws should not be in the way of integration).

40. Joe Carlson, *Caught Between Competing Pressures*, MODERN HEALTHCARE (Mar. 8, 2014), http://www.modernhealthcare.com/artcle/20140308/MAGAZINE/303089982/caught-between-competing-pressures.

41. Dennis Butts et al., *The 7 Components of a Clinical Integration Network*, BECKER'S HOSP. REV. (Oct. 19, 2012), http://www.beckershospitalreview.com/hospital-physician-relationships/the-7-components-of-a-clinical-integration-network.html/.

42. *See* Carlson, *supra* note 40 (discussing how Stark makes it difficult for hospitals to

The Stark Law prohibits conduct that is key to clinical integration—compensation arrangements.[43] Compensation arrangements prohibited by the Stark Law results in strict liability.[44] Prohibiting such arrangements also precludes reward payments to physicians for providing quality service or preventing readmission of a patient.[45] The law does not provide any exception for incentive payments.[46] Thus, incentives and rewards that may come along with the movement toward value-based care would be forbidden, making it difficult to sustain that movement. Without these incentives, providers will have little motivation to restructure their practices.

The exceptions that do exist only go as far as providing limited protection to providers who want to integrate.[47] The compensation exceptions allow payments for services using an hours-worked and fair-market value approach.[48] That is, the exception is based on the number of hours worked, instead of the achievement of results, and allows payment for items or services if set in advance and at fair market value.[49] This approach does not link the quality of care to the cost of care, which is the ACA's goal.

Further, "payment [under Stark] [may] not depend on volume or value of referrals,"[50] which causes physicians to be paid the same amount of money without assessing the quality of care linked to their services or any potential

contract and pay certain physicians); Matto & Turcotte, *supra* note 5, at 5 (arguing that the laws present legal challenges and concerns in structuring clinically integrated networks).

43. *See* 42 U.S.C. § 1395nn.

44. 42 U.S.C. § 1395nn; Santo, *supra* note 8, at 1403.

45. Butts, *supra* note 41.

46. Santo, *supra* note 8, at 1403.

47. *Id.*; *see also* Valiant, *supra* note 33, at 7 (stating that the current exceptions are "very restrictive").

48. Matto & Turcotte, *supra* note 5, at 3.

49. *Id.* at 3 n.6, 9.

50. Santo, *supra* note 8, at 1405.

savings the quality might have contributed to their practice.[51] This prohibition opposes the movement toward value-based care. A true integrated network offers its physicians rewards for achieving a certain level of quality and performance, for following standardized clinical protocols, and for contributing to organizational goals, all of which are not accurately reflected in the amount of hours worked.[52] Moreover, there is no benchmark data or method to determine the fair market value of quality-related payments.[53] As such, the Stark Law does not take into account the quality of care provided by the physicians it covers.

CMS never finalized its proposed rule issued in 2008 outlining an exception for incentive payments.[54] HHS stated that it is questionable "how a physician self-referral exception could be designed given that any new exception under [Stark] must present no risk of program or patient abuse."[55] This demonstrates HHS' unwillingness to work around or modify the law to facilitate integration. If physicians are all rewarded equally without assessing their actual contribution to value and quality, the conduct that the Stark Law was trying to prevent in the first place—overutilization of unnecessary services—cannot be deterred.[56] Moreover, this eliminates any quality inducement.

Although the ACA grants the Secretary of HHS authority to waive certain fraud and abuse provisions,[57] this measure to allow some form of integration

---

51. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-355, MEDICARE: IMPLEMENTATION OF FINANCIAL INCENTIVE PROGRAMS UNDER FEDERAL FRAUD AND ABUSE LAWS 21 (2012).

52. Matto & Turcotte, *supra* note 5, at 3.

53. *Id.*

54. Santo, *supra* note 8, at 1406.

55. *Id.* (quoting Notice of Meeting, 75 Fed. Reg. 57039-01 (Sept. 17. 2010)).

56. *See id.* at 1404 ("The effects of rewarding physicians equally for making an unequal contribution to achieve savings may have adverse effects on changing physician habits . . . .").

57. ACA § 1101, Pub. L. No. 111-148 § 3022(f); Kristin Madison, *Rethinking Fraud Regulation by Rethinking the Health Care System*, 32 HAMLINE J. PUB. L. & POL'Y 411, 417

is not enough. There is no certainty in the number or scope of the waivers that may be created to facilitate integration.[58] The waivers issued have been broad in their applicability.[59] HHS granted waivers for ACO pre-participation activity, participation in approved ACOs, and certain patient incentive payments.[60] Decisions on whether to apply a waiver for a certain provider would rest on a case-by-case basis.[61] This would lead to a non-uniform application of the Stark Law across the healthcare field, when the reform is attempting to unify the healthcare system. Further, these waivers have been primarily adopted for providers involved in pilot-programs, calling into question the long-term reliance of the waivers.[62] Clinical integration is the future system of healthcare providers, and the elimination of the Stark Law is not in HHS' near future.[63] Ever-changing, temporary waivers will not solve the problem for integration practices. Providers will need a steady and long-term measure that allows them to pursue the restructuring of their practices free from liability.

Finally, because the Stark Law only applies to providers with Medicare

(2010).

58. Madison, *supra* note 57; *see also* Santo, *supra* note 8, at 1409 (stating that "CMS has not yet issued comprehensive language on what [the] waivers will require.").

59. Santo, *supra* note 8, at 1408.

60. *Id.* at 1408–09.

61. *See* Robert G. Homchick & Sarah Fallows, *ACOs: Fraud & Abuse Waivers and Analysis*, DAVIS WRIGHT TREMAINE, LLP 3, *available at* https://www.healthlawyers.org/Events/Programs/Materials/Documents/HCT13/h_homchick.pdf (last visited Apr. 29, 2015) (discussing how in the case of already established ACO waivers, arrangements that do not fit within an established waiver will be evaluated on a case-by-case basis).

62. Santo, *supra* note 8, at 1409, 1412. The government's reliance on the waivers should be temporary. *Id.* at 1412.

63. *See id.* at 1412 ("[I]t is unlikely that a wholesale elimination of these regulations is likely anytime in the near future . . . ."); *see also* Carlson, *supra* note 40 (noting that it might not be that the Department of Justice has toughened enforcement of Stark, but the number of attorneys who want to prosecute those crimes has significantly increased because of the amount of money involved, and more whistle-blowers are also coming forward).

patients,[64] integration would preserve the two-tier system where the law applies to Medicare providers, but not to those that do not accept Medicare patients.[65] As discussed above, the Stark Law hinders many providers who wish to integrate.[66] In addition to the strict liability imposed and harsh penalties, the Stark Law may go as far as encouraging providers who realize they can be compensated for their quality of work in a clinically integrated network not covered by Stark, such as those who only see privately-insured or non-insured patients, to stop accepting Medicare patients altogether.[67] How can systems be fully integrated when providers have different standards? The degree to which hospitals and physician practices are integrated with each other and other sites varies,[68] thus the government must go through different exceptions, waivers, and analyses of the law based on the facts surrounding each provider, which furthers the multi-tier system. For the ACA's goals to be met, these tiers should be treated as close to equal as possible, if not eliminated.

IV. STARK REGULATION: TIME FOR A CHANGE

The Stark Law's shortfalls are so severe that its own author is advocating for the statute's repeal.[69] Furthermore, agencies have published and constantly updated exceptions to Stark.[70] These ever-changing exceptions are a deterrent for providers to restructure or integrate their practices because pro-

64. 42 U.S.C. § 1395nn.

65. Elise Dunitz Brennan & Hilary L. Velandia, *Do the PPACA Amendments to the Stark Whole Hospital Exception Mean the Evolution of a Two-Tier System?*, 4 J. HEALTH & LIFE SCI. L., 40 (2010).

66. *See infra* Part III.

67. Brennan & Velandia, *supra* note 65.

68. AM. HOSP. ASS'N, *supra* note 8, at 6.

69. Carlson, *supra* note 40.

70. *Id.*

viders lack the certainty that the new structure will be steady and in compliance with the law. Other providers might wait until the exception that will favor them is published. For a healthcare system to move toward complete integration, it requires more relaxed standards and regulations because it is an area in which providers will have to learn what works and what does not work as they ease into the new system. Although more relaxed standards could theoretically cause more fraud and abuse, separate regulations, such as the Anti-Kickback Statute, would still protect against fraud and abuse.

If waivers continue to be the rule, or exception, to Stark, they will require expanded coverage and much guidance from CMS.[71] Additional guidance would help providers who are uncertain of what they can and cannot do, and provide reassurance to such providers without compromising their practice.[72] The Stark Law has not been able to adjust to the changing system under the reform. While other pieces of the regulatory system move and adjust, this law is not flexible in application.[73] Since the system will keep changing until full integration occurs and providers integrate slowly, any waiver, exception, or alternate law HHS decides to enforce should have sufficient flexibility to adapt and change with the system.

A more radical approach would be to repeal Stark. As it stands today, Stark's enforcement is undefined.[74] What good comes from a severe statute that is not being applied uniformly to a system that seeks uniformity? When a system is decentralized, it fosters fraud because it has many moving parts across the border, preventing good oversight.[75] Therefore, if care is better

71. Santo, *supra* note 8, at 1413.
72. *See id.*
73. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 51, at 18.
74. Santo, *supra* note 8, at 1417 ("Recent statements by the Inspector General indicate that the statutes will remain in place with undefined enforcement applicability.").
75. Madison, *supra* note 57 at 418.

coordinated and there is better oversight of such care—the goals and importance of integration—then fraud is significantly reduced.[76] An integrated system allows quality to be assessed directly,[77] and Stark, as well as other fraud and abuse laws, may eventually be unnecessary. Furthermore, the ACA has provisions for public reporting, and adjusting payments based on quality and safety.[78] The policy underlying the implementation of Stark and the conduct it sought to deter is achieved by the goals of the ACA and clinical integration.[79] In other words, the fraud and abuse laws will be taken care of by the ACA and clinical integration. The Stark Law turns out to be superfluous, while being directly at odds with the goals of integration and the ACA—goals very similar to those of its initial underlying policy.

No matter how much flexibility the Stark Law is allowed, integrated networks would still face regulatory barriers with the other existing fraud and abuse laws because other types of financial incentives and arrangements would still be prohibited.[80] If providers are moving toward integration, perhaps the government's fraud and abuse regulation should as well with the consolidation of such laws. If the regulatory agenda is not coordinated, neither can the system move to coordinated integration.[81]

V. CONCLUSION

The ACA's goal of equally available, higher quality care at a minimum cost can only be achieved through clinical integration. However, the current

76. *Id.*
77. *Id.* at 419.
78. *Id.* at 425–26.
79. *Id.* at 427.
80. James F. Blumstein, *Of Doctors and Hospitals: Setting the Analytical Framework for Managing and Regulating the Relationship*, 4 IND. HEALTH L. REV. 211, 213 (2007).
81. Woodhall, *supra* note 4 ("The lack of a coordinated regulatory agenda creates special problems for integrated delivery system development.").

existence of Stark Law hinders the ACA from achieving its goal. By prohibiting conduct essential of clinically integrated systems, imposing strict liability with limited exceptions and case-by-case waivers, and creating different standards for providers, the Stark Law is an insurmountable barrier to integration. Major changes in the regulatory agenda need to occur before providers feel comfortable to begin moving toward an integrated practice without fear of violating such a harsh law. A reconsideration of the regulatory system with more relaxed standards will then allow the creation of fully-integrated networks, and in turn, an increase in the quality of care while reducing its cost.

ANNALS OF HEALTH LAW
Advance Directive

VOLUME 24 SPRING 2015 PAGES 26-39

Reassessing the Provider-Based Billing Model in Hospital-Acquired Physician Practices

Anna L. Leahy[*]

I. INTRODUCTION

After the enactment of the Patient Protection and Affordable Care Act (ACA), hospitals have begun to acquire physician practices in order to implement an integrated, value-based health care system.[1] To ensure a successful integration, hospitals must assess the administrative changes needed to provide efficient and affordable care.[2] Specifically, hospitals must choose a billing model. Hospitals may implement two different types of billing models for their offsite physician practices—the provider-based model or the free-standing model.[3]

Prior to August 1, 2002, the Centers for Medicare and Medicaid Services (CMS) had to designate hospital-acquired physician practices with provider-based status in order for the entity to charge under the provider-based model.[4]

---

[*] Juris Doctor Candidate, May 2016, Loyola University Chicago School of Law. Ms. Leahy is a staff member of Annals of Health Law.

1. *See The Value of Provider Integration*, AM. HOSP. ASS'N 1 (Mar. 2014) (explaining that providers are looking for ways to improve patient care, quality and lower costs); *see also* Elissa Moore & Bart Walker, *Hospitals and Health Systems: Provider-Based Status: The Rules and Common Issues*, HEALTH CARE L. MONTHLY (Apr. 2008), *available at* http://www.mcguirewoods.com/news-resources/publications/health_care/provider-status-determinations.pdf (stating some of the factors that have sparked hospitals' interests in acquiring physician practices including: "space limitations on the [hospital] campus, patient needs, population growth, convenience and other competitive factors" (alteration to original)).

2. *See The Value of Provider Integration*, *supra* note 1 (noting that providers choose to integrate in order to: streamline the processes in which patient information is obtained, ensure follow-up care, share financial risks, and ease transitions).

3. *Hospital Ownership of Physician Practices*, DEP'T OF HEALTH & HUMAN SERVS. 1 (Sept. 1999), *available at* https://oig.hhs.gov/oei/reports/oei-05-98-00110.pdf [hereinafter *Hospital Ownership*].

4. Memorandum from Ctrs. For Medicare & Medicaid Servs. and Dep't of Health & Human Servs. on Provider-based Status On or After October 1, 2002 1 (Apr. 18, 2003),

However, CMS altered this standard in a new rule published on August 1, 2002.[5] Under the new standard, a hospital-acquired physician practice does not need to inform CMS that they meet provider-based standards.[6] Rather, CMS provides incentives for providers to send in attestation forms explaining why they meet provider-based standards and issues minor penalties for entities that are found to violate provider-based status requirements.[7]

The changes in provider-based status requirements have done little to improve quality of care and caused an unexpected surge in the cost of patient bills for many Americans.[8] This article will argue that CMS's current rule for provider-based status counteracts the goals of the ACA, which focus on enhancing the quality and lowering the costs of care.[9] The current regulations

---

available at https://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/downloads/a03030.pdf [hereinafter Memorandum].

5. *See* 42 C.F.R. § 413.65(d) (2011) (listing requirements to gain provider-based status).

6. *See* Memorandum, *supra* note 4 (explaining that mandatory provider-based determinations under § 413.65(b) have been replaced with a "voluntary attestation process").

7. If a provider chooses to submit a self-attestation form explaining why it is eligible for provider-based status, and CMS later discovers that the entity was actually not eligible, CMS will only recover the overpayment for the period beginning when the attestation form was submitted. Memorandum, *supra* note 4. However, if the entity does not choose to submit a self-attestation form, and CMS determines that the entity does not meet provider-based status, CMS will recover overpayment for the period beginning on October 1, 2002. *Id.* For a sample self-attestation form, see the end of the memorandum, entitled SAMPLE ATTESTATION FORMAT. *Id.*

8. *See e.g.*, Anna Wilde Mathews, *Same Doctor Visit, Double the Cost*, WALL ST. J. (last updated Aug. 27, 2012) (describing a situation in which a man's bill for a procedure was four time greater than if he would have had done the procedure at another facility); Carol M. Ostrom, *Why you might pay twice for one visit to the doctor*, SEATTLE TIMES, *available at* http://www.seattletimes.com/seattle-news/why-you-might-pay-twice-for-one-visit-to-doctor/ (last updated Nov. 5, 2012) (discussing a patient who was charged $109 for her procedure and $228 for the facility fee, more than twice the cost of her procedure).

9. *See ObamaCareFacts: Facts on the Affordable Care Act*, OBAMACARE FACTS, http://obamacarefacts.com/obamacare-facts/ (last visited Feb. 19, 2015) (stating that the ACA's "goal is to give more Americans access to affordable, quality health insurance, and to reduce the growth in U.S. health care spending.");

> The Patient Protection and Affordable Care Act will improve the quality and efficiency of U.S. medical care services for everyone, and especially for those enrolled in Medicare and Medicaid. Payment for services will be linked to better quality outcomes. The Patient and Affordable Care Act will make substantial investments to improve the quality and delivery of care and support research to inform consumers about

allow entities to easily abuse the system and charge excessive fees through the provider-based model with little to no improvement to the quality of care.[10]

This article will first examine the background behind the different billing models. It will begin by explaining the differences between provider-based billing and free-standing billing, and then explain the differences between the old and new rules regarding billing practices in hospital-acquired physician practices. Second, this article will analyze the implications regarding the final rule. Finally, this article will propose changes to the current regulations regarding billing practices. The changes that should be made to the current regulations include: (1) greater price transparency,[11] (2) implementing a more formal approval process awarding provider-based status—as opposed to the

---

> patient outcomes resulting from different approaches to treatment and care delivery . . . *Payment accuracy will improve*.

The Patient Protection and Affordable Care Act, RESPONSIBLE REFORM FOR THE MIDDLE CLASS, *available at* http://www.dpc.senate.gov/healthreformbill/healthbill04.pdf (last visited Apr. 23, 2015) (stating the goals of the ACA) (emphasis added).

10. *Hospital Ownership*, *supra* note 3. Although CMS rejected the OIG's recommendation that provider-based designation be eliminated for physician practices that are not on the campus of the hospital in hopes of encouraging integration of care, OIG plans to review these regulations once again in 2015. *See Work Plan Fiscal Year 2015*, OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS. 3 (explaining that the OIG intends to evaluate the services provided in provider-based facilities to see whether these facilities actually meet provider-based status and the impact on Medicare payments); *see also* AMERICAN COLLEGE OF PHYSICIANS POLICY ON PROVIDER-BASED BILLING 2 (Apr. 2014), *available at* http://www.acponline.org/acp_policy/policies/provider_based_billing_2013.pdf [hereinafter AMERICAN COLLEGE OF PHYSICIANS] (stating that "[i]t is simply not appropriate for payers and patients to be subjected to increased costs for the same level and quality of care because the physical location and/or the business arrangement of the practice are different from a freestanding physician office.").

11. *See* REPORT OF THE CONNECTICUT ATTORNEY GENERAL CONCERNING HOSPITAL PHYSICIAN PRACTICE ACQUISITIONS AND HOSPITAL-BASED FEES 4 (Apr. 16, 2014), *available at* http://www.ct.gov/ag/lib/ag/press_releases/2014/20140416_oag_report_hospitalmdacquisitions_hospitalbasedfacfee.doc200x.pdf [hereinafter REPORT OF THE CONNECTICUT ATTORNEY GENERAL] (stating that "[c]onsumers cannot make informed choices, and markets cannot function efficiently, when price of goods and services cannot be readily determined."). For the federal government's definition of "price transparency," see *id.* (defining "'price transparency' as 'the availability of provider-specific information on the price for a specific health care service or set of services to consumer and other interested parties'").

current self-attestation process,[12] (3) greater oversight of entities that claim provider-based status,[13] and (4) harsher punishments for entities that fail to maintain the requirements of provider-based status.[14]

II. BACKGROUND

When a hospital acquires a physician practice, it may choose from two different billing models for federal health plans—the free-standing payment model and the provider-based payment model.[15] These billing models affect how Medicare reimburses entities for services.[16] Under the free-standing model, the hospital treats the physician practice as a separate entity from the hospital.[17] Therefore, the physician practice charges patients without the overhead facility fees from the hospital.[18] On the other hand, a hospital-acquired physician practice using the provider-based system is treated as part of the hospital.[19] Here, the patient will receive two bills: one for the physician fee and one for the facility fee.[20] The facility fee includes the overhead costs

12. *See* Memorandum, *supra* note 4, at 2 (explaining the self-attestation process).

