

2018

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Recommended Citation

Brewer, Thomas W. (2018) "Regulatory Implications of the Comprehensive Care for Joint Replacement Demonstration Project," *Saint Louis University Journal of Health Law & Policy*: Vol. 11 : Iss. 2 , Article 4.

Available at: <https://scholarship.law.slu.edu/jhlp/vol11/iss2/4>

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**REGULATORY IMPLICATIONS OF THE COMPREHENSIVE CARE
FOR JOINT REPLACEMENT DEMONSTRATION PROJECT**

THOMAS W. BREWER *

ABSTRACT

An often overlooked provision in the Patient Protection and Affordable Care Act is the authorization of demonstration projects which incentivize providers to develop, implement, and test novel, cost-cutting approaches to care delivery. One such project, the Comprehensive Care for Joint Replacement demonstration project, encourages providers across the continuum of care to collaborate on strategies that improve the quality of and lower the cost of complete joint replacements. The project allows providers to share the benefits of cost savings, and liabilities for cost overruns, across the surgeons performing procedures, acute care facilities, and post-acute care facilities. Arrangements of this type, outside of the demonstration project, could potentially expose participants to liability under federal laws prohibiting certain financial relationships between providers. It is therefore important to understand the regulatory implications for the creation and operation of provider networks. It is also possible these relationships may need to be unwound if the demonstration project were to end. Finally, it is also possible these models may be adopted outright and become permanent programs. This article will explore the underlying regulatory structure implicated in cost-sharing arrangements with a focus on those potential issues implicit in the Comprehensive Care for Joint Replacement demonstration project.

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I. INTRODUCTION

Health care is often referred to as the most heavily regulated industry in the United States.¹ In 2004, the Cato Institute estimated health care regulation to cost the average American household more than \$1,500 per year.² While reliable estimates related to the effects of regulation on the overall quality of care are difficult to find,³ it is nearly axiomatic that regulatory compliance on the part of clinicians cuts into valuable time spent with patients.⁴ One cannot help but assume this intrusion has deleterious effects on quality of care as well as patient and clinician satisfaction.

Federal regulations are clearly in the sights of President Trump. He signed an Executive Order calling for two federal regulations to be purged for every one new regulation promulgated.⁵ Although it is too soon to fully understand how this order will play out, Republican controlled Congress and like-minded cabinet secretaries are not expected to offer any substantial pushback.⁶

It is certainly not the case that our system of regulation has led the United States to be a leader in the efficient delivery of health care. In fact, the United States, despite spending the most on health care, both in terms of raw costs⁷ and percent of Gross Domestic Product (GDP),⁸ lags far behind other modernized countries in quality-of-care measures.⁹ This is not to say that, given the complex and fragmented nature of our health care system, we would not be worse off with

1. *An Unhealthy Burden*, THE ECONOMIST (June 28, 2007), <http://www.economist.com/node/9407716> (last visited Jan. 26, 2017); Christopher J. Conover, *Health Care Regulation: A \$169 Billion Hidden Tax*, POL'Y ANALYSIS, Oct. 4, 2004, at 3.

2. Conover, *supra* note 1, at 1. This estimate is almost certainly inflated due to the inclusion of health care services that are required by regulation (such as the cost of actually providing care under EMTALA), not merely the costs of the administration of the regulation.

3. One report did find an increase in quality metrics from direct clinical regulation for long-term care residents. See CHARLES PHILLIPS ET AL., REPORT ON THE EFFECTS OF REGULATION ON QUALITY OF CARE: ANALYSIS OF THE EFFECT OF REGULATION ON THE QUALITY OF CARE IN BOARD AND CARE HOMES 2 (1995).

4. Robert I. Field, *Why Is Health Care Regulation So Complex?*, 33 PHARMACY & THERAPEUTICS 607, 607 (2008).

5. Exec. Order No. 13771, 82 Fed. Reg 9,339, 9,339 (Jan. 30, 2017).

6. See generally Binyamin Appelbaum & Jim Tankersley, *The Trump Effect: Business, Anticipating Less Regulation, Loosens Purse Strings*, N.Y. TIMES (Jan. 1, 2018), <https://www.nytimes.com/2018/01/01/us/politics/trump-businesses-regulation-economic-growth.html> (last visited Feb. 5, 2018).

7. KAREN DAVIS ET AL., MIRROR, MIRROR ON THE WALL, 2014 UPDATE: HOW THE U.S. HEALTH CARE SYSTEM COMPARES INTERNATIONALLY 8 (2014), <http://www.commonwealthfund.org/publications/fund-reports/2014/jun/mirror-mirror> (last visited Jan. 26, 2018).

8. David Squires & Chloe Anderson, *U.S. Health Care from a Global Perspective: Spending, Use of Services, Prices, and Health in 13 Countries*, COMMONWEALTH FUND 8 (Oct. 2015), http://www.commonwealthfund.org/~media/files/publications/issue-brief/2015/oct/1819_squires_us_hlt_care_global_perspective_oecd_intl_brief_v3.pdf.

9. *Id.* at 7.

a more laissez faire regulatory climate, but we should be able to agree that what we have now is not producing the kinds of results we would like to see as a nation. Moreover, the cost of health care is expected to grow at a rate higher than the expansion of the overall economy in the foreseeable future.¹⁰

There have been numerous attempts, with varying levels of success, in the past seventy-five years to reform and/or control the cost of health care.¹¹ Riding an electoral wave in the 2008 election that brought single-party control to Congress and the White House, the Obama administration was able to negotiate passage of the most comprehensive health care reform and expansion legislation since President Lyndon Johnson's Great Society created Medicare and Medicaid. The Patient Protection and Affordable Care Act (ACA)¹² affected patients and payors by mandating coverage, emphasizing preventative services, expanding public programs such as Medicaid, creating a system of subsidies and penalties to incentivize individuals to purchase health care on newly created exchanges, and requiring expanded coverage from private insurers.¹³

The ACA figured prominently in the political rhetoric of the last presidential campaign.¹⁴ Although efforts at an immediate "repeal and replace" have stalled, it is almost certain that many aspects of this legislation will be modified or abandoned under ensuing legislation.¹⁵ Despite strong support in some quarters for repealing "Obamacare," many of the law's constituent parts such as protection for care of pre-existing conditions, dependent coverage until age twenty-six, and coverage for birth control enjoy broad support.¹⁶ This conundrum may mean that certain aspects of the law will remain with us for some time. Thus, it is still useful to look at the history of the law.

While the ACA stopped short of introducing a single-payor system, it contains multiple provisions aimed at reforming the very structure of health care

10. See Sean P. Keehan et al., *National Health Expenditure Projections, 2015–25: Economy, Prices, and Aging Expected to Shape Spending and Enrollment*, 35 HEALTH AFF. 1522, 1528 (2016).

11. Catherine Hoffman, *National Health Insurance—A Brief History of Reform Efforts in the U.S.*, KAISER FAMILY FOUND. 1 (2009), <https://kaiserfamilyfoundation.files.wordpress.com/2013/01/7871.pdf>.

12. Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 (2010).

13. Even a cursory discussion of the Affordable Care Act would be well outside the scope of this article. See generally *Summary of the Affordable Care Act*, KAISER FAMILY FOUND. 1–10 (2013), <http://files.kff.org/attachment/fact-sheet-summary-of-the-affordable-care-act>.

14. PEW RESEARCH CTR., 2016 CAMPAIGN: STRONG INTEREST, WIDESPREAD DISSATISFACTION 31 (2016), <http://www.people-press.org/2