13. *See Hospital Ownership*, *supra* note 3, at 2 (stating that only a small number of hospitals are subject to a full audit, which means some hospitals could be receiving reimbursements for provider-based payments when they do not meet the requirements for provider-based status); Lawrence W. Vernaglia, *Is Provider-Based Reimbursement Going Away*, HEALTH CARE L. TODAY (Nov. 14, 2014), *available at* http://www.healthcarelawtoday.com/2014/11/13/is-provider-based-reimbursement-going-away/ (noting that there are increasing "compliance concerns for provider-based violations," and there is a push to encourage providers to self-audit their facilities for violations).

14. For a discussion of the current penalties for entities that violate provider-based status regulations see Memorandum, *supra* note 4, at 2–3. In the Office of Inspector General's 1999 report, the OIG suggested that CMS seek legislation that would sanction hospitals for failing to make its provider-based designation known. *See Hospital Ownership*, *supra* note 3, at 4; *but see* C.F.R. § 413.65(b) (2012) (indicating that CMS still has not sought out sanctions because CMS will only collect a certain amount of overpayment if a health care facility is found to violate provider-based designation).

15. *Hospital Ownership*, *supra* note 3.

16. *Id.*

17. Lawrence W. Vernaglia and Jeffrey R. Bates, *Hospital self-audits of "provider-based" status*, HEALTH CARE COMPLIANCE ASS'N 35 (Oct. 2012), *available at* http://www.foley.com/files/Publication/c9d094c2-7334-4dd6-813f-20a44abc6639/Presentation/PublicationAttachment/1a41d4bc-6744-4ee9-80ac-267c342e3f25/CT10-12.pdf.

18. *Id.*

19. *Id.*

20. *Hospital Ownership*, *supra* note 3.

of the hospital.[21] Although the physician fees under the provider-based payment models are reduced, provider-based bills are often greater than free-standing bills.[22] This price increase comes with little to no change in the quality of care.[23]

Prior to the enactment of legislation regarding provider-based status in 2002, CMS's biggest concerns about mistaken provider-based determinations were overpayments by Medicare, excessive coinsurance payments, inadequate supervision of outpatient departments, and failure to meet the main campus's standards for health and safety.[24] In 1999, the Office of Inspector General (OIG) of the Department of Health and Human Services (HHS) published a report stating that approximately sixty-two percent of for-profit and not-for-profit general hospitals purchased or owned physician practices as a result of the changing health care industry.[25] Due to the increasing prevalence of hospital-acquired physician practices in the marketplace, CMS should reevaluate the current regulations.[26]

In 1999, the OIG made several recommendations regarding CMS's regulations on provider-based designations and off-campus physician practices to address the increases in Medicare reimbursements and copayments.[27] First, the OIG suggested that CMS eliminate provider-based designations for off-

21. *Id.*
22. *Id.*
23. *Hospital Ownership*, *supra* note 3.
24. *The Final Provider-Based Status Rule*, MCDERMOTT WILL & EMERY (Apr. 14, 2000), http://www.mwe.com/publications/uniEntity.aspx?xpST=PublicationDetail&pub=4373.
25. *Hospital Ownership*, *supra* note 3.
26. *Id.*; *see The Value of Provider Integration*, *supra* note 1 (explaining that hospitals and physician practices have been integrating at an increasing pace in order to provide more uniform care after the enactment of the ACA); Katie Sullivan, *Hospital employment on the rise among primary care physicians*, FIERCEHEALTHCARE (July 15, 2014), *available at* http://www.fiercehealthcare.com/story/hospital-employment-rise-among-primary-care-physicians/2014-07-15 (explaining that the percentage of hospital-employed primary care physicians has increased from 10 to 20 percent from 2012 to 2014); *see also* Ostrom, *supra* note 8 (explaining that it has become more common for physician bills to increase as hospitals purchase physician practices).
27. *Hospital Ownership*, *supra* note 3, at 3.

campus physician groups that were acquired by hospitals and instead treat all entities as free-standing clinics.[28] Second, the OIG recommended that CMS monitor any clinics that are granted provider-based status to ensure that such clinics maintained the necessary requirements to meet provider-based status.[29] Third, the OIG suggested that hospitals should inform fiscal intermediaries of all past and current purchases of physician practices in order to keep accurate records of entities that may seek provider-based status.[30] Fourth, the OIG proposed that sanctions be included for clinics that violate provider-based regulations.[31] Although CMS ultimately agreed that the current system allowed for fraud and abuse, it did not agree with eliminating the provider-based status designation altogether.[32]

Despite suggestions from OIG regarding potential revisions to provider-based payment rules, CMS's new rule disregarded these suggested changes and made it easier for entities to gain provider-based status.[33] Although CMS still requires that an entity meet certain requirements to gain provider-based status, the new system does not require providers to report or attest to CMS

28. *See id.* at 15 (explaining that treating all hospital-acquired physician practices as free standing entities "would financially benefit Medicare beneficiaries by eliminating the coinsurance inequities they are currently experiencing when they receive services in provider-based, rather than free-standing, facilities.").

29. *Id.* at 3.

30. *See id.* at 16 (noting that it is important for fiscal intermediaries to be aware of hospital-acquired physician practices to ensure that fiscal intermediaries can identify the costs associated with these entities).

31. *Id.* Provider-based criteria include requirements regarding the location, supervision, accreditation, ownership and control, integration, how the entity holds itself out to the public, and financial integration of hospital-acquired physician practices. *See id.* at App. A, at 20–22 (listing the provider-based criteria).

32. *See id.* at App. B, at 23–24 (stating CMS "believe[s] that encouraging the integration of delivery systems is desirable, and development of provider-based entities can help serve this end in many instances," but also recognizing the need for "safeguard[s]" against abuse of excessive Medicare reimbursements).

33. *See generally*, Memorandum, supra note 4 (discussing the new requirements regarding provider-based billing).

that they meet the provider-based requirements.[34] Rather, the attestation process to obtain a provider-based status designation through CMS is optional.[35] This self-attestation process provides minimal incentives for a provider to submit an attestation and allows providers to abuse the system. As a result, the costs of care have continued to rise without changes in the quality of care in many hospital-acquired physician practices.[36]

A. Provider-Based Status Established Under the Final Rule

The main requirements an entity must satisfy in order to meet provider-based status include: (1) having the same licensure as the main provider, (2) providing integrated clinical services, (3) financial integration, and (4) notifying the public of the status.[37] Additionally, off-campus providers must be able to demonstrate the same operation and control as the main provider, that they are under the same administration as the main provider, that the main provider supervises them, and they must meet certain location requirements.[38]

These new requirements for provider-based status have made it easier for on-campus facilities to qualify for provider-based payments.[39] For instance, some entities may only need to change documents and forms so that the physician's office and the hospital can coordinate care more efficiently.[40] On the

34. *Id.* at 2.

35. *See id.* (explaining that mandatory provider-based determinations were replaced with a "voluntary attestation process" under C.F.R. § 413.65(b)(3) (2012)).

36. *Hospital Ownership*, *supra* note 3. For instance, many patients are shocked to see the increase in their coinsurance payment after visiting a doctor's office they have been to for years, but has recently been bought by a hospital. REPORT OF THE CONNECTICUT ATTORNEY GENERAL, *supra* note 11, at 2. If more regulations were in place, patients could make more informed health care decisions prior to getting an increased bill. *See id.* at 17 (explaining that increased awareness of the overhead fees associated with provider-based billing will allow consumers the option of seeking a lower cost health care service).

37. Moore & Walker, *supra* note 1, at 4.

38. *Hospital Ownership*, *supra* note 3, at 5–6.

39. Lawrence A. Manson & Allwyn J. Baptist, *Assessing the Cost-Effectiveness of Provider-Based Status*, 56 HEALTHCARE FIN. MGMT. 52 (Aug. 31, 2002), *available at* 2002 WL 5446255.

40. *Id.*

other hand, some entities will still have to focus on changing overhead personnel to make the physician group more integrated with the hospital.[41]

The first major way the new provider-based rules made it easier for entities to gain provider-based status was through the self-attestation process.[42] Under Section 413.65(b)(3) of the Code of Federal Regulations (CFR), a provider may choose to submit an attestation form so that CMS can assess whether they are qualified for a provider-based designation.[43]

Although submitting an attestation form is not required, there are benefits to filing an attestation form.[44] For instance, if a provider chooses to self-attest, it will receive a provider-based determination if it meets all the requirements.[45] However, if CMS finds that the provider does not meet the requirements, CMS will only recover the overpayment the provider received for the period beginning when the attestation was filed.[46] Alternatively, if a provider chooses not to self-attest and CMS later determines that the facility does not meet the requirements, CMS will recover overpayment for the period beginning on October 1, 2002.[47]

A provider will also benefit from self-attestation if the relationship between the physician's office and hospital changes to where provider-based requirements are no longer met.[48] If the provider properly submits materials regarding the change in status, CMS will only require that the facility stop billing as a provider-based entity as of the date of its determination.[49] If a

41. *Id.*
42. *See* Memorandum *supra* note 4, at 2 (explaining how entities are no longer required to attain provider-based determinations).
43. *Id.* However, in the past providers had to submit an attestation form to CMS, then the Health Care Finance Administration (HCFA), which stated that the facility satisfied the requirements for provider-based status. Moore & Walker, *supra* note 1, at 3. CMS would review these attestations and evaluate whether the entities met provider-based status. *Id.*
44. Memorandum, *supra* note 4, at 2.
45. *Id.*
46. *Id.*
47. *Id.*
48. *Id.*
49. *Id.*

provider does not self-attest or fails to submit material regarding a change in status, CMS will recover overpayments beginning on the date in which the material change occurred.[50]

III. IMPLICATIONS OF THE FINAL RULE

Since the enactment of the ACA, most providers have been looking for ways to improve patient care, quality of care, and to lower the costs of care to account for the various penalties and savings incentives imposed by the ACA.[51] Therefore, many health systems have begun to integrate in order to streamline the processes in which patient information is obtained, follow-up care is provided, and to share financial risk.[52] Although integration of care is a key component to reform, it is also important to ensure that proper regulations are set into place so that hospitals are not able to abuse the system and unnecessarily charge patients excessive fees.[53]

Hospitals contend that charging patients through the provider-based system is essential to help curve the prices paid in order to comply with the new

50. Moore & Walker, *supra* note 1, at 5–6; *The Value of Provider Integration*, *supra* note 1; *see generally The Patient Protection and Affordable Care Act*, *supra* note 8 (explaining the essential purpose of the ACA).

51. *The Value of Provider Integration*, *supra* note 1.

52. *Id.*; *see Hospital Ownership*, *supra* note 3 (noting that hospitals have been buying physician practices due to the changing landscape of the healthcare industry); REPORT OF THE CONNECTICUT ATTORNEY GENERAL, *supra* note 11 (stating that at least 600 hospital mergers occurred within 2007 and 2012, and at least 247 of those occurring during 2012, partially due to the ACA and its emphasis on integrated health care); *see also* Michael A. Cooper et al., *Hospital Physician Integration: Three Key Models*, AM. HEALTH LAWYERS ASS'N 2 (Oct. 2011) (noting that healthcare reform caused health care systems to find ways to improve hospital-physician relationships through integrated networks).

53. Even though CMS disagreed with eliminating the provider-based billing model, CMS recognized that Medicare reimbursement could be "advantageous" for some health care groups. *See Hospital* Ownership, *supra* note 3. *See e.g.*, Sandra G. Boodman, *Extra Health-Care Facility Fees Take Many Patients by Surprise*, WASH. POST (Oct. 6, 2009), http://www.washingtonpost.com/wp-dyn/content/article/2009/10/05/AR2009100502910.html (estimating that facility fees create an additional $30,000 of revenue for hospitals); REPORT OF THE CONNECTICUT ATTORNEY GENERAL, *supra* note 11, at 7 (stating that Medicare reimbursement for colonoscopies in freestanding ambulatory surgical centers is about $362, while reimbursement for hospital-based outpatient departments is about $643).

rules under the ACA.[54] However, an overwhelming number of critics argue that facility fees are basically "disguised price increases" that are causing the price of care to skyrocket.[55] This is especially a concern when the entity is an off-campus facility that provides services that a hospital would not be able to provide in the first place.[56]

Additionally, it is difficult for patients to discern whether a physician's practice is part of a hospital because such practices are often in the same building as other practices, which are not part of the hospital.[57] However, even if a patient determines that his provider bills under the provider-based system, it will still be difficult to determine whether a fee is associated with the actual cost of care or just disguised as cost shifting.[58] This particular issue led to a number of class action suits in 2006, which resulted in many refunds to patients.[59] For instance, a provider-based entity charged a patient $1,133 for a toenail clipping with a $418 facility fee just to check for toe fungus.[60] It was later discovered that the patient could have had the same procedure at a different facility not associated with the hospital for a maximum cost of $269.[61]

CMS actually counteracted the original goals of the ACA—providing low-cost, efficient care—by making it easier for providers to bill under the provider-based method. For instance, family premiums were thirty percent

54. *Id.*
55. *See* Boodman, *supra* note 53 (explaining that facility fees are similar to charging one fee for a haircut and charging a separate fee to sit in the chair). See other examples in *supra* note 53 and accompanying text.
56. *See id. See e.g.*, AMERICAN COLLEGE OF PHYSICIANS, *supra* note 10, at 2 ("While there are certainly instances where the additional technology and other services of a hospital facility are necessary to a physician office visit, many visits to internal medicine specialists, including most standard evaluation and management (E&M) office visits . . . do not require the availability of those additional services.").
57. *Id.*
58. *Id.*
59. Boodman, *supra* note 53.
60. *Id.*
61. *Id.*

higher in 2012 than in 2007.[62] It is likely that these prices will continue to rise as hospitals and other main providers gain more bargaining power to set prices.[63] After all, these entities are becoming more powerful as they purchase other facilities.[64] Therefore, stricter regulations should be in place to ensure that facilities do not abuse provider-based billing practices if they choose to integrate.

IV. SUGGESTED SOLUTIONS

This article recognizes the importance of integrating care. However, the current regulations that allow hospital-acquired physician practices to bill using the provider-based system opens the door to potential abuses, which increase the costs of care with little to no change in quality of care.[65] Therefore, a more rigid set of regulations with greater oversight of the billing practices of hospital-acquired physician practices is necessary. Potential changes could

62. REPORT OF THE CONNECTICUT ATTORNEY GENERAL, *supra* note 11, at 4. This demonstrates that health care payers have been shifting the costs of care to consumers with the rising costs of health care. *Id.*

63. *Id.*

64. *Id.* There is also a fear that as health systems integrate they will have more power to negotiate reimbursement prices which will lead to higher costs of health care. *Id.* This will allow many hospitals to form "monopolies," as health systems gain more negotiation power. *Id.*

65. Every year, the OIG makes a list of billing areas that it thinks has the highest potential for fraud and abuse. It has selected provider-based billing in hospital-acquired physician practices as an area of concern for the past several years. *See Work Plan Fiscal Year 2015*, *supra* note 10, at 3 (evaluating the extent that hospital acquired-physician practices comply with CMS standards for provider-based billing and also comparing the differences in Medicare reimbursements between free-standing and provider-based facilities); *Work Plan Fiscal Year 2014*, OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS. 2–3 (comparing Medicare payment differences in provider-based and free-standing clinics); *Work Plan Fiscal Year 2013*, OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS. 2 (noting the Medicare Payment Advisory Commission stated concerns about the incentives presented by the provider-based billing system). *See also* AMERICAN COLLEGE OF PHYSICIANS, *supra* note 10, at 3–4 (stating that "a 6.7 percent increase" in outpatient facilities that bill under the provider-based system likely led to an increase in Medicare reimbursements with no change in care because the same procedures were still being performed in the same facilities).

include: (1) greater price transparency,[66] (2) implementing a more formal approval process for facilities wishing to charge through the provider-based system,[67] (3) greater oversight of entities that are granted provider-based status,[68] and (4) harsher punishments for entities that fail to meet provider-based requirements.[69]

First, greater price transparency will allow patients to know exactly what they are charged for, which will limit the excessive fees that hospitals are able to charge.[70] If entities are forced to show what they are charging for, they are more likely to keep their prices reasonable to limit liability.[71] Second,

66. AMERICAN COLLEGE OF PHYSICIANS, *supra* note 10, at 3. Although CMS requires provider-based facilities to be transparent about its prices, it does not specify how facilities should inform the public about their billing procedures. *Id.* Creating a clearer standard for acceptable transparency policies can help consumers make informed decisions regarding their health care. *Id.*

67. Prior to the enactment of the new regulations regarding provider-based billing, the OIG expressed concerned that many fiscal intermediaries were unaware that the hospitals purchased any physician practices. *See Hospital Ownership*, *supra* note 3, at 9. However, under the new regulations, hospitals do not even have to submit an attestation form regarding their provider-based billing status. *See* C.F.R. § 413.65(b)(3) (2012) (explaining that health care facilities only need to submit attestation forms if they wish to receive a *designation* of provider-based status).

68. *But see* Nina Youngstrom, *Provider-Based Rules Trigger 2nd Hospital Settlement; CMS Targets Shared Space*, HEALTH BUS. DAILY (Apr. 16, 2015), *available at* http://aishealth.com/archive/rmc040615-01 (stating that CMS is beginning to "crack[]" down on health care facilities that have shared space arrangements).

69. *See Hospital Ownership*, *supra* note 3, at App. B, at 24 (showing CMS's responses to OGI report about provider-based facilities). Although CMS agreed that sanctions should be sought for providers who abuse provider-based billing, the only recourse continues to be overpayment under the final rule. *Id.*

70. *See* AMERICAN COLLEGE OF PHYSICIANS POLICY ON PROVIDER-BASED BILLING 3–4 (Apr. 2014), *available at* http://www.acponline.org/acp_policy/policies/provider_based_billing_2013.pdf (reasoning that hospitals and hospital-owned physician practices should be transparent about their billing policies so that patients are aware that they will be billed for a facility fee); *see also* Boodman, *supra* note 53 (Critics of provider-based billing "regard the fees as disguised price increases that ratchet up the cost of care at a time consumers can least afford it.").

71. *See* D. Andres Austin & Jane G. Gravelle, *CRS Report for Congress: Does Price Transparency Improve Market Efficiency? Implications of Empirical Evidence in other Markets for the Health Sector*, CONG. RES. SERV. 1 (July 24, 2007), *available at* http://fas.org/sgp/crs/secrecy/RL34101.pdf (explaining that "[l]ack of transparent prices may contribute to price discrimination, which can cause different customers to pay higher prices."); Uwe E. Reinhart, *Health Care Price Transparency and Economic Theory*, PHYSICIANS FOR A NATIONAL HEALTH PROGRAM (Oct. 22, 2014), *available at* http://pnhp.org/blog/2014/10/22/important-uwe-reinhardt-on-health-care-price-transparency-and-economic-theory/ ("Use of

facilities that wish to bill under the provider-based method should be required to gain approval. If facilities are forced to report their compliance with the regulations, it will be easier for CMS to determine which entities are abusing the system.[72] Third, there should be greater oversight of entities that are granted provider-based status. The current system allows entities to bill as they wish and there is little oversight to ensure that facilities are complying with provider-based regulations.[73] Finally, there should be harsher penalties for entities that fail to maintain provider-based status requirements. Currently, CMS only recovers the difference in overpayment when facilities abuse the system, but this does little to deter providers from abusing the system.[74] If stricter sanctions are in place, it is more likely that facilities will comply with provider-based status regulations.

V. CONCLUSION

As providers strive to integrate to comply with the standards set forth under the ACA, it is important that their billing practices are monitored in order to control the prices in the health care marketplace. If there are not stricter regulations, patients will continue to be charged excessive fees that do little to add to the quality of care. Currently, it is very easy for a facility to abuse the provider-based billing system. If stricter regulations and greater oversight

---

price transparency information was associated with lower total claims payments for common medical services. The magnitude of the difference was largest for advanced imaging services and smallest for clinician office visits.").

72. *See* Memorandum, *supra* note 4, at 2 (explaining that "the mandatory requirement for provider-based determinations has been replaced with a voluntary attestation process," so providers no longer have to receive a provider-based determination to bill under provider-based billing).

73. *See Hospital Ownership*, *supra* note 3 (explaining that provider-based entities should be monitored to ensure they are billing for the correct services). Currently, providers who gain provider-based determinations from CMS must report any changes in their provider-based status to CMS. *The Final Provider-Based Status Rule*, *supra* note 24. However, there is no sanction or penalty for entities that fail to make this report. *Id.*

74. *See* Boodman, *supra* note 53 (stating that provider-based billing is "the latest gimmick to generate additional revenue for hospitals" (quoting Alan Sager, a professor of health policy and management) (internal quotations omitted)).

of this system are not set in place, this system will continue to be counterintuitive to the original goals of the ACA.

ANNALS OF HEALTH LAW
Advance Directive

VOLUME 24 SPRING 2015 PAGES 40-51

Saving the Safety Nets: The Patient Protection and Affordable Care Act and Hospital Readmissions Reduction Programs

Sarah Kitlinski[*]

I. INTRODUCTION

The enactment of the Patient Protection and Affordable Care Act (ACA) impacted insurers, patients, and providers by attempting to raise accountability of all parties involved in promoting the delivery of health care.[1] Although the ACA contains provisions related to many different parties, one provision entails the enactment of the Hospital Readmissions Reduction Program (HRRP), a program designed to reduce excessive readmission rates as determined by the Centers for Medicare and Medicaid Services (CMS) through the Medicare Program.[2] On October 1, 2012, the HRRP began to penalize hospitals in order to reduce the frequency of rehospitalizations for Medicare patients.[3] Although hospitals have had a few years to adjust to the provisions of the HRRP, CMS has not observed great success at reaching the threshold for these readmissions because of failure to account for the many factors that may affect readmissions, such as a patient's diagnoses and severity of illnesses.[4]

[*] Juris Doctor Candidate, May 2016, Loyola University Chicago School of Law. Ms. Kitlinski is a staff member of Annals of Health Law.

1. *See generally* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 141 (2010) (codified as amended in scattered sections of 42 U.S.C.).

2. Karen E. Joynt & Ashish K. Jha, *A Path Forward on Medicare Readmissions*, 386 NEW ENGL. J. MED. 13, 1175 (2013).

3. *Id.*

4. Julia James, *Health Policy Brief: Medicare Hospital Readmissions Reduction Program*, HEALTH AFF. 1 (Nov. 12, 2013), *available at* http://healthaffairs.org/healthpolicybriefs/brief_pdfs/healthpolicybrief_102.pdf.

One type of provider greatly affected by the HRRP is the safety-net hospital. A safety-net hospital provides a significant amount of care to vulnerable populations, such as the uninsured or individuals with low-incomes.[5] Safety-net hospitals are not identified by ownership, but are instead "distinguished by their commitment to provide access to care for people with limited or no access to health care due to their financial circumstances, insurance status, or health condition."[6] Often, safety-net hospitals provide a substantial proportion of care to individuals with complex illnesses and disease, but still do not receive the financial assistance they need from Medicare and other federal government payment sources.[7]

Prior to the HRRP, Medicare would pay for all rehospitalizations, except for those that occurred within twenty-four hours of discharge.[8] Now with the enactment of the HRRP, CMS focuses on the thirty-day readmissions period for three specific conditions: heart failure, heart attack, and pneumonia.[9] These relevant conditions are evaluated for readmissions because they cause high volume of admissions or high expenditures to Medicare.[10] By focusing on these conditions that cost more for frequent readmissions, CMS attempts to reduce the costs caused by these unnecessary readmissions by enforcing penalties on hospitals.[11] However, safety-net hospitals do not have the financial resources to reduce frequent readmissions, and CMS places a substantial

5. *What is a Safety Net Hospital?*, NAT'L ASS'N OF PUB. HOSP. & HEALTH SYS. 1, *available at* http://literacynet.org/hls/hls_conf_materials/WhatIsASafetyNetHospital.pdf (last accessed Apr. 29, 2015).

6. *Id.*

7. Joynt & Jha, *supra* note 2, at 2.

8. Stephen F. Jencks, Mark V. Williams & Eric A. Coleman, *Rehospitalizations among Patients in the Medicare Fee-for-Service Program*, 360 NEW ENG. J. MED. 14, 1419 (2009).

9. Mark Morell & Alex T. Krouse, *Accountability Partners: Legislated Collaboration for Health Reform*, 11 IND. HEALTH L. REV. 225, 261 (2014).

10. 42 C.F.R. § 412.152 (1) (2013).

11. "While some penalties are as small as one hundredth of a percent, hospitals with the highest readmission rates are losing 3 percent of each payment, an increase from a maximum punishment of 2 percent last year [2013]. The increase brings the top penalties to the full force authorized by the federal health law." Jordan Rau, *Medicare Fines 2,610 Hospitals in Third Round of Readmission Penalties*, KAISER HEALTH NEWS 2 (October 2, 2014).

financial burden on these facilities through penalties for readmissions without providing any assistance to enact programs for better post-discharge care.[12]

Through further changes within the hospital structure, adjustments from CMS, and accountability of the patient population, the HRRP can work to ensure hospitals provide the best care without being unduly burdensome.[13] This article will discuss the problems with excessive readmissions and provide some suggestions that all parties can take in order to meet the goals of the HRRP without causing great financial difficulty for safety-net hospitals. Part II examines why excessive readmissions are a problem. Part III recounts how CMS implemented the HRRP, why CMS enacted it, and what intention it had in its enactment. Part IV considers what CMS missed in its enactment of the HRRP. Part V discusses the challenges that safety net hospitals face in this program, and Part VI offers solutions to address the shortcomings of this policy.

II. PROBLEMS WITH EXCESS READMISSIONS

One of the problems that stems from excessive readmissions is the fact that patients who are frequently readmitted either did not receive the care they needed the first time or did not receive proper support following their hospital stay.[14] By imposing a readmissions penalty on hospitals with excessive readmissions, CMS attempted to make up for the "troubling fee-for-service incentives that encourage greater volume of care and fail to reward improvements that lead to a reduction in readmissions."[15] Hospitals may also

12. *Id.*

13. Debra J. Lipson & Samuel Simon, *Issue Brief: Quality's New Frontier: Reducing Hospitalizations and Improving Transitions in Long-Term Care*, 7 MATHEMATICA POL'Y RES., INC. 1, 3 (Mar. 2010), *available at* http://www.nasuad.org/sites/nasuad/files/hcbs/files/180/8980/LTQAbrief.pdf.

14. Clifford Marks, Saranya Loehrer & Douglas McCarthy, *Hospital Readmissions: Measuring for Improvement, Accountability, and Patient*, COMMONWEALTH FUND 1 (Sept. 2013).

15. *Id*. at 5.

profit on readmissions with an estimated eighteen to twenty percent of Medicare patients who are readmitted within thirty days of discharge.[16]

Frequent readmission of Medicare patients also poses a great financial burden to CMS. About one in five Medicare patients are readmitted within thirty days of discharge, and this number increases beyond the thirty-day period.[17] Looking past the Medicare-imposed timeframe, about one out of every three patients will become readmitted within three months of discharge, placing a large burden on funding constraints, but also negatively affecting the community by failing to properly provide adequate health care to its members.[18] Across the United States, CMS estimates that readmission costs amount to as much as $17 billion annually.[19]

These readmissions cost hospitals and their staff significant resources, especially when looking to the populations that safety-net hospitals serve.[20] Safety-net hospitals are left to "disproportionately care for the sickest and poorest patients" while remaining at risk for penalties because the HRRP fails to account for socioeconomic status, and the severity or complexity of an illness or disability.[21] CMS may have had commendable goals in creating the HRRP, however, hospitals that serve the most vulnerable populations are hit the hardest with HRRP penalties without assistance or acknowledgement of other factors, such as low mortality rates.[22]

Finally, before CMS implemented the HRRP, some hospitals did not have an incentive to reduce the readmission rates of their patients.[23] Readmissions

16. Morell & Krouse, *supra* note 9, at 259-60.
17. Ann Marie Marciarille. *Healing Medicare Hospital Recidivism: Causes and Cures*, 37 AM. J. L. & MED. 41, 44-45 (2011).
18. Morell & Krouse, *supra* note 9, at 260.
19. Melissa Winborn, Joyce Alencherril & José A. Pagán, *A News Media Analysis of the Economic and Reputational Penalties of the Hospital Readmissions Reduction Program*, J. OF HEALTH CARE ORG., PROVISION, & FIN. 1 (2014).
20. Marks, Loehrer & McCarthy, *supra* note 14, at 1.
21. Joynt & Jha, *supra* note 2, at 1176.
22. *Id.* at 1177.
23. Rau, *supra* note 11.

potentially meant more services that a hospital could bill and as a result, facilities had no incentive to reduce readmissions.[24] While there is no evidence that hospitals purposely provided treatment that may have led to frequent readmissions, hospitals may have been less willing to provide follow-up care or work with a network of providers in order to prevent readmissions if these programs were unduly burdensome and they would save, if not earn, from allowing readmissions. If hospitals made internal changes to reduce readmissions before the enactment of the HRRP, not only were such efforts not compensated, but it put them at risk to lose money if beds remained empty.[25] Even though reducing readmissions can help save the hospital resources, it can also cause them to lose the revenue generated by common readmissions.[26]

III. CMS' ACTION WITH THE HOSPITAL READMISSIONS REDUCTION PROGRAM

CMS acknowledged the problem with excessive hospital readmissions, not only for the financial burden the agency faced, but also for the care of patients who were revolving in and out of hospitals.[27] CMS established admirable goals in creating the HRRP, pushing for a group effort in the delivery of health care and the assurance of stable health after hospital visits.[28] CMS' policy penalizes hospitals and focuses on the transitions involved in health care, determining that hospitals need to account for post-discharge care before the patient leaves the hospital.[29]

The HRRP emphasizes the importance of the hospital's job in the continuum of care, focusing on the quality of care provided while a patient is in the hospital and the effectiveness of the discharge instructions in follow-up

24. *Id.* at 1.
25. James, *supra* note 4, at 1-2.
26. *Id.*
27. Marks, Loehrer & McCarthy, *supra* note 14, at 1.
28. Jencks, Williams & Coleman, *supra* note 7, at 1427.
29. Marks, Loehrer & McCarthy, *supra* note 14, at 1.

care.[30] In 2014, Kaiser Health News reported that Medicare was fining "a record number of hospitals—2,610—for having too many patients return within a month for additional treatment."[31] CMS not only gathers this information in order to penalize hospitals with excessive readmissions, but also to provide the information regarding the readmission rates for all pertinent hospitals to the public.[32] The HRRP places a great burden on hospitals for the potential readmissions of Medicare patients, while ignoring the fact that not all readmissions represent a failure of the hospital's provision of care.[33]

IV. WHAT IS MEDICARE MISSING IN THE HOSPITAL READMISSIONS REDUCTION PROGRAM?

Although CMS had optimistic intentions in creating the HRRP, the program lacks some necessary components in order to make a long-term adjustment to the provision of health care. The main purpose of this program is not only to save on unnecessary federal spending, but also to ensure that patients receive appropriate care, getting treatment in the hospitals, and gaining knowledge of their conditions or illnesses to prevent unnecessary readmissions in the future.[34] Unnecessary readmissions represent fragmented care that patients receive in a hospital, but do not account for necessary post-discharge care.[35] It is not only necessary for hospitals to work with other providers to reduce readmission rates, but also to determine ways to prevent certain admissions altogether, or help transition vulnerable patients into

30. Morell & Krouse, *supra* note 9, at 261.
31. Rau, *supra* note 11, at 1.
32. 42 C.F.R. § 412.154 (f) (2014).
33. "Most rehospitalizations [84.4% among patients who were discharged after initial hospitalization for medical conditions and 72.6% among patients who were discharged after surgical procedures] were for medical diagnoses." Jencks, Williams & Coleman, *supra* note 8, at 1421.
34. Wendy K. Mariner, *The Affordable Care Act and Health Promotion: The Role of Insurance in Defining Responsibility for Health Risks and Costs*, 50 DUQ. L. REV. 271, 292 (2012).
35. Marks, Loehrer & McCarthy, *supra* note 14, at 2.

appropriate environments, such as long-term care facilities.[36] By failing to address the demographics of certain populations, as well as individual needs such as socioeconomic status, living environment, or age, Medicare places a great burden on hospitals, most notably safety-net hospitals that serve a disproportionate share of vulnerable populations that may need assistance to implement these programs.[37]

Another issue that CMS failed to account for is whether the hospital is the only entity in this equation that should be held liable.[38] The HRRP does not account for the events or circumstances that may take place outside of the hospital that can account for readmissions.[39] For example, certain social determinants of health including housing, income, environment, and employment can lead to the development of chronic diseases, which may account for the excessive readmissions.[40] If certain external factors make it more likely for someone to have a chronic condition, this can lead to an increased need for treatment and readmissions that do not meet the goals as determined by Medicare.[41]

V. CHALLENGES FOR SAFETY-NET HOSPITALS

Safety-net hospitals often assist populations that deal with financial or other challenges that may increase the likelihood of getting sick after discharge, regardless of whether or not the hospital follows through.[42] Safety-net hospitals provide a significant volume of services that may be uncompensated or undercompensated, and the same HRRP penalties apply for readmissions that may be out of their control.[43] A hospital may be able to provide the

36. Lipson & Simon, *supra* note 13, at 1.
37. Mariner, *supra* note 34.
38. Marks, Loehrer & McCarthy, *supra* note 14, at 2.
39. Joynt & Jha, *supra* note 2, at 1176.
40. Mariner, *supra* note 34, at 273-74.
41. *Id.* at 292.
42. Rau, *supra* note 11, at 3.
43. Marks, Loehrer & McCarthy, *supra* note 14, at 4.

best care possible for a certain patient, but if the patient lacks necessary resources post-discharge, then readmission almost seems inevitable.[44] As mentioned previously, if these patients do not have primary care physicians, proper living conditions, or a solid understanding of discharge instructions, it makes the patient more likely to return to the safety-net hospital due to no fault of the provider.[45]

It is not only the socioeconomic status of the patients, but other factors regarding the patient population that contribute to safety-net hospitals' inability to meet the demands of the HRRP. For instance, not only does the lack of financial stability among vulnerable populations affect these hospitals, but such hospitals are also affected by "language and cultural barriers to complying with discharge instructions, lack of resources to purchase medications, and fewer options for post-discharge care."[46] It may be difficult for a safety-net hospital to account for each individual patient's post-discharge needs without the necessary funds to implement programs.[47] Rather than imposing a penalty on these facilities, CMS should work to provide these safety-net facilities with the resources they need to deliver improved post-discharge care and potentially impose a penalty in the future once programs are implemented.[48]

Safety-net hospitals still receive full penalties even when it becomes obvious that they cannot meet the expectations imposed upon them by CMS. For example, this may occur when the number of hospitals that receive fines greatly outweighs the number of hospitals that meet CMS standards.[49] From a policy standpoint, the Obama administration may not want to provide any

44. *Id.*
45. Marks, Loehrer & McCarthy, *supra* note 14, at 4.
46. James, *supra* note 4, at 4.
47. *Id.*
48. *Id.*
49. Rau, *supra* note 11, at 1.

favorable treatment to safety-net hospitals because it does not want to encourage the provisions of a lower quality of care for low-income patients.[50] This outlook could hurt safety-net hospitals at a time when they need assistance. In a study of safety-net hospital readmissions, analysts determined that one-third of readmissions were potentially avoidable, but the hospitals' remaining two-thirds were penalized even though they were beyond their control.[51]

Sometimes these readmissions result from a lack of resources that is common in safety-net hospitals.[52] For example, complex procedures that may not necessarily constitute emergency situations have limited availability over weekends or holidays due to the lack of resources by such hospitals.[53] The lack of resources for weekend and holiday services may account for readmissions if a patient cannot wait to see a provider.[54] Some of the hospitals that successfully reduced readmissions implemented strategies such as post-discharge nurse follow-ups or creating a system with primary care providers that ensures patients have scheduled visits after release from the hospital.[55] The effective readmissions reduction strategies that other facilities have begun to develop, such as post-discharge follow-ups by nurses and other hospital staff, are often "expensive and unaffordable for many institutions, particularly safety-net institutions."[56] Safety-net hospitals' Medicare reimbursement is reduced each year after they fail to meet the threshold for readmissions reductions, and they cannot develop programs to address high readmissions

50. *Id.* at 3.
51. Eri Shimizu et al., *Readmissions at a Public Safety Net Hospital*, 9 PUB. LIBR. OF SCI. ONE 3, 5 (Mar. 2014).
52. Joynt & Jha, *supra* note 2, at 1177.
53. Shimizu et al., *supra* note 51, at 6.
54. *Id.*
55. James, *supra* note 4, at 4.
56. *Id.*

rates when their funding continues to decrease.[57] CMS should attempt to assist these facilities develop strategies to reduce readmissions before implementing such penalties.

VI. SOLUTIONS FOR SAFETY-NET HOSPITALS

Based on the number of unique problems that safety-net hospitals experience, it is apparent that solutions to these problems must come from multiple sources. The first place where these changes should begin involves the creator of the HRRP program: CMS. One beneficial change would be to assess penalties against safety-net hospitals according to the timing of the readmission.[58] When looking at the thirty-day penalty period, readmissions within the first week following discharge "may reflect poor care coordination or inadequate recognition of post-discharge needs, whereas readmission [four] weeks later are far more likely to be due to the underlying severity of a patient's disease."[59] By acknowledging how far along the thirty-day period a patient is when returning to the hospital, CMS can look into whether a readmission occurred as a result of inadequate care during the first hospital stay, or rather, as a result of a serious condition that may require more frequent admissions.[60] This way, hospitals can have a narrower focus on what they are missing in patient care and where they are providing adequate care.

The HRRP focuses on hospitals' need to make a change to reduce readmissions, and while there are steps that providers can take to do so, certain facilities like safety-net hospitals may not have the resources necessary to implement successful change.[61] Moreover, CMS does not endorse measures

57. *Id.* at 3.
58. Joynt & Jha, *supra* note 2, at 1177.
59. *Id.*
60. *Id.*
61. Lipson & Simon, *supra* note 13, at 2.

to prevent avoidable hospitalizations.[62] Based on the facilities currently experimenting with new methods to reduce readmissions, successful programs must use a group of strategies at one time in order to succeed.[63] Some of the more useful strategies include "provider and patient education, care management, coordination of acute and primary care, and greater use of skilled staff."[64] These approaches may help safety-net hospitals avoid excessive readmissions, but again, each strategy requires financial resources that safety-net hospitals do not necessarily have; especially if the hospitals are constantly under pressure from CMS' reduction of their Medicare funding.[65]

The final solution should come from the patient population itself. The ACA attempts to establish some personal accountability when it comes to health care, but for populations that do not have the resources necessary to maintain a healthy lifestyle, this becomes a complicated issue.[66] There is a general belief that many chronic diseases come from behavioral factors including substance use, poor diet, and lack of physical activity.[67] There are many steps that individuals can take to account for their personal care and prevent constant readmissions, such as an individual's "willingness and ability to follow through on annual physicals, participate in preventative wellness activities including appropriate screenings, and follow physician-recommended treatments."[68] Taking preventative measures may help reduce readmissions, but the population and safety-net hospitals cannot do it alone. Instead of enforcing penalties, the government can help create public programs for the population. If the government implemented assistance programs, it would be appropriate to enforce penalties on hospitals that fail to reduce their

62. *Id.*
63. *Id.* at 3.
64. *Id.*
65. Joynt & Jha, *supra* note 2, at 1176.
66. Mariner, *supra* note 34, at 329.
67. *Id.* at 273-74.
68. Morell & Krouse, *supra* note 9, at 250.

readmissions. These programs need to provide "preventative services, safer social and built environments, research, and education."[69]

VII. CONCLUSION

The HRRP intends to correct problems within hospitals, deterring readmissions through penalties, and providing an incentive to deliver better care to patients in the long term.[70] Although CMS' goals are commendable, they disproportionately affect safety-net hospitals.[71] Readmissions in these safety-net facilities do not necessarily reflect poor quality because there are many other factors involved in determining why readmissions occur.[72]

In order for safety nets to survive and thrive during a time when their revenue stream may be in jeopardy, they need to work with other providers to create a collective approach to the provision of health care. By CMS recognizing the flaws in the current program and making adjustments to account for safety-net hospitals, which are put at a great disadvantage through this program, such hospitals will be better equipped to provide quality care.

69. Mariner, *supra* note 34, at 329.
70. James, *supra* note 4, at 4.
71. Marks, Loehrer & McCarthy, *supra* note 14, at 1.
72. Shimizu et al., *supra* note 51, at 6.

ANNALS OF HEALTH LAW
Advance Directive

VOLUME 24 SPRING 2015 PAGES 52-63

The Inherent Volatile Nature of Physician-Owned Distributors and its Impact on Clinical Integration

Eric Chung[*]

I. INTRODUCTION

Since its origin in California, physician owned distributors (PODs), otherwise known as physician owned companies, have expanded rapidly across the nation.[1] Dealing primarily with orthopedic implant surgical devices, PODs impact the traditional implant supply chain model by allowing physicians to simultaneously possess ownership rights in a POD and work at a hospital that orders devices from these PODs.[2] The fraud and abuse issues stemming from these controversial arrangements carry the potential to significantly and negatively impact a patient's quality of treatment.[3]

The purpose of clinical integration is to improve the outcome of patient treatment by increasing the quality and efficiency of care while effectively managing costs.[4] With the trend moving toward value-based business standards, clinically integrated networks (CINs) have become key in the health care industry.[5] The CIN model encourages teamwork and effective communication between physicians, hospitals, and other providers to better inject

[*] Juris Doctor Candidate, May 2016, Loyola University Chicago School of Law. Mr. Chung is a staff member of Annals of Health Law.

1. STAFF OF S. FIN. COMM., 112TH CONG., REP. ON PHYSICIAN OWNED DISTRIBUTORS (PODS): AN OVERVIEW OF KEY ISSUES AND POTENTIAL AREAS FOR CONGRESSIONAL OVERSIGHT 3 (June 2011), *available at* http://www.finance.senate.gov/newsroom/ranking/download/?id=274abe2e-ee0d-489e-9498-6542c0476cf5.

2. *See id.* at 2.

3. *See id.* at 6.

4. *See Moving Health Care Forward, Five Barriers to Clinical Integration in Hospitals (and what to do about them)*, AM. HOSP. ASS'N 1, http://www.aha.org/content/00-10/5barrierstoclininteg.pdf (last visited Apr. 29, 2015) [hereinafter *Moving Health Care Forward*].

5. *See id.* (Clinical integration can be approached in various ways, including collaborations among hospitals, doctors, and other entities).

quality health care services into patient populations.[6]

Although not necessarily a distinct business model, PODs tread into the relationship between the hospitals, surgery centers, and manufacturers by establishing themselves as middleman entities, disrupting an already established network.[7] Traditionally, medical device implants were sold almost exclusively to hospitals directly from the manufacturers.[8] The main difference between the traditional implant supply chain model and PODs is ownership by ordering or referring physicians.[9]

This article will argue that although there may be opportunities for PODs to lower healthcare costs, there also are significant regulatory concerns that surround POD proliferation. These regulatory concerns are primarily fraud and abuse issues arising from a physician's mixed financial interests.[10] Moreover, these concerns work against effective clinical integration, indicating that it would ultimately be better to avoid working with PODs altogether. Part II of this article explores the basic premise of a POD and what has driven its expansion. Part III delves into the regulatory concerns inherent in a POD and its current status under the United States Department of Health and Human Services Office of Inspector General (OIG). Part IV explains how PODS can jeopardize clinical integrations and CINs. Finally, Part V concludes with the position that entities aiming for well functioning and sustainable clinical integration should take considerable and cautionary steps to avoid this "Pandora's box"[11] or beware of the inevitable negative outcomes.

---

6. *Id.*

7. STAFF OF S. FIN. COMM., *supra* note 1, at 2.

8. *Id.* ("The manufacturer and its representatives provide services to the institution along with the implants, including order and delivery, stocking and restocking, sterilization, selection, delivery and deployment of external instrumentation, and assistance to surgeons in the operating room.").

9. *See id.* ("Many PODs lack any operating history or experience.").

10. *See id.* at 5.

11. Kathleen McDermott & Jacob J. Harper, *Anti-Fraud Concerns for Physician-Owned Distributors for Medical Device Products: What's New Is Old. We Won't Be Fooled Again*, MORGAN, LEWIS & BOCKIUS LLP 2 (Mar. 2013), http://advamed.org/res.download/288.

II. POD BASICS AND ITS DRIVE TO EXPANSION

Generally, groups of surgeons form PODs to sell, distribute, and deliver their own devices to institutions where these physician-investors work.[12] This business arrangement gives surgeons greater authority in selecting the devices they will use while simultaneously sharing in the profits.[13] The origin and rapid expansion of PODs are due to a variety of factors that have increasingly and negatively affected physicians: decline in reimbursements, growth in patient volumes, and increased demand on time.[14] In order to compensate for these changes, PODs provide an alternate, albeit questionable, revenue source.[15]

There are currently three principal POD models.[16] The Physician Distributor Model acts as a true middleman by buying implants from manufacturers and reselling to hospitals to which the physician investors would then refer their patients.[17] The Physician Manufacturer Model acts as the implant manufacturer by outsourcing its device production.[18] The Physician Group Purchasing Organization (GPO) is a specific framework that seeks to utilize the GPO safe harbor within the federal anti-kickback statute (AKS).[19]

---

12. STAFF OF S. FIN. COMM., *supra* note 1, at 2.
13. *Id.* at 5.
14. John E. Kelly & Anne P. McNamara, *Physician-Owned Medical Device Distributors: A Controversial Business Model*, 9 A.B.A. HEALTH ESOURCE (Oct. 2012), http://www.americanbar.org/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1012_kelly.html.
15. *Id.*
16. STAFF OF S. FIN. COMM., *supra* note 1, at 3.
17. *Id.*
18. *Id.*
19. *Id.*; 42 C.F.R § 1001.952; *see also Understanding Group Purchasing Organizations and the Safe Harbor Provision*, HEALTH SUPPLY CHAIN ASS'N, *available at* http://c.ymcdn.com/sites/www.supplychainassociation.org/resource/resmgr/research/safe_harbor.pdf (last visited Apr. 29, 2015) ("Enacted by Congress in 1987, the Medicare and Medicaid Patient Protection Act 1987 allows GPOs to charge administrative fees to suppliers while providing services to hospitals. In 1991, HHS promulgated Safe Harbor regulations reflecting Congress' intent to permit contract administration fees. Given that GPOs arrange for the referral of business to health care suppliers [through negotiating contracts for the benefit of their health care provider members] and receive an administrative fee in return for these services, this situation could trigger the federal Anti-Kickback Statute. 'Safe Harbor' regulations describe how health care providers are required to structure their financial transactions

These three models mark an evolution from the original PODs of Northern California.[20] PODs first appeared in early 2003 and were initially limited to orthopedic and implant devices, but are currently expanding to cardiac implant devices.[21] PODs' influence in the spinal implants market has grown concurrently with their market presence as characterized by an October 2013 OIG report on Spinal Devices.[22] Currently, there are at least twenty states that have various operational PODs, with roughly forty in California.[23]

The OIG report states that in 2012 Medicare paid hospitals a total of $3.9 billion for 178,789 spinal surgeries.[24] The report also states that PODs supplied nearly one fifth of the total devices used in spinal fusion surgeries billed to Medicare in 2011.[25] Sixty-six percent of the hospitals surveyed reported purchasing medical devices from PODs owned by their practicing physicians.[26] Therefore, the OIG study results demonstrate that physicians with conflicts of interest open up the potential for fraud and abuse by increasingly influencing hospital-purchasing decisions regarding medical implant devices.

---

so that they comply with federal law.").

20. STAFF OF S. FIN. COMM., *supra* note 1, at 3.

21. *Id.*

22. OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., SPINAL DEVICES SUPPLIED BY PHYSICIAN-OWNED DISTRIBUTORS: OVERVIEW OF PREVALENCE AND USE 18 (2013), *available at* http://oig.hhs.gov/oei/reports/oei-01-11-00660.pdf [hereinafter SPINAL DEVICES] (characterizing PODs as carrying "a substantial presence" in the spinal implants market). Of the 589 hospitals that were part of the study, 203 of the hospital purchased spinal devices from PODs. *Id.* at 10.

23. STAFF OF S. FIN. COMM., *supra* note 1, at 3 ("While originally there were a handful of PODs primarily based in Northern California which first brought this issue to the forefront, it is the rapid proliferation of the PODs over the past 18-24 months which has raised a number of concerns regarding the structure of the PODs.").

24. *Id.* at 1. While Medicare Part A pays hospitals under the Inpatient Prospective Payment System (IPPS), Medicare Part B pays surgeons separately under the Medicare Physician Fee Schedule. *Id.* at 4.

25. *Id.* at 7 (Twenty-five percent of these surgeries were performed in California and Texas).

26. *Id.* at 12.

III. REGULATORY CONCERNS INHERENT IN PODS

Proponents argue that a properly structured POD does not create any liabilities, but rather reduces substantial health care costs by providing patients with favorable prices.[27] These favorable prices, as stated by the proponents, are possible through negotiations between the POD and the device manufacturer, considering that the manufacturer does not need to spend money in marketing its products.[28] In response, POD opponents argue that "this is a false metric because it does not take into account several critical and material factors in a true cost analysis."[29] Proponents point out that PODs do not explicitly violate any federal regulation.[30] However, the implicit possibility of violating the AKS and Stark Law, along with an overall nationwide state of confusion, renders the POD a risky investment that deters from effective clinical integration.[31]

The latest OIG special fraud alert concerning PODs signifies an increase in scrutiny with the statement, "We believe that PODs are inherently suspect under the anti-kickback statute."[32] This fraud alert deters any defense of ignorance by warning all hospitals and doctors of the inherent deceitful nature of PODs.[33]

A. Anti-Kickback Statute

The primary purpose of the AKS is to protect patients and federal health programs from fraud and abuse.[34] The AKS is an intent-based statute, which

27. STAFF OF S. FIN. COMM., *supra* note 1, at 5.

28. Kelly & McNamara, *supra* note 14.

29. STAFF OF S. FIN. COMM., *supra* note 1, at 5.

30. Basil Besh et al., White Paper: Physician-Owned Distributorships and Other Options to Reduce Implant Costs, CAL. ORTHOPEDIC ASS'N 2 (2012), *available at* http://www.coa.org/docs/WhitePaperPODfinal.pdf.

31. STAFF OF S. FIN. COMM., *supra* note 1, at 5.

32. OFFICE OF INSPECTOR GEN., DEP'T OF HEALTH & HUMAN SERVS., SPECIAL FRAUD ALERT: PHYSICIAN-OWNED ENTITIES 3 (2013), https://oig.hhs.gov/fraud/docs/alertsandbulletins/2013/POD_Special_Fraud_Alert.pdf. [hereinafter SPECIAL FRAUD ALERT]

33. *See generally id.*

34. 42 U.S.C. § 1320a-7b (1994) ("Whoever knowingly and willfully makes or causes

an entity or individual owner of a POD can violate if the purpose of that POD is to induce referrals for devices reimbursable under a federal health care program.[35] Furthermore, the legality of a POD is dependent upon its operational safeguards and the conduct of its physician-investors.[36] This aspect of variation among PODs allows for physician-investor groups nationwide to use different creative methods to avoid fraud and abuse implications.[37] Violation of this statute carries both criminal and civil liability in the form of exclusion from federal health care programs, imprisonment, and significant fines.[38]

It only takes one instance of referral inducement to violate the AKS.[39] The financial incentives that PODs offer to surgeon-owners create a variety of concerns, including corruption, overutilization, and increased costs to the other parties involved.[40] The increased complexity involved in the relationships between PODs and health care providers calls for a greater need of oversight within each organization to ensure operational compliance. The OIG offers guidance to such organizations by delineating the seven elements of an effective compliance program.[41] In order for institutions to be compliant

---

to be made any false statement or representations of a material fact in any application for any benefit or payment under a Federal health care program."); *see also Moving Health Care Forward*, *supra* note 4 ("The law states that anyone who knowingly and willfully receives or pays anything of value to influence the referral of federal health programs business, including Medicare and Medicaid, can be held accountable for a felony. Today, the law has bee stretched to cover any financial relationship between hospitals and doctors".).

35. U.S.C. § 1320a-7b (1994); *See also* Mark T. Morrell & Jaya F. White, *Heightened Regulatory Scrutiny Facing Innovative POD Arrangements,* 7 J. HEALTH & LIFE SCI. L. 44, 61, (2015).

36. Morrell & White, *supra* note 35, at 61.

37. *See id.* at 62-63 ("How should attorneys structure a POD so that it complies with the Anti-Kickback Statute? A general framework would include an arrangement where ownership interest, governance, and control of the POD should be proportional to capital contribution.").

38. *Id.* at 59-60.

39. *See id.* at 59.

40. SPECIAL FRAUD ALERT, *supra* note 32, at 2.

41. Publication of the OIG Compliance Program Guidance for Hospitals, 63 Fed. Reg 8987 (Feb. 23, 1998).

with regulations, education, monitoring, and auditing are essential to minimizing liability.[42] It is, however, a safer and more cost effective option for providers and payors to avoid working with PODs rather than become involved in a relationship with a third party distributor where the risk of federal liability is only one step away.[43]

Proponents of PODs argue that such organizations lower health care costs;[44] however, a 2013 OIG study revealed that device costs for POD implant surgeries were not lower than those for other surgeries.[45] Using a sample size of 589 hospitals, the study failed to reflect the supposed benefits of PODs.[46] Furthermore, the Patient Protection and Affordable Care Act (ACA) reduces the intent requirement for the AKS by providing that "[a] person need not have actual knowledge of this section or specific intent to commit a violation of this section."[47] Physicians considering the POD option must take into consideration this lowered threshold as well as increased government scrutiny.[48] The U.S. Senate Finance Committee has especially been critical of PODs and released a report stating that PODs do not lower healthcare costs, but instead provide a breeding ground for a wide host of liabilities.[49]

---

42. *Id.* (The OIG states 7 elements to an effective compliance program: 1) monitoring and auditing; 2) designation of compliance officer; 3) training and education; 4) establishing lines of communication; 5) creating appropriate incentives; 6) establishing disciplinary standards; and 7) implementing policies).

43. *See generally* STAFF OF S. FIN. COMM., *supra* note 1, at 8.

44. *Id.* at 5 ("One of the key assertions of the POD model is that they are lowering healthcare costs by providing products at a lower price than a medical device manufacturer or non-POD distributor...Proponents of the POD argue that the model allows them to engage in arms-length negotiations with the device manufacturer to secure a price for the product, which is usually lower than that which is offered to other purchasers, including hospitals.").

45. OFFICE OF INSPECTOR GEN., *supra* note 22, at 9.

46. *See id.* at 5.

47. Patient Protection and Affordable Care Act, Pub L. 111-148, § 6402(f), 24 Stat. 119, 759 (2010) (codified at 42 U.S.C. § 1320a-7b(b)); *See also* Morrell & White, *supra* note 35, at 61 ("Because the intent requirement has been reduced in the almost 20 years since the first case addressing physician self-referral joint venture arrangements, physicians contemplating POD arrangements need to be even more mindful to structure such an arrangement properly.").

48. Morrell & White, *supra* note 35, at 55.

49. *See generally* STAFF OF S. FIN. COMM., *supra* note 1.

B. Physician Self-Referral Law (Stark)

The original primary purpose of the Stark Law was to prevent physicians from referring patients to facilities in which the physician had a financial interest.[50] Stark is a strict liability statute that restricts physicians from making designated health services (DHS) referrals, payable by federal health care programs, to entities in which the physician, or an immediate family member, has a financial interest.[51] Such financial interest includes ownership, investment, or compensation.[52] Additionally, DHS include physical therapy services, inpatient and outpatient hospital services, durable medical equipment, and a wide variety of other categories.[53] Although PODs are not as prone to violate the AKS, Stark may still be of concern.[54]

The Centers for Medicare and Medicaid Services (CMS) has taken the stance that PODs do not "necessarily" need to perform the DHS and therefore are not an entity in explicit violation of Stark.[55] However, there are various POD arrangements that carry Stark liability. For example, when a physician decides to sell DHS categorized medical devices to a hospital where the physician also has a referral relationship, liability under the Stark Law may arise.[56] While parties may seek to use the indirect compensation exception to escape Stark liability, regulations require that there not be any AKS violation as well.[57] Although there is not a great deal of regulation and guidance from

---

50. *See Moving Health Care Forward*, *supra* note 4. ("However, a tight web of regulations and other prohibitions that have grown up around the law can now ban arrangements designed to encourage hospitals and doctors to team up to improve patient care in a clinical integration program.").

51. 42 U.S.C. § 1395nn (2010).

52. *Id.*

53. *Id.*

54. Morrell & White, *supra* note 35, at 63.

55. *Id.* at 64.

56. *Id.* at 64-65; 42 C.F.R. § 411.351 (2015) (DHS categorized medical devices include radiation therapy supplies, prosthetic devices and supplies, and orthotics).

57. Kelly & McNamara, *supra* note 14 ("Hospitals are protected by the statute's "indirect compensation" exception if they can demonstrate that any compensation provided from the hospital to the referring physician is fair market value for services and items actually provided, and if such compensation is not determined in any manner that takes into account the value or

the government, Stark issues may evolve depending on CMS' position long-term.

IV. HOW PODS JEOPARDIZE CLINICAL INTEGRATIONS AND CINS

While there may be various interpretations on what makes clinical integration successful, an overall consensus exists that there must be a well communicated and educated collaboration among various health care providers to secure higher quality services.[58] The establishment of a POD would add another layer of complexity involving federal regulatory liabilities.

Simply put, clinical integration is the coordination of different components, such as human resources, information and technology, and diagnostic services, to enhance the quality and value of patient care while reducing extraneous costs.[59] Over the past twenty-three years, hospital services have fallen into "perpetual fragmentation," which has led to an increase in health care costs and decrease in communication among providers, and overall a deteriorating health care system.[60] Clinical integration arises as a much-desired approach by focusing on patient care.[61] There are numerous factors that allow hospitals and physicians to efficiently work together to deliver higher quality care at a lower cost to patients.[62] PODs inherently work against clinical integration by exposing patients to potentially unnecessary, harmful, and

volume of physician referrals.").

58. *See generally Clinical Integration the Key to Real Reform*, AM. HOSP. ASS'N 2 (Feb. 2010), *available at* http://www.aha.org/research/reports/tw/10feb-clinicinteg.pdf.

59. Alice Gosfield, *What is the Legal Infrastructure?*, in 2007 HEALTH LAW HANDBOOK, § 3:14 (Alice G. Gosfield ed., 2007) (West 2013).

60. Jason Goldwater & Larry Yuhasz, *Consideration for Clinical Integration*, TRUVEN HEALTH ANALYTICS 2 (2011), *available at* http://truvenhealth.com/portals/0/assets/HOSP_11363_0712_ClinicalIntegration_WP_Web.pdf ("As a result, the traditional role of the hospital to aggregate services from providers is changing. Care has once again returned to a state of perpetual fragmentation, and many of the costs and difficulties that led to early reform efforts under Clinton are worse than ever.").

61. *See* Dennis Butts et al., *The 7 Components of a Clinical Integration Network*, BECKER'S HOSP. REV. (Oct. 19, 2012), http://www.beckershospitalreview.com/hospital-physician-relationships/the-7-components-of-a-clinical-integration-network.html.

62. *See id.* (Some of these include legal options, physician leadership, the flow of funds, contracting options, and performance improvement).

wasteful procedures.[63] In worst-case scenarios, both surgeons and hospitals would be liable for various fraud and abuse violations, while the patients receive inefficient care.[64]

Accountable Care Organizations (ACO) are another form of alternative care models where physicians, hospitals, and other care providers come together to improve the delivery of health care.[65] Although CMS and the OIG do not prohibit ACOs from purchasing products from PODs, the Senate Finance Committee has highly discouraged this relationship.[66] The OIG explicitly stated its intent that any relation with a POD could lead to highly detailed financial and operational scrutiny by the OIG.[67] This is another example of how it is an altogether more beneficial and less complex option in avoiding working with PODs.[68]

Four occurrences depict a common process in which PODs jeopardize clinical integration: 1) corruption of medical judgment by the physician investor, 2) medically unnecessary procedures, 3) overutilization of surgical procedures, and 4) various degrees of penalties for the hospital and physician.[69] The first category is due to the financial incentives that PODs carry for physician investors.[70] The U.S. Senate Finance Committee stated, "The

63. *See* STAFF OF S. FIN. COMM., *supra* note 1, at 5.

64. *See id.* at 5-6.

65. Jan Anderson & Ryan McAteer, *Physician-Owned Medical Device Distributors: Improper Inducement or Effective Cost Management Arrangement?*, J. HEALTH CARE COMPL. 9 (May-June 2014), *available at* http://www.polsinelli.com/~/media/Articles%20by%20Attorneys/Anderson_Jan_McAteer_May_2014.

66. *Id.* ("The Senate Finance Committee also sought to prohibit ACOs from *purchasing* products or services from entities that are owned by physicians participating in an ACO.").

67. *Id.* at 9-10 ("Since any arrangement with a POD will be considered unlawful *even if one purpose* of the arrangement is to induce or secure referrals, the relationship between a hospital or health facility and a POD should be scrutinized carefully be legal counsel prior to commencing the arrangement.").

68. *Id.*

69. SPECIAL FRAUD ALERT, *supra* note 32, at 2.

70. *Id.*

very nature of PODs seem to create financial incentives for physician investors to use those devices that give them the greatest financial return."[71] Hospitals currently involved with PODs may have been influenced into the relationship in order to avoid losing referrals from their surgeons.[72] When a physician investor's primary mindset is not focused on the patient and second-rate courses of treatment are used, clinical integration is stifled.[73]

A corruption of medical judgment for physician investors would lead to an excessive number of unnecessary procedures.[74] A patient's course of treatment is determined by medical necessity, and this concept is undermined when physician investors order more procedures than are medically necessary[75] or use their own company's implants when higher quality products are available.[76] Multiple reports show that the number of various surgical procedures has increased significantly ever since the expansion of PODs.[77] Finally, a variety of penalties including stiff fines, exclusion from the Medicare program, and even imprisonment, could also substantially impact a hospital.[78]

V. CONCLUSION

Hospitals must be aware of the formidable penalties that AKS and Stark violations carry. Exclusion from federal health care programs would essentially shut down most hospitals, leading to a host of problems, primarily an underserved patient population.[79] The inherent regulatory violations from

71. STAFF OF S. FIN. COMM., *supra* note 1, at 5.

72. Tom Bulleit & Peter Holman, *Ominous Outlook for Physician-Owned Distributors*, LAW360 (Sept. 2014).

73. *See generally* STAFF OF S. FIN. COMM., *supra* note 1.

74. Kelly & McNamara, *supra* note 14.

75. Morrell & White, *supra* note 35, at 80.

76. SPECIAL FRAUD ALERT, *supra* note 32, at 2.

77. *See* SPINAL DEVICES, *supra* note 22, at 18.

78. Morrell & White, *supra* note 35, at 59 ("The Anti-Kickback Statute is broadly drafted, and a conviction under the statute constitutes a felony punishable by a maximum fine of $50,000, imprisonment up to five years, or both.").

79. SPECIAL FRAUD ALERT, *supra* note 32, at 2.

PODs are an unnecessary risk that essentially decreases efficiency by requiring hospitals to allocate more time and effort in compliance oversight.[80] While it is helpful to have a well-functioning compliance program, an altogether better solution is to avoid working with PODs.[81]

PODs carry inherent regulatory risks that work against the purpose of clinical integration, which is to better serve the patient population. For hospitals to enter into a relationship with such a questionable and controversial arrangement that federal agencies repeatedly criticize is detrimental to effective clinical integration. With a trend toward explicitly prohibiting the use of PODs, hospitals focusing on improving a patient's quality of treatment should take the necessary steps to avoid PODs. These steps may include having educational discussions with employed surgeons, increasing internal monitoring, and implementing and improving policies regarding ownership rights in distributor companies. Due to the lack of regulatory oversight and the possibility of considerable financial return for physicians, it is no surprise that PODs proliferated to the present extent.

80. *See id.*
81. Publication of the OIG Compliance Program Guidance for Hospitals, *supra* note 41.

ANNALS OF HEALTH LAW
Advance Directive

VOLUME 24 SPRING 2015 PAGES 64-76

Time to Rethink the Illinois Corporate Practice of Medicine Doctrine in the PPACA Healthcare Market Era

James Flannery[*]

I. INTRODUCTION

Although the Patient Protection and Affordable Care Act (PPACA) brings the United States closer to the admirable goal of universal access to health care, health care policy must go beyond increased access and also focus on lowering costs and increasing the quality of care. In order to address these issues, policymakers and healthcare professionals turn to clinical integration.[1] Clinical integration refers to the greater coordination of patient care across people, functions, activities, and sites over time in order to enhance the quality and efficiency of patient care.[2] The corporate practice of medicine doctrine impedes efforts to promote efficient delivery and financing of health care by physicians through clinical integration.[3]

The corporate practice of medicine doctrine prohibits persons or entities not licensed by the state in which they reside from providing medical services or from excessively influencing the delivery of said services.[4] The doctrine

[*] Juris Doctor Candidate, May 2016, Loyola University Chicago School of Law. Mr. Flannery is a staff member of Annals of Health Law.

1. *See* STEPHEN M. SHORTELL ET AL., REMAKING HEALTH CARE IN AMERICA: BUILDING ORGANIZED DELIVERY SYSTEMS 27 (2nd ed. 2000) (discussing a well integrated system links facets within the system together, gives rise to greater financial performance and quality).
2. *Id.* at 28.
3. *See* Nicole Huberfeld, *Be Not Afraid of Change: Time to Eliminate the Corporate Practice of Medicine Doctrine*, 14 HEALTH MATRIX 243, 244-45 (2004) ("In increasingly integrated health care delivery systems, the corporate practice of medicine doctrine does nothing to improve quality, efficiency, or accountability.").
4. *Id.* at 243.

is structured in three prongs.[5] The first prong, and the main focus of this article, prohibits a non-licensed person or corporation from employing a physician or healthcare professional to practice medicine.[6] Second, entities that provide health care services, including partnerships, professional corporations, nonprofit corporations, and various other entities, are generally prohibited from control or ownership by non-licensed persons or corporations.[7] Third, licensed professionals cannot divide or share professional fees with a non-licensed person or entity.[8] This would essentially amount to assisting an unlicensed person to practice medicine, which could lead to an improper influence on the medical professional's conduct.

Although not found in a specific statute, the corporate practice of medicine doctrine is enforced in Illinois.[9] In an era of greater need for clinical integration, the corporate practice of medicine doctrine in Illinois should be relaxed. Specifically, the corporate practice of medicine doctrine in Illinois should be codified to avoid potential confusion. Additionally, the doctrine should include limited exceptions for organizations to hire their own physicians to treat employees with their permission, and must be free from any influence on the physician's independent medical judgment. Furthermore, the doctrine should be relaxed to allow independent practitioners to join with self-insured companies, to in turn lead to additional clinical integration.

This article will delve into how this approach to the corporate practice of medicine doctrine in Illinois will promote clinical integration. Part II of this article will examine the history of the corporate practice of medicine doctrine

---

5. *Id.* at 244.
6. *Id.*
7. *Id.*
8. *See id.*
9. *See* Mary H. Michal et al., *Corporate Practice of Medicine Doctrine 50 State Survey Summary*, CTR. TO ADVANCE PALLIATIVE CARE, 5 (Sept. 2006), *available at* http://www.nhpco.org/sites/default/files/public/ palliativecare/ corporate-practice-of-medicine-50-state-summary.pdf (The chart indicates which states possess statutes enforcing the doctrine. No statute is listed for Illinois).

in Illinois. Part III will focus on the doctrine as applied by other states. Part IV will promote the idea of relaxing the corporate practice of medicine doctrine in Illinois to allow independent physicians to join with self-insured employers to in turn help promote clinical integration, followed by a conclusion in Part V.

II. HISTORY OF THE CORPORATE PRACTICE OF MEDICINE DOCTRINE IN ILLINOIS

Under the Illinois Hospital Licensing Act, only licensed hospitals and hospital affiliates may employ licensed physicians if they meet certain requirements.[10] The requirements are extensive and include that, (1) the employed physician is a member of the medical staff of the hospital or affiliate; (2) independent physicians not employed by the employing entity periodically review the quality of the medical services provided by the employed physician to improve patient care; (3) the employing entity and the employed physician sign a statement that acknowledges the employer shall not unreasonably exercise control, direct, or interfere with the employed physician's exercise of his or her professional judgment; and (4) the physician and employed entity establish a mutually agreed upon independent review process.[11]

Because the statute does not expressly implement the corporate practice of medicine doctrine, the doctrine developed through Illinois case law.[12] The first instance in which the Illinois Supreme Court encountered the doctrine occurred in *Dr. Allison, Dentist, Inc. v. Allison*.[13] In *Allison*, the plaintiff corporation owned and operated a dental practice and entered into a contract

10. 210 ILL. COMP. STAT. 85/10.8 (2001).

11. *Id.*

12. *See* Michal et al., *supra* note 9 at 5 (Stating, "case law appears to prohibit unlicensed corporations from employing physicians to provide medical services; however, case law allows licensed hospitals to employ physicians because licensed hospitals possess legislative authority to provide medical services.").

13. Berlin v. Sarah Bush Lincoln Health Ctr., 688 N.E.2d 106, 110 (Ill. 1997) Discussing "the court first encountered the corporate practice of medicine doctrine in *Dr. Allison, Dentist, Inc. v. Allison*".

with the defendant dentist.[14] The defendant later breached the agreement with the plaintiff after he opened a dental office and began to practice directly across the street from the corporate dental parlors.[15] The court dismissed the case on grounds that the plaintiff was practicing dentistry in violation of the Dental Practice Act of 1933, which prohibited corporations from practicing dentistry.[16]

The Illinois Supreme Court addressed the corporate practice of medicine doctrine as it pertained to medicine a year after the *Allison* decision in *Kerner v. United Med. Serv., Inc.* In *Kerner*, a corporation operated a low-cost health clinic in which duly licensed physicians rendered all medical services.[17] The State brought suit against the corporation alleging that it illegally engaged in the practice of medicine in violation of the Medical Practice Act.[18] The Court stated that only individuals may obtain a license to practice medicine, and no corporation could meet the requirements of the statute essential to the issuance of a license.[19] Additionally, the Court invoked the Business Corporation Act and held that the practice of medicine is not included in the Act's authorization of the formation of corporations for "any lawful purpose."[20]

Illinois courts did not apply the corporate practice of medicine rule set out in *Kerner* until *Berlin v. Sarah Bush Lincoln Health Ctr*.[21] In *Berlin*, the Illinois Supreme Court faced the issue of whether the doctrine prohibits corporations that are licensed hospitals from employing physicians to provide

14. Dr. Allison, Dentist, Inc. v. Allison, 196 N.E. 799, 799 (Ill. 1935).
15. *Id.*
16. *Id.* at 800-01.
17. People ex rel. Kerner v. United Med. Serv., Inc., 200 N.E. 157, 158 (Ill. 1936).
18. *See id.* The Attorney General of Illinois filed a petition for leave to file an information to require the defendant United Medical Services, Inc., a domestic corporation, to show by what warrant it holds a franchise to practice medicine.
19. *Id.* at 163.
20. *Id.* at 164.
21. *Berlin*, 688 N.E.2d at 111.

medical services.[22] The plaintiff doctor sought to have a restrictive covenant contained in an employment agreement with defendant health center declared unenforceable.[23] The defendant, a nonprofit corporation, was duly licensed under the Hospital Licensing Act to operate a hospital.[24] The circuit court, relying primarily on *Kerner*, determined that the health center, through hiring the doctor to practice medicine as its employee, violated the prohibition against corporations practicing medicine.[25] The divided appellate court affirmed the circuit court ruling.[26]

The Illinois Supreme Court reversed the lower court's ruling and instead distinguished *Berlin* from both *Kerner* and *Allison*.[27] The Court noted that neither *Kerner* nor *Allison* involved employment of physicians by a hospital or involved a corporation licensed to provide health care services to the general public.[28] The Court thus declined to apply the corporate practice of medicine doctrine to licensed hospitals.[29] The Court reasoned that the corporate practice of medicine doctrine is appropriate to a general corporation that does not possess a licensed authority to offer medical services to the public, but when a corporation is allowed by state law to operate a hospital, such a prohibition is inapplicable.[30] The Court further noted the public policy concerns that support the doctrine are inapplicable to licensed hospitals where the concern for control over a physician's professional judgment is alleviated by a

22. *Id.* at 107.
23. *Id.*
24. *Id.*
25. *Id.* at 108.
26. *Id.*
27. *Id.* at 112.
28. *Id.*
29. *Id.*
30. *Id.* at 113.

separate medical staff responsible for the quality of the medical services provided.[31] The Court then emphasized that any concerns over the commercialization of health care are relieved when a licensed hospital is the physician's employer because hospitals have an independent duty to provide for the patient's health and welfare.[32]

III. THE CORPORATE PRACTICE OF MEDICINE DOCTRINE IN OTHER STATES

Although Illinois adopted the corporate practice of medicine doctrine via case law, many states have not ruled on the matter, or instead expressed exceptions in case law or attorney general opinions.[33] Illinois should take a similar approach to states that relaxed the doctrine, in order for employers to play a role in clinical integration.

For example, state regulations in Indiana allow certain entities or professionals to employ physicians to provide medical services so long as they refrain from control or influence over the licensed physician's professional medical judgment.[34] Specifically, Indiana law provides a list of contractual relationships that do not constitute an unlawful practice of medicine.[35] Indiana holds that a contractual relationship between licensed physicians and a hospital, physician, psychiatric hospital, health maintenance organization, and many others does not constitute an unlawful practice of medicine.[36]

In Iowa, on the other hand, state statutes and regulations do not address

---

31. *Id.* at 113-14.
32. *Id.* at 114.
33. *See generally*, Michal, *supra* note 9. This source lists thirty-six states in which statutes do not address the corporate practice of medicine doctrine.
34. *Id.* at 6.
35. *Id.*
36. 25 IND. ADMIN. CODE § 25-22.5-1-2(c) (2013). In addition to a contractual relationship between licensed physicians and a hospital, physician, psychiatric hospital, and health maintenance organization, the exceptions also include a health facility, dentist, registered nurse or licensed practical nurse, midwife, optometrist, podiatrist, chiropractor, physical therapist, or psychologist as a lawful practice of medicine.

the corporate practice of medicine doctrine.[37] Instead, the Iowa Attorney General noted in an opinion that Iowa courts employ an in-depth factual analysis to determine whether there is a violation of the corporate practice of medicine doctrine.[38] Iowa courts look at the dominion and control over both the physician's treatment and decisions to determine whether a prohibited employment relationship exists, and not the designation provided in the contractual arrangement between the employing entity and the physician.[39]

Unlike Indiana and Iowa, South Dakota takes a different approach to the doctrine via statute.[40] South Dakota law prohibits an employer-employee physician relationship in which the agreement or relationship either directly or indirectly influences the physician's independent judgment concerning the practice of medicine, treatment, or diagnosis of a patient.[41] Additionally, South Dakota does not allow a corporation to profit from the practice of medicine, such as by the corporation charging higher fees for services than that which he would otherwise reasonably charge if he or she worked independently.[42]

IV. LOOSENING THE CORPORATE PRACTICE OF MEDICINE DOCTRINE IN ILLINOIS

The corporate practice of medicine doctrine certainly serves an important purpose by prohibiting employers from exerting inappropriate influence over

37. Michal, *supra* note 9, at 6.

38. Physicians and Surgeons; Licensing, 1992 Iowa Op. Att'y Gen. 28, 7 (1991).

39. *Id.* at 5.

40. S.D. CODIFIED LAWS § 36-4-8.1 (Current through the 2014 Regular Session). Although the statute has not been directly challenged in court, the statute lays out specifically that when an agreement either directly influences the physician's independent judgment concerning the practice of medicine, treatment, or diagnosis of a patient, it constitutes a violation. The statute also prohibits allowing a corporation to profit from the practice of medicine. Illinois should follow suit with South Dakota and clearly lay out what constitutes a violation of the doctrine.

41. *Id.*

42. *Id.*

a physician's professional medical judgment in regards to diagnosis and treatment of patients.[43] However, Illinois should take a similar approach to South Dakota in terms of reforming its corporate practice of medicine doctrine. Specifically, due to the absence of a statute, Illinois should, like South Dakota, codify the doctrine and identify exceptions that would allow for an employer-employee relationship. Specifically, the statutory exceptions should include relationships in which the employer does not influence, either directly or indirectly, the physician's independent professional medical judgment in terms of diagnosis and treatment. This approach would help identify the doctrine and provide examples as to when a relationship does not violate the doctrine.

The theoretical rationale for the doctrine is that because only a person can undergo the training needed for a professional license, a corporation or artificial person cannot be licensed and thus cannot practice medicine.[44] From a practical and policy standpoint, rules against the corporate practice of medicine carry the intent to prevent commercial exploitation of health care by organizations motivated by profit rather than commitment to patient wellbeing and quality of care.[45] If the approach to the corporate practice of medicine doctrine changed via the proposal in this article, problems of control, divided loyalty, and commercialism would have little effect on the physician's relationship with the patient.[46] More likely than not, such a relationship would involve a physician employed by a corporation to treat employees and promote wellness. The physician, however, would not be able to treat the general

43. *See* Jessica A. Axelrod, *Article: The Future of the Corporate Practice of Medicine Doctrine Following Berlin v. Sarah Bush Lincoln Health Ctr.*, 2 DePaul J. Health Care L. 103, 105 (1997) (citing three justifications for the corporate practice of medicine doctrine including that the prohibition 1) increases physician autonomy over medical judgments, 2) limits a sense of divided loyalty between the physicians and their profit-seeking employer, and 3) reduces the commercialization of health care and the possible exploitation of patients).

44. Arnold J. Rosoff, 17 CUMB. L. REV. 485, 491 (1986-1987).

45. *Id.*

46. Axelrod, *supra* note 43, at 120.

public as a physician employed by a non-hospital corporation. The loosening of the doctrine in Illinois would provide more options for the independent practitioner, improve overall patient wellness, and promote clinical integration.

Over the past decade, independent practitioners have increasingly closed their practices and integrated into larger health care systems and hospitals.[47] In 2012, the number of physicians in the United States who practiced outside of a hospital, clinic, or large group fell to thirty-nine percent, down from fifty-seven percent in 2000.[48] Eighty-seven percent of those who closed their independent practices blamed the cost of doing business, sixty-one percent cited managed care, and more than fifty percent noted the burden of converting to electronic health records.[49] Additionally, in regards to newly hired physicians, more than seventy-five percent will be hospital employees within two years as compared to eleven percent eight years ago.[50]

Needless to say, this data coupled with an increasing number of recent large hospital system mergers illustrates that independent physicians might need to look elsewhere for employment opportunities in order to compete.[51]

---

47. *See* Steve Jacob, *Texas a Last Bastion for Independent Physicians,* DALLAS/FORT WORTH HEALTHCARE DAILY (Apr. 9, 2014), http://healthcare.dmagazine.com/2014/04/09/texas-a-last-bastion-for-independent-physicians/. (Citing various polls in which physicians practicing outside a hospital fell over the past decade, due to increased costs, managed care, and electronic health records).

48. *Id.*

49. *Id.*

50. *Id.*

51. Kristen Schorsch, *Presence Health Is New Name of Combined Provena-Resurrection,* CRAIN'S CHICAGO BUS. (Feb. 17, 2012), http://www.chicagobusiness.com/article/20120217/NEWS03/120219790/presence-health-is-new-name-of-combined-provena-resurrection; *see* Andrew L. Wang, *Advocate, NorthShore Merger Would Create Giant Hospital Network,* CRAIN'S CHICAGO BUS. (Sept.12, 2014), http://www.chicagobusiness.com/ article/20140912/ NEWS03/140919949/ advocate-northshore-merger-would-create-giant-hospital-network (Reporting on the merger of Provena Health and Resurrection Health Corp. in 2012, as well as the merger between Advocate Health Care and NorthShore University HealthSystem).

Such mergers also put pressure on a dwindling number of independent hospitals to consider partnering with larger hospital systems.[52] While these large systems merge and promote clinical integration throughout their institutional structure, independent physicians may be forced to continue to close their doors due to a lack of any sort of competitive advantage.[53] A different approach to the corporate practice of medicine doctrine in Illinois to allow for employer-employee relationships in which the employer cannot exercise influence over the physician's professional medical judgment would provide a more flexible alternative for the independent physician. With the creation of the accountable care organization under the PPACA which allows for fully integrated physician groups, coupled with a drive towards more value based payment models, more independent physicians will need to turn elsewhere to keep their doors open.[54]

The ability of corporations to hire their own physicians as an option for their employees to receive treatment effectively incorporates the employer

52. Wang, *supra* note 51.

53. According to a 2011 survey of healthcare organization executives, "two out of three said they were receiving more employment requests from physicians and they planned to increase their physician hiring over the next three years." Jacob, *supra* note 47. Additionally, third-year medical residents are increasingly bypassing independent physician practices to work as salaried employees in hospitals and larger medical organizations. *Id.* "About half said they were ill-prepared to handle the business side of medicine because they receive no formal instruction in medical school on how to negotiate contracts or manage reimbursement." *Id.* The article also notes that more physician revenue means seeing more patients, which is subsidized by hospitals. *Id.* Finally, the article notes that "the biggest difference in having such a high percentage of independent affiliated physicians is the lack of an ability to create compensation incentives to reward performance goals ….[and that] it is easier to control the patient volume with employed physicians." *Id.*

54. *See* Christi J. Braun, *Clinical Integration: The Balancing of Competition and Health Care Policies*, CPI ANTITRUST J. (October 2010); *See also* Bob Spoerl, *PPACA Upheld: 8 Issues Hospitals Should Keep in Mind Moving Forward*, BECKER'S HOSPITAL REV., (June 29, 2012) http://www.beckershospitalreview.com/news-analysis/ppaca-ruled-okay-8-issues-hospitals-should-keep-in-mind-moving-forward.html (citing the changes to payment and delivery models under the PPACA).

into the role of promoting clinical integration. Many employers want to remove themselves from the role of paying for their employees' health care, but it is plausible that in the coming years many companies will increasingly integrate into a role that includes an increase in the management of their employees' health care.[55] Healthy and productive employees help lead to profits, and many employers spend thousands of dollars each year in an attempt to attract, train, improve, and retain their employees.[56] As a result, employers can play a role as health care integrators if the corporate practice of medicine doctrine is relaxed.

Application of the corporate practice of medicine doctrine extends beyond the scope of its purpose and instead impedes improvement in the efficiency of health care delivery.[57] Relaxing the corporate practice of medicine doctrine in Illinois to allow for these employers to both improve employee wellness and essentially incorporate them into a clinical integration role will promote efficiency.[58] The role that the employer will play with a relaxation of the corporate practice of medicine doctrine involves six aspects.[59] First, the employer would be self-insured, which would include a deductible and health savings accounts to help cover the employee's health cost.[60] Second, primary care physicians and nurse practitioners would be on the company or contractor firm payroll, and would serve as the primary care physicians to employees and their families.[61] These providers would oversee medical care decisions,

55. CLAYTON M. CHRISTENSEN ET AL., THE INNOVATOR'S PRESCRIPTION: A DISRUPTIVE SOLUTION FOR HEALTH CARE 204 (2009).

56. *Id.*

57. Adam M. Freiman, *Comment: The Abandonment of the Antiquated Corporate Practice of Medicine Doctrine: Injecting a Dose of Efficiency Into the Modern Health Care Environment*, 47 EMORY L.J. 697, 746 (1998).

58. CHRISTENSEN ET AL., *supra* note 55, at 204.

59. *See generally*, *id.* at 207-08.

60. *Id.* at 207.

61. *Id.*

and their performance would be measured and compensated by the improvement in an employee's health.[62]

Third, employers could contract directly with hospitals, outpatient and retail clinics, and whenever possible, would direct care for disorders still in the realm of intuitive medicine to these outside facilities.[63] The employer would promote self-care if appropriate, encourage the use of retail clinics, and direct employees to low-cost medical tourism hospitals abroad when expensive procedures may be required for treatment.[64] Fourth, employers would provide employee-access to personally controlled electronic health records in a format compatible with the systems of hospitals and other health care facilities.[65] Fifth, in an effort to reduce and treat behavior-dependent chronic diseases like obesity and diabetes, employers would contract with disease management network operators to manage the patient's adherence to treatment programs.[66] Sixth, employers would implement financial rewards for good behaviors such as weight loss, increased exercise, cessation of smoking, and compliance with treatment plans.[67] Some companies, like Quad/Graphics in Wisconsin, successfully implemented innovative programs like this, which resulted in improved employee health and integration across the board.[68]

---

62. *Id.* at 208.

63. *Id.*

64. *Id.*; *See also* Steven J. Thompson, *Medical Tourism and Travel: What it Means for Your Hospital*, BECKER'S HOSPITAL REV., (June 08, 2012) http://www.beckershospitalreview.com/hospital-management-administration/medical-tourism-and-travel-what-it-means-for-your-hospital.html (Defining medical tourism as patients taking an overseas trip to seek medical treatment. Typically the treatment sought is expensive in the United States, whereas it is substantially cheaper in many instances at the overseas destination. The motivation is typically price, and many overseas institutions have gained a reputation for quality medical services at a lower cost).

65. CHRISTENSEN ET AL., *supra* note 55, at 208

66. *Id.*

67. *Id.*

68. *See*, *id.* at 209-11. Quad/Graphics is a company headquartered in Milwaukee, Wisconsin, which set up its first primary care clinic in 1990 as a way to bypass the middlemen in medicine and to control costs. By 2009, the company

V. CONCLUSION

In an era of increasing demand for higher quality of care at the lowest cost possible and increased regulatory requirements under the PPACA, a different approach to the corporate practice of medicine doctrine in Illinois could help ease the transition into additional clinical integration. Codifying and relaxing the doctrine to identify and permit employer-employee relationships where the employer does not exercise influence or control over the physician's independent medical judgment as to diagnosis and treatment would allow for an alternative employment method for independent physicians. This is particularly important in a time where more and more health care systems are consolidating, thus providing the independent physician with less leverage and increasing the competition. Additionally, relaxing the doctrine in Illinois to allow for physicians to seek employment with self-insured employers would promote both clinical integration and employee wellness because both the physician and employer would have a more direct role in the coordination of employee health care.

---

operated four medical centers. The medical centers offer family practice, internal medicine, pediatrics, obstetrics, gynecology, minor surgical procedures, lab work, injury rehabilitation, and physical examinations. The services are free to both employees and their families. The services emphasize wellness rather than treating illness, through programs that focus on combating chronic diseases such as obesity and diabetes. Quad/Graphics is self-insured and contracts directly with local hospitals and specialists for situations that require advanced care. The system cut the company's health-care costs, reduced morbidity and employee absenteeism, and increased employee wellness. Quad/Graphics spends more on primary care than other companies, but the investment helps keep employees and their families from requiring care in hospitals and from high-cost specialists.

ANNALS OF HEALTH LAW
Advance Directive

VOLUME 24 SPRING 2015 PAGES 77-89

Clinical Integration and Payer Contracts: A Balancing Act

Mary Buckley[*]

The passage of the Patient Protection and Affordable Care Act (PPACA) means changes for health care and those who pay for it. As these changes include an increase in the insured population and increased eligibility for Medicaid, United States employers, government entitlement programs, and private insurers will have more healthcare costs to manage.[1] To manage these costs, it is imperative that healthcare providers and payers minimize excess costs and align incentives to maximize efficiency and value.[2] One way to do this is through the creation of clinically integrated care networks, where healthcare providers work together to share best practices and various resources in order to provide higher quality care.[3] Clinical integration is strengthened further when payers recognize the value in these systems and coordinate with healthcare providers in order to deliver superior insurance coverage for consumers.[4] Finance and quality generally go hand in hand when it comes to transitioning successful clinically integrated networks to

[*] Juris Doctor Candidate, May 2016, Loyola University Chicago School of Law. Ms. Buckley is a staff member of Annals of Health Law.

1. *Key Features of the Affordable Care Act by Year*, HHS.GOV: U.S. DEP'T OF HEALTH & HUMAN SERVS., http://www.hhs.gov/healthcare/facts/timeline/timeline-text.html (last visited Apr. 24, 2015).

2. Donald M. Berwick & Andrew D. Hackbarth, *Eliminating Waste in US Health Care*, 307 JAMA 1513, 1513-14 (2012), *available at* http://news.medicine.duke.edu/wp-content/uploads/2013/08/Eliminating-Waste-in-US-Healthcare-Berwick.pdf.

3. *Clinical Integration Knowledge Hub*, AETNA HEALTH, http://www.athenahealth.com/knowledge-hub/clinical-integration/what-is-clinical-integration (last visited Apr. 24, 2015) [hereinafter *Knowledge Hub*].

4. *Clinical Integration*, PERSHING YOAKLEY & ASSOCS., http://www.pyapc.com/healthcare-consulting/clinical-integration/ (last visited Apr. 24, 2015).

systems participating in value-based payments.[5] However, to fully develop clinically integrated networks, it is crucial that those at the forefront carefully consider ways to attract providers and patients to adapt to changing attitudes in healthcare today.[6] Vanderbilt University Medical Center has considered some of these strategies, but its course of action is not without flaws.[7]

This article examines the characteristics of the Vanderbilt Health Affiliate Network and the delivery of care through the clinically integrated network itself, as well as through partnerships with payers. This article advocates for a careful balance between past characteristic flaws of traditional managed care and necessary measures for future successful value-based payments. In doing so, Part I explains background information on the PPACA's emphasis on efficiency in health care, detailing clinical integration and capitation.[8] Part II details the Vanderbilt Health Affiliate Network and its popularity with insurers.[9] Parts III and IV then note some of the strengths of the clinically integrated network for purposes of patient satisfaction, while arguing that these may present challenges if not monitored or strategically implemented.[10] Finally, Part V describes some of the successes of the Vanderbilt network in terms of physician satisfaction compared to historical weaknesses from managed care.[11]

I. BACKGROUND ON CLINICAL INTEGRATION AND PPACA

The Federal Trade Commission defines clinical integration as "a group of

5. JASON GOLDWATER & LARRY YUHASZ, CONSIDERATIONS FOR CLINICAL INTEGRATION, TRUVEN HEALTH ANALYTICS 1, 4-5 (2011) (describing how clinical integration helps lay the groundwork for working relationships necessary for coordinated care, such as value based payments like risk-adjusted reimbursement, pay-for-performance, and economic credentialing).

6. *Id.*

7. *See infra* notes 27-34 and accompanying text (discussing the background of Vanderbilt University Medical Center's clinically integrated network).

8. *See infra* Part I.

9. *See infra* Part II.

10. *See infra* Parts III and IV.

11. *See infra* Part V.

providers who mutually choose to work together and commit to a united cause: to improve outcomes and reduce costs through the employment of evidence-based medicine and continuous process improvement."[12] The importance of this movement stems from initiatives to alleviate historical issues in healthcare delivery and payment.[13] The PPACA encourages efficiency in health care, responding to crippling healthcare spending as a result of misaligned financial incentives.[14] The financial incentives of clinically integrated networks do not function the same as an accountable care organization (ACO), which encourages value in healthcare for Medicare beneficiaries.[15] This is because ACOs assume financial risk for efficiency of care where clinically integrated networks do not.[16] However, the networks still function as a cost saving mechanism, particularly for intellectual capital and coordination, cutting down on unnecessary or duplicative treatment.[17] Key components of clinically integrated networks tend to feature measures like shared electronic health record databases, best practices, guidelines for care, and hospital-physician coordination.[18] Nonetheless, clinically integrated networks are, at times, merely a means for providers to lay the groundwork for bundled payments and other payment methods requiring financial risk.[19]

Capitation and bundled payments are one way for providers to limit

12. *Vanderbilt Health Affiliated Network to Offer Expanded Options*, VANDERBILT UNIV. MED. CTR. REPORTER (Oct. 4, 2013), http://news.vanderbilt.edu/2013/10/vanderbilt-health.

13. *See* GOLDWATER & YUHASZ, *supra* note 5, at 4; *see also The Economic Case for Health Reform*, WHITEHOUSE.GOV (last visited Apr. 24, 2015) ("Some of the strongest evidence of such inefficiencies comes from the tremendous variation across states in Medicare spending per enrollee, with no evidence of corresponding variations in either medical needs or outcomes. These large variations in spending suggest that up to 30 percent of health care costs (or about 5 percent of GDP) could be saved without compromising health outcomes.").

14. *See* Berwick & Hackbarth, *supra* note 2.

15. James J. Pizzo & Mark E. Grube, *Getting to There from Here: Evolving ACOs Through Clinical Integration Programs*, KAUFMAN, HALL & ASSOCS. 4 (2011), *available at* http://www.advocatehealth.com/documents/app/ci_to_aco.pdf.

16. *Id.*

17. *Id.*

18. *Id.*

19. *See* GOLDWATER & YUHASZ, *supra* note 5, at 4.

healthcare spending through value creation and efficiency in care.[20] By providing a set amount of money per patient regardless of labor or supplies, capitation and bundled payments place financial responsibility on providers to provide effective and efficient care.[21] This contrasts with traditional reimbursement where providers are reimbursed on a fee-for-service basis through receipt of reimbursement per service provided.[22] Fee-for-service reimbursement incentivizes providers to increase service volume and not necessarily spend healthcare dollars wisely.[23] Due to the traditional excess spending resulting from fee-for-service reimbursement, recent healthcare payment trends indicate a shift towards value-based payment methods like capitation and bundled payments.[24] These payments were traditionally utilized by managed care organizations, but may become more widespread for other health insurance organizations.[25] This shift in payment makes provider adaptation to coordination and efficiency even more important, and clinically integrated networks seek to address these aims.[26]

II. VANDERBILT HEALTH AFFILIATE NETWORK

One clinical integration success story is the Vanderbilt Health Affiliate Network (VHAN) developed by Vanderbilt University Medical Center in

20. Andrew Ruskin, *Capitation: the Legal Implications of Using Capitation to Affect Physician Decision-making Processes*, 13 J. CONTEMP. HEALTH L. & POL'Y 391, 392 (1997).

21. *Id.*

22. *Id.*

23. Robert E. Mechanic, *In Health Care, Fee-for-Service Is A Perverse Incentive*, N.Y. TIMES (Mar. 6, 2014), http://www.nytimes.com/roomfordebate/2014/03/05/hospital-systems-vs-private-practice-doctors/in-health-care-fee-for-service-is-a-perverse-incentive.

24. SHIFTING FROM FEE-FOR-SERVICE TO VALUE-BASED CONTRACTING MODEL, UNITED HEALTHCARE (2012), *available at* http://consultant.uhc.com/assets/vbc_overview_flier.pdf.

25. Bob Herman & Melanie Evans, *Transformers Push to Modify Pay Must Overcome Legacy System*, MODERN HEALTHCARE (Jan. 31, 2015), http://www.modernhealthcare.com/article/20150131/MAGAZINE/301319987/transformers-push-to-modify-pay-must-overcome-legacy-system.

26. *Clinical Integration: The Key to Real Reform*, AM. HOSP. ASS'N TRENDWATCH 4-5 (Feb. 2010).

Nashville, Tennessee.[27] Vanderbilt University Medical Center has accomplished clinical integration through its creation of the VHAN.[28] In doing so, Vanderbilt created a strategy that enabled it to form the largest clinically integrated network in the country.[29] Vanderbilt began its initiative to form a clinically integrated network by creating collaborative relationships with other hospitals and physician practices.[30] These relationships are centered on sharing infrastructure in order to coordinate care and cut down on administrative waste.[31] Further, VHAN network participants interact through communication, governance, organization, and the development of novel medical record forms.[32] The success of these measures allowed VHAN to demonstrate its efficiency and value to other providers to expand its network.[33] Through this initiative, Vanderbilt successfully formed a system of 3,200 physicians and other providers caring for two million patients under VHAN.[34]

III. VHAN SUCCESSES IN INSURANCE

Clinically integrated networks as a means to encourage healthcare efficiency will also heavily depend on attractiveness to payers.[35] Coordination between payers and providers is paramount.[36] Patients will be further incen-

27. *See* infra notes 23-29 and accompanying text.

28. Patricia Kirk, *Vanderbilt University Medical Center Forms Nation's Largest Clinically Integrated Network that Includes its Own Health Insurance Offering*, DARK DAILY: CLINICAL LAB. AND PATHOLOGY NEWS AND TRENDS (Jul. 9, 2013), http://www.darkdaily.com/vanderbilt-university-medical-center-forms-nations-largest-clinically-integrated-network-that-includes-its-own-health-insurance-offering.

29. *Id.*

30. *Id.*

31. VANDERBILT UNIV. MED. CTR., VANDERBILT UNIVERSITY MEDICAL CENTER STRATEGY FRAMEWORK 2013 13 (2013), *available at* http://www.mc.vanderbilt.edu/documents/strategy/files/VUMC_strategy_framework_v4.pdf.

32. *Id.*

33. *Id.*

34. *About Us*, VANDERBILT HEALTH AFFILIATED NETWORK, http://vhan.com/about-us/ (last visited Apr. 24, 2015).

35. *See* GOLDWATER & YUHASZ, *supra* note 5, at 6.

36. *Id.*

tivized to utilize providers within a clinically integrated network if they ensure that they have low-cost access to quality care through their health insurance.[37]

Vanderbilt has already begun to successfully market its clinically integrated network by partnering with health insurance providers to deliver insurance plans based upon networks of physicians.[38] Although assumption of financial risk is not normally included in clinical integration, successful clinical integration attracts payers wishing to efficiently manage healthcare costs.[39] In the case of VHAN, those assuming costs for health care utilized the network in two ways.[40] First, VHAN providers self-insure their employees, offering employees the network from which to choose providers.[41] Second, Aetna offers the network as an insurance product.[42]

Vanderbilt's method of offering its clinically integrated network as an insurance product was a low-risk way to test a provider-insurer relationship.[43] To create a stable base for its network, Vanderbilt made strides by keeping an eye on the movement to value-based payments but not alienating providers and patients.[44] In doing so, Vanderbilt began providing its network as self-

37. *See* Lori Fox Ward, Best of Both Worlds: Physician Benefits of Joining Clinically Integrated Networks, VALENCE HEALTH: INDUST. PERSPECTIVE, *available at* http://valence-health.com/uploads/files/Valence_Health_Industry_Perspective_Best_of_Both_Worlds.pdf

38. *FAQ*, VANDERBILT HEALTH AFFILIATED NETWORK, http://vhan.com/providers/faq (last visited Apr. 24, 2015).

39. *See* GOLDWATER & YUHASZ, *supra* note 5, at 6.

40. David R. Posch & John A. Lutz, *The Vanderbilt Experience: An Expanding Clinically Integrated Network*, NAVIGANT PULSE 18, 20 (2013).

41. *Id.*

42. Paul Govern, *Area Employers Learn More About Affiliate Network's Benefits*, VANDERBILT NEWS (Nov. 29, 2012), http://news.vanderbilt.edu/2012/11/area-employers-learn-more-about-affiliate-network-benefits/.

43. *Id.*

44. *See infra* notes 45-51 and accompanying text.

insurance by managing the healthcare of the 70,000 employees and dependents of the network.[45] In January 2013, under the VHAN health plan, Vanderbilt employees could be treated at any VHAN participating facility.[46] By starting with its own employees, Vanderbilt and Aetna had access to a preexisting pool of insured individuals, which enabled them to market the product without having to start from scratch.[47] After offering the network only to its employees and their families, Vanderbilt worked with large employers to design similar programs offering the network as an insurance product.[48]

In January 2014, Aetna began offering VHAN as an insurance plan, expanding the network's reach to Tennessee employers.[49] The 2014 health plan for Vanderbilt faculty and staff included two "tiers" of coverage administered by Aetna.[50] Tier one included a range of affiliated providers at a lower cost compared to non-affiliated Aetna providers while tier two included access to Aetna's national network of providers.[51]

Although VHAN's success has evolved due to its attractiveness to payers and employers, it appears as though the system is making gradual movements towards capitation and bundled payments in order to attract providers who may be slow to change.[52] This is an effective way to align independent physicians with a system without acquiring their physician practices.[53] It allows physicians to remain independent but benefit from intellectual capital and technology that otherwise may be difficult to obtain.[54] In order to participate

45. *See* Posch & Lutz, *supra* note 40.
46. *Id.*
47. *Id.*
48. *Id.*
49. *Id.*
50. *See Vanderbilt Health Affiliated Network to Offer Expanded Options*, *supra* note 12.
51. *Id.*
52. *See FAQ*, *supra* note 38.
53. *See Knowledge Hub*, *supra* note 3.
54. *Id.*

in VHAN, providers are not required to contract with VHAN-Aetna exclusively; therefore, providers can maintain financial flexibility and assume lower risks.[55] Additionally, providers participating in VHAN maintain base payer contracts when they become a part of VHAN.[56] After the network becomes fully integrated, the VHAN system may enter comprehensive contracts that include reimbursement rates tied to value achieved through clinical initiatives.[57] Once risk capabilities increase, contracts may progress to bundled payments, global payments, and capitation.[58]

VHAN-Aetna's tier program is one way to provide care within a clinically integrated network as a variation on a narrow network insurance product.[59] Tier one providers offered by the VHAN-administered health plan provide enrollees with lower co-pays and deductibles.[60] While consumers are financially incentivized to go to these providers, they are not prohibited from going elsewhere.[61] Enrollees in the VHAN-Aetna plan may choose to seek care from within the tier two level, which includes any other Aetna provider.[62] This is positive for purposes of facilitating consumer choice and preference.[63] For example, a VHAN enrollee may have the option to continue to see his or her primary care physician (provided he or she is an Aetna physician) outside

55. *See FAQ*, *supra* note 38.
56. *Id.*
57. *Id.*
58. *Id.*
59. A narrow network insurance product is one where enrollees receive care within a network of providers, where the insurance covers costs. David Blumenthal, *Narrow Networks: Boon or Bane?*, THE COMMONWEALTH FUND (Feb. 24, 2014), http://www.commonwealthfund.org/publications/blog/2014/feb/narrows-networks-boon-or-bane. Generally, insurance companies are able to negotiate lower prices within these networks, leading to lower co-pays and deductibles. *Id.*
60. *See FAQ*, *supra* note 38.
61. *Id.*
62. *Id.*
63. *See The Origins of Managed Health Care*, adapted from PETER R. KONGSTVEDT & PETE FOX, *Chapter 1: An Overview of Managed Care*, *in* THE ESSENTIALS OF MANAGED HEALTH CARE 1, 13 (5th ed. 2007), *available at* http://www.jblearning.com/samples/0763759112/59117_CH01_Pass2.pdf [hereinafter *Origins*].

of the network.[64] If a patient has a particularly good relationship with a physician and does not mind paying the extra expense, the patient is still covered by the insurance.[65]

IV. POTENTIAL CHALLENGES PRESENTED BY VHAN'S INSURANCE MODEL

VHAN's initiative of synching a clinically integrated network with Aetna in order to provide high quality, low cost care is a progressive movement towards capitation and bundled payments. However, in doing so, the organization must balance initiatives to appease physicians and patients with lessons from past managed care models.[66] One risk VHAN-Aetna takes when allowing its enrollees to seek care outside of the integrated network is reduced efficiency in care.[67] By allowing enrollees to leave the clinically integrated network, VHAN may perpetuate some of the measures its clinically integrated network attempts to combat.[68] For example, patients may be subject to repeat diagnostic tests, conflicting treatment plans, or adverse prescription drug reactions due to non-streamlined practices or medical records.[69]

A managed care model of note is the health maintenance organization (HMO). The United States Department of Health and Human Services defines HMOs as insurance plans that limit coverage from care by doctors who work for or contract with the HMO (excluding out-of-network coverage except in cases of emergency), focus on integration, and promote prevention

64. *See FAQ*, *supra* note 38.
65. *See id.*
66. *See Knowledge Hub*, *supra* note 3.
67. *See* Press Release, Kaiser Permanente, Integrated Health Care Delivery System and Electronic Health Records Support Medication Adherence (Sept. 6, 2011), http://share.kaiserpermanente.org/article/integrated-health-care-delivery-system-and-electronic-health-records-support-medication-adherence/ (offering prescription adherence as an example of a measurable success integrated networks have accomplished).
68. *See* GOLDWATER & YUHASZ, *supra* note 5, at 2-3.
69. *See Knowledge Hub*, *supra* note 3.

and wellness.[70] Although the VHAN-Aetna product is *not* an HMO,[71] its movement toward managed care may cause the health plan offered by Aetna and VHAN to more closely resemble an HMO as the organization moves towards risk-based payments.[72]

The reality and potential range of issues arising from allowing consumers a diluted form of a managed care product are evident in the history of HMOs.[73] Organizations administering HMOs experienced and continue to experience less success when they do not have as much control over costs, often arising with weakened integration.[74] Physician-hospital organizations (PHOs) were one aspect of HMOs where physicians contracted with an HMO to form integrated delivery systems.[75] Most of these arrangements featured fee-for-service payments, while some featured capitated payments.[76] These arrangements generally did not manage risk well because most allowed all physicians with hospital privileges to participate instead of limiting participation to only efficient physicians suited for patient value.[77] PHOs also commonly lacked organization, infrastructure, management, and other resources that are imperative to successful coordinated care.[78] Further, open-ended HMO products that employers sought in the 1980s and 1990s allowed enrollees to self-refer outside the network with traditional cost sharing.[79] By al-

70. *Health Maintenance Organization (HMO)*, HEALTHCARE.GOV, https://www.healthcare.gov/glossary/health-maintenance-organization-HMO/ (last visited Apr. 24, 2015).

71. *See FAQ*, *supra* note 38.

72. *Id.*

73. *See* CLAYTON M. CHRISTENSEN ET AL, THE INNOVATOR'S PRESCRIPTION, 228-230 (McGraw Hill, 2009).

74. Debra S. Wood, *Risky Business: Lending to Health Maintenance Organizations and Physician Practice*, 1 N.C. BANKING INST. 322, 336-37 (1997).

75. *See Origins*, *supra* note 63, at 8

76. *Id*.

77. *Id.*

78. *Id.*

79. Marsha R. Gold, *HMOs and Managed Care*, 10 HEALTH AFF. 189, 202 (1991).

lowing patients to receive de-centralized care, healthcare expenditures become more costly.[80] Additionally, carve-out companies (i.e., provider networks specializing in the management of a specific disease or condition) weakened efficiency and coordination efforts.[81] This inefficiency drove reintegration of the carved out networks back into HMOs in order to coordinate in-network and out-of-network patient care.[82]

With this background in mind, VHAN system must carefully weigh the risk of allowing enrollees to receive care at out-of-network providers. Some of the previous issues associated with HMOs can arise from a tiered approach to insurance in and outside of a clinically integrated network.[83] If patients do not stay within a managed care network, the financial incentive is significantly weakened, and the goal of holistic health will be less certain to occur.[84] In order for VHAN to efficiently equip itself to address value-based payments, it should be aware of this history. The option for a fragmented network of providers must be alleviated when capitation and bundled payments become more imminent.[85] When provider incentives are not aligned, patient care is less efficient because different providers do not have an incentive to provide the utmost quality of care if someone else will assume that cost.[86]

V. VHAN PHYSICIAN INCENTIVES

As opposed to its patient incentives, VHAN incentivizes physicians to join the network in ways that have fewer drawbacks.[87] VHAN is merely laying

80. *Id.* at 203.
81. *Origins*, *supra* note 63, at 8.
82. *Id.*
83. *See infra* notes 84-86 and accompanying text.
84. *See* Wood, *supra* note 74, at 325-26.
85. *See* GOLDWATER & YUHASZ, *supra* note 5, at 2-3.
86. *Capitation, Rate Setting, and Risk Sharing*, AM. COLL. OF HEALTHCARE EXEC, 20 - 4, -5, *available at* http://www.ache.org/pubs/hap_companion/gapenski_finance/online%20chapter%2020.pdf.
87. *See infra* notes 84- 88 and accompanying text.

the groundwork for managed care arrangements of the future; therefore, certain features characteristic of traditional managed care programs are appropriately absent from its system.[88] Previous managed care arrangements featured physician alienations, like requiring authorizations, excluding them from networks, and bargaining for lower prices.[89]

These typical features are all but present from VHAN.[90] Physicians have minimal costs required to join the network, but gain a plethora of intellectual capital and access to patients in the VHAN network, as well as goodwill associated with the Vanderbilt Health System.[91] Further, physicians do not have to exclusively treat patients who have a certain kind of health insurance or are in the VHAN network.[92] As a member of the network, physicians are enabled to accept other methods of payment in addition to the Aetna-VHAN plan.[93] Additionally, no service needs approval, like in an HMO.[94] These measures all present a low-risk option for physicians who want to align with a large system to prepare for value-based payments, yet are not comfortable with giving up all control by becoming a part of a large health system through a merger or acquisition.[95]

VI. CONCLUSION

Clinically integrated networks are clearly utilized by healthcare providers to prepare for the value-based payments necessary to cut excess and remain attractive in the healthcare market.[96] It is important, however, for providers

88. *See FAQ*, *supra* note 38.
89. Ezekiel J. Emanuel, *Why Accountable Care Organizations Are Not 1990s Managed Care Redux*, 307 JAMA 2263, 2263 (2012).
90. *See infra* notes 84-88 and accompanying text.
91. *See FAQ*, *supra* note 38.
92. *Id.*
93. *Id.*
94. *Id.*
95. *Id.*
96. *See* Pizzo & Grube, *supra* note 15, at 4.

to remember the recent past and keep a careful eye on how networks are effectively utilized by payers, patients, and physicians. This requires careful balancing of concerns related to consumers, patient-quality, and physician satisfaction.

Measures taken by those initiating the networks clearly have addressed these factors, but as payment makes a shift to value-based payments, further change may be necessary in order to ensure health care remains efficient. VHAN's insurance initiatives wisely facilitate some degree of consumer choice, but the history of managed care reveals that too much flexibility may result in drawbacks elsewhere.[97] The strategies VHAN used to attract physicians to the network seem to present fewer areas for concern, especially considering how they contrast with unpopular managed care requirements and procedures.[98] As health care continues to evolve, clinically integrated providers should utilize this information in order to best respond to the demands of the industry.

97. *See supra* Sections III-IV.
98. *See supra* Section V.

ANNALS OF HEALTH LAW
Advance Directive

VOLUME 24 SPRING 2015 PAGES 90-105

Respect for the Dying: How Clinically Integrated Networks Can Aid the Existing POLST Paradigm in Honoring Patients' End-of-Life Care Choices

Arianne Clayton[*]

"Death is normal. Death may be the enemy, but it is also the natural order of things."[1] While death is inevitable for everyone, few subjects are more difficult to acknowledge than death. For many individuals death is not a sudden event, but rather an inevitable consequence of aging or the result of acute illness.[2] To the elderly or terminally ill, the process of dying is not a strictly medical event, but an emotional, and to some, spiritual experience.[3] Ideally, end-of-life care would combine patient approved treatment and care measures with social, psychological, and spiritual support.[4] However, this multi-faceted and patient-centered approach to end-of-life care is not always provided to the patient.[5] The United States' health care system has struggled to provide a solution to fill the gap between the end-of-life care that patients want and the care they actually receive.[6]

[*] Juris Doctor Candidate, May 2015, Loyola University Chicago School of Law. Ms. Clayton is a staff member of Annals of Health Law.

1. ATUL GAWANDE, BEING MORTAL: MEDICINE AND WHAT MATTERS IN THE END 20 (Profile Books, Ltd., 2014).

2. INST. OF MED., *The Delivery of Person-Centered, Family-Oriented End-of-Life Care*, *in* DYING IN AMERICA: IMPROVING QUALITY AND HONORING INDIVIDUAL PREFERENCES NEAR THE END OF LIFE, 1 (National Academies Press, 2014).

3. *Id.* at 1-2.

4. *Id*.

5. Randall Krakauer et al., *Opportunities to Improve the Quality of Care for Advanced Illness*, 28 HEALTH AFF. 5, 1357-59 (2009).

6. INST. OF MED., *Policies and Payment Systems to Support High-Quality End-of-Life Care*, DYING IN AMERICA: IMPROVING QUALITY AND HONORING INDIVIDUAL PREFERENCES NEAR THE END OF LIFE, 1 (National Academies Press, 2014).

Physician and author Atul Gawande accurately notes "our most cruel failure in how we treat the sick and the aged is the failure to recognize that they have priorities beyond merely being safe and living longer."[7] While some progress has been made in ensuring that patients' end-of-life choices are discussed and ultimately followed, there is still a need for a coordinated and effective model that truly gives patients a sense of autonomy when it comes to these choices. Thus, this article will propose that a clinically integrated network, such as an accountable care organization (ACO) utilizing the existing Physician Orders for Life-Sustaining Treatment (POLST) Paradigm, may provide a solution to ensuring that a patient's end-of-life choices are ultimately followed by health care providers. In order to logically present this model as a solution to end-of-life care issues facing the aging and terminally ill, this article will first discuss the background and present end-of-life care decision options available to patients. Specifically, this article will focus on the POLST Paradigm and discuss the benefits and drawbacks of the model. Then, this article will discuss how a clinically integrated health care network can integrate the POLST Paradigm and solve some of the issues presented by the stand-alone POLST Paradigm, drawing on some of the successes of private sector reform initiatives.

I. END-OF-LIFE CARE: A COSTLY GAP IN HEALTH CARE REFORM

The United States health care system is in a state of rapid change, and at the crux of the 2010 Patient Protection and Affordable Care Act (ACA) is the notion that the patient is put in charge of his or her health care.[8] Yet in spite of these changes, the Institute of Medicine (IOM) Committee on Care at the End of Life, in assessing how the current health system affects Americans

7. GAWANDE, *supra* note 1, at 395.

8. *About the Law*, U.S. DEP'T OF HEALTH & HUMAN SERVS., http://www.hhs.gov/healthcare/rights (last visited Mar. 4, 2015).

near the end-of-life, found the system to be disorganized and terribly inefficient in the treatment of these patients.[9] The Committee found that these patients often experience insufficient treatment and management of pain, frequent and medically risky transitions across health care settings, and added stress upon the patients' families.[10]

Currently, Medicare and Medicaid, the nation's largest health care programs, "perversely provide disincentives for any provider to invest in coordination of care that might lessen the need of patients for health care because . . . such investments result in fewer payments for medical or hospital services."[11] In addition to these "perverse" incentives is the idea that "death is a failure," and that it is the job of medical professionals to ensure "health and survival."[12] While the ACA has brought changes in financial incentives and organizational arrangements to provide quality patient-centered care at lower costs, there are gaps from the standpoint of care for patients with advanced illnesses.[13] An important gap is that the ACA does not measure or reward greater access to coordinated, compassionate care for people with advanced and serious illness, nor does the Act establish mechanisms for reimbursing clinicians for the conversations necessary to engage in advance care planning with these patients.[14]

Additionally, people near the end of life often require a substantial amount

9. INST. OF MED., *supra* note 6, at 1

10. *Id* at 1, 14. Statistics indicate "the average number of transitions from one site of care to another in the patients last 90 days of life increased from 1.2 per decedent in 2001 to 3.1 in 2009 with more than 14 percent of the transitions taking place in the last 3 days of life." The resultant risks from these frequent transitions are higher rates of infection, medical errors, delirium, and falls. Moreover, these transitions may precipitate an earlier onset of death for these terminal patients.

11. *Id.* at 10.

12. INST. OF MED., APPROACHING DEATH: IMPROVING CARE AT THE END OF LIFE 96 (National Academies Press, 1997) ("Hospital culture often regards death as a failure, in part because modern medicine has been so successful in rescuing, stabilizing, or curing people with serious medical problems, and in part because a significant minority of acutely ill and injured patients who die often do so before the end of a normal life span.").

13. INST. OF MED., *supra* note 2, at 43-44.

14. *Id.*

of expensive care. Studies show that twenty-five percent of all Medicare spending is for the five percent of patients who are in their final year of life, and a majority of the money is allocated to the last couple of months of life.[15] A 2011 study on breast cancer costs found that while treatment costs are initially steep, if the treatment is successful, the costs eventually take a downward trend.[16] However, the same study noted that in terminal cases the costs took a steep and increasingly upward climb until the patient's last year of life, where the study calculated the average costs of the last year of life to be $94,000.[17] Additionally, a more generalized 2006 study showed that eighty-two percent of Medicare spending in patients' final three months of life was for hospital care.[18] Modern medicine has progressed so far that death can be continuously pushed back to the tune of thousands of dollars and a battery of treatments.[19]

In addition to Medicare dollars, there is a human cost associated with current practices in end-of-life care. Gawande's observations in the intensive care unit (ICU) note that these interventions toward the end-of-life often provide very little benefit to patients, and argue that most terminal patients view spending his or her final days in the ICU as a type of failure. [20] In addition to this sentiment, one commonality among the patients Gawande profiled was

15. GAWANDE, *supra* note 1, at 202 (citing Gerald F. Riley & James D. Lubitz, *Long-Term Trends in Medicare Payments in the Last Year of Life*, 45 HEALTH SERVICES RES. 565-76 (2010)).

16. GAWANDE, *supra* note 1, at 203 (citing Angela B. Mariotto et al., *Projections of the Cost of Cancer Care in the United States: 2010–2020*, 103 J. OF NAT'L CANCER INST. 117 (2011)); *see also* M. J. Hassett & E. B. Elkin, *What Does Breast Cancer Treatment Cost and What Is It Worth?*, HEMATOLOGY/ONCOLOGY CLINICS OF N. AM. 829-41 (2013) (finding "that medical spending for a breast cancer patient in the first year of diagnosis averaged an estimated $28,000, the vast majority of it for the initial diagnostic testing, surgery, and, where necessary, radiation and chemotherapy. Costs fell after that to about $2,000 a year.").

17. *Id.*

18. INST. OF MED., *supra* note 6, at 14.

19. GAWANDE, *supra* note 1, at 203 ("Our medical system is excellent at trying to stave off death with $12,000-a-month chemotherapy, $4,000-a-day intensive care, $7,000-an-hour surgery. But, ultimately, death comes, and few are good at knowing when to stop.").

20. GAWANDE, *supra* note 1, at 202-05.

the lack of a coordinated plan for patients' end-of-life treatment,[21] demonstrating that the failure to meaningfully address patients' end-of-life wishes comes at a high monetary cost in addition to the emotional cost of the patients' choice on how they will spend their final moments of life.[22]

However, in spite of these issues, the ACA and the changing landscape of health care in America has nevertheless spurred dialogue on how to best ensure patients' end-of-life needs and choices are met.[23]

II. RIGHT TO DIE: PAST AND PRESENT MEASURES TO ENSURE PATIENTS' CHOICES REGARDING THEIR END-OF-LIFE CARE ARE MET

In American jurisprudence there is no right more sacred that an individual's personal autonomy and the self-determination over his or her own body.[24] In regard to the notion of body autonomy in the context of medical treatment, it was perhaps best stated by Justice Cardozo in a 1914 Court of Appeals of New York decision: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body."[25] This "right of determination" is especially critical in the context of end-of-life care.[26] For certain individuals, the possibility of extending life is not only welcome but meaningful and preferable for a variety of personal, ethical, or

21. *Id* at 203-05.

22. *Id.* at 203-05. Gawande noted one seventy-year-old patient had metastatic lung cancer and fungal pneumonia, which arises at the end stage of illness, and had decided to forgo treatment. The patient was pushed by her oncologist to continue treatment and she soon ended up in the ICU on a ventilator. Another patient with end stage respiratory and renal disease had mentioned she did not want to die in the ICU as her husband did with a tracheostomy and a feeding tube, yet her children did not want to let her die and asked to proceed with life sustaining treatment—a permanent tracheostomy, a feeding tube, and a dialysis catheter. In both of these cases there was no mention of any sort of end-of-life plan or directive to realize these patients' wishes.

23. *See generally* INST. OF MED., *supra* note 6; Thaddeus Mason Pope, *Clinicians May Not Administer Life Saving Treatment without Consent: Civil, Criminal and Disciplinary Sanctions*, 9 J. of Health & Biomed. L. 213, 218-28 (2013); GAWANDE, *supra* note 1; Physician Orders for Life-Sustaining Treatment Paradigm, *About the National POLST Paradigm*, http://www.polst.org/about-the-national-polst-paradigm (last visited Mar. 4, 2015).

24. Cruzan v. Dir., Mo. Dep't of Health, 497 U.S. 261, 269 (1990).

25. Pope, *supra* note 23, at 215.

26. *See id.* at 218-21.

moral reasons.[27] On the other hand, for some individuals an artificially prolonged life is one that will serve only to extend the dying process and will add to the physical and mental anguish they are already suffering.[28] Courts have upheld a patient's right to refuse life-sustaining treatment since the 1970s; however, there still exists a "prevalence of unwanted life-sustaining treatment."[29] Advocacy in the form of advance directives came as a result of this unwanted treatment.

Advance directives, also referred to as living wills, are written, legal instructions regarding the patients' preferences for medical care in the event the patient is unable to make decisions themselves.[30] The document provides a treatment guide for doctors and caregivers in the case of an accident or terminal illness and provides for the appointment of a medical power of attorney.[31] However, advance directives have had little success for several reasons.[32] The lack of success in directing care according to patient wishes often occurs because advance directives "1) do not address the specific here-and-now medical circumstances of the patient; 2) they often do not get recorded in the medical record; 3) they do not necessarily follow patients across health care settings; and 4) they do not dictate a care plan through medical orders and clinical protocols."[33] Chief among the reasons for the lack of success achieved by advance directives is that many patients have not completed an advance directive, and when they do, they do not always travel with the patient.[34] Advance directives are not a medical order and therefore are often not

27. *Id.* at 218.
28. *Id.* at 218.
29. *Id.* at 218-21.
30. *Living Wills and Advance Directives for Medical Decisions*, MAYO CLINIC (Nov. 11, 2014), http://www.mayoclinic.org/healthy-living/consumer-health/in-depth/living-wills/art-20046303.
31. *Id.*
32. *See generally* Pope, *supra* note 23 at 226.
33. NAT'L POLST PARADIGM TASK FORCE, POLST LEGISLATIVE GUIDE 6 (2014), *available at* http://www.polst.org/wp-content/uploads/2014/02/2014-02-20-POLST-Legislative-Guide-FINAL.pdf.
34. Pope, *supra* note 23, at 226.

included in a patient's medical record.[35] A number of surveys and statistics reflect the poor rate of advance directive utilization.[36] Alarmingly, the most significant study of clinician compliance with patient instructions, the Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatments (SUPPORT), found after a two-year observational study that only forty-seven percent of physicians knew their patients' preferences regarding cardiopulmonary resuscitation (CPR).[37]

The POLST Paradigm was developed and tested in Oregon in 1991 by a group of medical ethicists as a response to the issues discussed above.[38] The National POLST Paradigm Task Force (NPPTF) came together in 2004 to establish standards for the forms and to help states implement and develop their own POLST programs.[39] POLST was developed not to replace advance directives but to supplement them.[40] POLSTs differ from advance directives in that only patients with serious illness or frailty, whom a healthcare professional would reasonably expect to die within one year, should have a POLST.[41] Additionally, a POLST is an immediately actionable medical order, and is a single-page standardized form.[42] Unlike do not resuscitate (DNR) orders, a POLST addresses not just CPR, but a range of life-sustaining

35. NAT'L POLST PARADIGM TASK FORCE, *supra* note 33, at 6.

36. *See* Pope, *supra* note 23, at 224-25 (listing a number of studies and statistics regarding physician compliance with advance directives). One study found that clinicians overrode advance directives 25% of the time, and another similar study found that only 58% of clinicians followed advance directives "most or all of the time." Additionally, yet another study found clinicians deviate from patient instructions in 65% of cases, instead looking to prognosis, family wishes and the perceived quality of life.

37. *Id.* at 225.

38. The National POLST Paradigm, *History: About the National POLST Paradigm*, *available at* http://www.polst.org/about-the-national-polst-paradigm/history/ (last visited April 25, 2015).

39. *Id.*

40. Physician Orders Life-Sustaining Treatment Paradigm, *POLST and Advance Directives*, http://www.polst.org/advance-care-planning/polst-and-advance-directives (last visited Mar. 4, 2015).

41. NAT'L POLST PARADIGM TASK FORCE, *supra* note 33.

42. Pope, *supra* note 23 at 227-28.

interventions, such as IV fluids, antibiotics, a feeding tube, and artificial breathing.[43] The POLSTs are also easily identifiable, usually by a bright color, and are easily transportable due to this identifier.[44] Moreover, a POLST registry program in Oregon has reported success in transferring forms to an online database, which has provided easier access to the patients' order for providers in emergency and primary care situations.[45] Furthermore, data from the Oregon POLST registry shows that the in-hospital death rate is 6.4% among patients with POLST orders for comfort measures, as compared to 44.2% among those with orders for full treatment.[46] Similarly, Utah and a few other states have taken initiatives to establish electronic POLST (ePOLST) registries.[47] The one drawback of these initiatives is that the ePOLST registry currently operates on a separate "data repository" and is not presently integrated with electronic health records (EHRs) or health information exchanges (HIEs).[48] However, the Utah ePOLST initiative intends for future work to explore a way to integrate the systems.[49]

The POLST Paradigm presents a model that works to emphasize conversations in advance care planning between patients, their loved ones, and providers to ensure that the patient's end-of-life care wishes are articulated and ultimately complied with.[50] However, the POLST Paradigm is not without its flaws. Presently, POLST is not yet universally available. Sixteen states have

43. *Id.* at 227.

44. *Id.* at 227.

45. *See* PHYSICIAN ORDERS LIFE-SUSTAINING TREATMENT PARADIGM , OREGON POLST REGISTRY ANNUAL REPORT 6 (2012), *available at* http://www.polst.org/wp-content/uploads/2013/05/2012-Oregon-POLST-Registry-Annual-Report.pdf.

46. Susan Tolle, *Clinical Decisions: End of Life Advance Directive*, 372 N. ENG. J. MED. 667, 668 (2015).

47. Jeffrey Duncan et al., *Electronic End-of-Life Care Registry: the Utah ePOLST Initiative*, AMIA ANNUAL SYMPOSIUM PROCEEDINGS 2 (2013), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3900183.

48. *Id.* at 7 ("Given the limited funding and short timeline of development, interoperability was considered in system requirements and a decision was made to focus on developing the concept, policy, and user community.").

49. *Id.*

50. *See* NAT'L POLST PARADIGM TASK FORCE, *supra* note 33, at 5.

endorsed POLST Paradigm programs, and another twenty-eight are in various stages of development.[51] First and foremost, states do not require clinicians to use POLST forms.[52] Additionally, the National POLST Paradigm task force has not attempted to provide a model POLST act because each state has its own "frameworks and complexities" in regard to existing health care laws.[53] Each state then necessarily requires customization for the program to work within the state.[54] Some of the common issues with POLST Paradigms in differing states are surrogate authority, out-of-hospital DNR protocol barriers, and lack of recognition of POLST forms across state lines. Additionally, only a minority of states have a statute or regulation that explicitly recognizes POLST forms from other states.[55]

While the POLST Paradigm may face some barriers to implementation in certain states, the model is flexible enough for each state to adapt POLST forms to the state's specific needs. Moreover, federal law is clear with respect to a hospital's obligation to honor patient direction of health decisions.[56]

Additionally, the Centers for Medicare & Medicaid Services (CMS) has never explicitly discussed POLST in its regulations, manuals, or transmittals; thus where a POLST is permissible under state law as an appropriate clinical procedure for honoring patients' care goals, it is fully consistent with federal

51. Tolle, *supra* note 46.

52. *See* NAT'L POLST PARADIGM TASK FORCE, *supra* note 33, at 19.

53. *Id.* at 1.

54. *Id.*

55. *Id.* at 26-27 (citing to Colorado, Maryland, Iowa, New Jersey, Utah, Idaho, West Virginia, and Rhode Island statutes).

56. NAT'L POLST PARADIGM TASK FORCE, *supra* note 33, at 22 (citing 42 C.F.R. §482.13(b)). ("The patient has the right to participate in the development and implementation of his or her plan of care. The patient or his or her representative (as allowed under State law) has the right to make informed decisions regarding his or her own care. The patient's rights include being informed of his or her health status, being involved in care planning and treatment, and being able to request or refuse treatment.")

rules.[57] As states adopt POLST Paradigms, the main issues surrounding POLSTs involve informing the patient about their rights under the particular POLST Paradigm in addition to the medical and personal conversation between the provider and patient.

III. CLINICALLY INTEGRATED NETWORKS PRESENT A SETTING FOR SUCCESSFULLY IMPLEMENTING THE POLST PARADIGM AND ENSURING RESPECT FOR THE PATIENT'S END-OF-LIFE CARE CHOICES

A key feature of the ACA is that the law "puts consumers back in charge of their health care."[58] Yet, in spite of health reform's focus on patient rights, the current health system still faces difficulty in realizing patients' end-of-life care choices for the variety of reasons stated in the aforementioned sections of this article.[59] However, existing public and private clinically integrated network models present an opportunity to successfully implement the POLST paradigm.

The American Hospital Association defines clinical integration as "the coordination of patient care across conditions, providers, settings, and time in order to achieve care that is safe, timely, effective, efficient, equitable, and patient-focused."[60] In the public sector, the ACA specifically encourages the development of ACOs, which are healthcare organizations comprised of hospitals, doctors, and other healthcare providers who align to provide coordinated, high quality care to their Medicare patients.[61] The goal is to ensure that each particular patient receives appropriate and necessary care across pro-

57. *Id.* at 22.

58. *About the Law*, *supra* note 8.

59. *See supra*, Part I End-of-Life Care: A Costly Gap in Health Care Reform.

60. Am. Hosp. Assoc., *Clinical Integration*, http://www.aha.org/advocacy-issues/clininteg/index.shtml (last visited Mar. 4, 2015).

61. *Accountable Care Organizations (ACO)*, CTRS. FOR MEDICARE & MEDICAID SERVS., http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/index.html?redirect=/ACO (last modified Jan. 6, 2015).

vider settings while avoiding the administration of unnecessary services, preventing medical errors and reducing readmission rates.[62] To incentivize eligible providers, hospitals, and suppliers to participate in the ACO program, the Medicare Shared Savings Program (Shared Savings Program) under Section 3022 of the Affordable Care Act is set up in such a way to reward ACOs that lower their growth in health care costs while meeting performance standards on quality of care and putting patients first.[63] Thus far, the thirty-two pioneer ACO programs in existence achieved some measurable success with improvements in quality.[64] However, these ACO programs are still in the initial phases and studies on the impact that these programs have on health care quality are still forthcoming.[65] Nevertheless, the initial ACO program illustrated yet another gap in the ACA with regards to patients with advanced serious illness needing end-of-life care.[66] As previously stated in Part I, the ACA did not include greater access to coordinated care for patients at the end-of-life as one of the quality benchmarks in the ACO program.[67] Moreover, under the ACO program, participating beneficiaries who suffer from advanced serious illnesses, who get transferred to a post-acute care or hospice setting, may no longer belong or be "attributable" to the ACO if those care-settings are not participants in the ACO.[68] Therefore, those patients will no longer have access to the coordinated care efforts of the ACO.[69] Making matters worse, Medicare beneficiaries are currently required to forgo curative (treatment) care in order to receive access to palliative (comfort) care services

62. *Id.*

63. *Shared Savings Program*, CTRS. FOR MEDICARE & MEDICAID SERVS, http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html?redirect=/sharedsavingsprogram (last modified Mar. 19, 2015).

64. Inst. of Med., *supra* note 6, at 42.

65. *Id.*

66. *Id.* at 43.

67. *Id.* 41-44.

68. *Id.* at 43.

69. *Id.*

offered by hospices.[70] Thus, the coordinated program that has the potential to be the most beneficial to patients requiring end-of-life treatment either severely limits the patients' treatment options at best, or at worst, excludes the patients from the program altogether.

In March 2014, CMS announced a pilot program entitled the Medicare Care Choices Model, which allows patients to receive palliative care and curative care concurrently.[71] The stated purpose of the model is three-fold: to determine (1) if beneficiaries who qualify for coverage under the Medicare hospice benefit would chose to receive the palliative services normally provided in hospice care if they could additionally maintain access to their curative care providers; (2) if access to those services will result in improved quality of care and patient satisfaction; and (3) if this combined palliative and curative care treatment plan has any effect on the curative treatment provided or the hospice treatment provided to the patient.[72] The program will limit patient participation to those beneficiaries with "advanced cancers, chronic obstructive pulmonary disease, congestive heart failure and HIV/AIDS."[73] Since applications for the pilot program are currently under review there is no present data on the initiative.[74] Moreover, there has been no specific mention of involving patients in their end-of-life care decisions beyond choosing to accept both palliative and curative care.[75]

By contrast, the private sector has found greater success in implementing

70. *Medicare Choices Model*, CTRS. FOR MEDICARE & MEDICAID SERVS., http://innovation.cms.gov/initiatives/Medicare-Care-Choices (last visited Mar. 24, 2015).

71. *Medicare Choices Model Fact Sheet*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Mar. 18, 2014), http://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2014-Fact-sheets-items/2014-03-18.html.

72. *Medicare Choices Model*, *supra* note 66.

73. *Id.*

74. *See Medicare Choices Model supra* note 67 (last visited April 26, 2015). The current phase of the program is in "Stage: Applications under review" therefore there have yet to be studies conducted to assess the success or failure of the program.

75. *Id.*

a coordinated care approach to patients suffering from advanced serious illness.[76] In particular, Aetna's Compassionate Care program, launched in 2004, implemented a specialized coordinated care management program for a population of Medicare Advantage and commercially insured members.[77] In this program, nurse care managers are trained specifically to manage patients with terminal illness.[78] In each case the nurse managers complete an assessment of the patient's needs and coordinate his or her medical care across treatment settings, provide personal support to the patient and family, and most importantly, provide education to support informed end-of-life-care decision-making.[79] In the ten years since the implementation of the program, Aetna has reported an eighty-two percent reduction in days spent in hospital acute care settings, an eighty-six percent reduction in days spent in intensive care units, and a seventy-eight percent reduction in emergency room use.[80] Most importantly, the program has yielded extremely high satisfaction levels on the part of the patients,[81] proving that shifting end-of-life care focus on the patient and the patients' needs and wishes results in greater quality of care with higher patient satisfaction. However, Aetna and a handful of other private sector payment initiatives only apply to patients within their insurance pool, and their approaches to end-of-life care varies by program.[82] In addition to applying to a narrow category of beneficiaries, the IOM noted that another drawback surrounding these private-sector networks is the lack of "rigorous

76. Krakauer et al., *supra* note 5, at 2; INST. OF MED., *supra* note 6, at 44-45.

77. *Id.*

78. *Id.*

79. *Id.*

80. Randall Krakauer, *People with Advanced Illness Deserve Comfort and Treatment*, AETNA (Feb. 11, 2015), http://news.aetna.com/end-of-life-care-dr-k/. (noting satisfaction levels above 90 for patients and their caregivers participating in the Compassionate Care Program).

81. *Id.*

82. INST. OF MED., *supra* note 6, at 44-45 (Kaiser-Permanente, Sutter Health, and Highmark, Inc. are among some of the private health programs attempting to create advanced care planning programs).

independent evaluation" of these initiatives when it comes to data reflecting access, quality, and cost.[83]

Nevertheless, these private-sector initiatives have made strides in shifting the focus of end-of-life treatment to what the patient wants and needs. Time will tell if the CMS Medicare Care Choices will have similar success, however, it is still an important step towards giving patients with advanced serious illness more control over their health care. Additionally, although the current ACO model does not adequately address patients' end-of-life care needs, the program is still based upon a model of health care that focuses on providing coordinated care across treatment settings for patients.[84] Clinically integrated networks present the ideal vehicles to integrate the POLST Paradigm into the patient care setting. The POLST paradigm is designed for a setting where communication between health care professionals and patients with serious advance illness who will likely die within the year is coordinated and tracked across all treatment settings.[85]

IV. CONCLUSION

In discussions of health reform it is easy to get trapped in the clinical language of roles – provider, payer, patient – to the point where we forget that at the end of the day the focal point of health reform is supposed to be on people. As previously discussed, people have needs beyond merely being safe and living longer.[86] Instead, Gawande aptly notes, "For humans, life is meaningful because it is a story."[87] Humans are active participants in their story, and that active participation should not dissipate when it comes to end-

83. INST. OF MED., *supra* note 6, at 44; These private sector initiatives release their own findings in regards to patient satisfaction outcomes. *See also* INST. OF MED., *supra* note 2, at 26-28. There are a number of different quality indicators proposed by the National Quality Forum and CMS as well as different organizations, but no one set has been utilized to calculate quality metrics, thus creating some methodological issues with studies on end-of-life care interventions.

84. *See* ACO, *supra* note 60.

85. *See* NAT'L POLST PARADIGM TASK FORCE, *supra* note 33, at 5.

86. *See supra* page 1.

87. Gawande, *supra* note 1 at 387.

of-life care. While the ACA has made some strides towards accomplishing the lofty goal of placing the individual back in charge of his or her own health care, there is still plenty of room for improvement, especially when it comes to end-of-life care.

However, there are mechanisms already in place within the current health care system that can help bridge the health reform gap with regard to patients' end-of-life care. As the IOM recognizes, the key component to creating a more patient-centered, coordinated, and quality health care delivery system is the "high-performing team" with the patient and their family at the center.[88] This approach is equally important and effective when providing end-of-life care treatment to terminal patients, and a clinically integrated network is the best way to provide such a "team." ACOs as clinically integrated networks have the potential to provide the "high-performing team" approach necessary to effectively coordinate end-of-life care for patients. The system incentivizes the providers to communicate with each other to coordinate the patients' care across all settings to ensure that the patient gets the right care at the right time.[89] Thus, ACOs provide an efficient platform for ensuring that providers communicate with their patients regarding his or her end-of-life care preferences and provides a program where those treatment preferences can be honored. The POLST paradigm presents providers with a form that not only serves as a medical order, but also communicates terminal patients' wishes for his or her end-of-life care.[90] The form gives patients and providers a platform to discuss the best end-of-life care treatment options for the patient and

88. INST. OF MED., *supra* note 2 at 22.

89. *See infra* Section III: Clinically integrated networks present a setting for successfully implementing the POLST paradigm and ensuring respect for the patient's end-of-life care choices.

90. *See infra* Section II. Right to Die: Past and present measures to ensure patients' choices regarding their end-of-life care are met.

allows for the process to be on going and collaborative to best meet the patients needs.[91]

A clinically integrated network such as an ACO provides an ideal vehicle for the implementation of the POLST paradigm. These two programs working in tandem have the potential to ensure that terminal patients' end-of-life care wishes are not only articulated, but also respected across care settings. However, to achieve this result there needs to be continued reform in regards to both ACOs and the POLST paradigm. Incentives for coordination of end-of-life care should be included in the ACO program moving forward. CMS and HHS should endorse the use of the POLST paradigm, and encourage funding for the transition of the paper form into EHRs. Finally, additional research on the outcomes of the private care models such as AETNAs Compassionate Care Program should be encouraged.

91. *Id.*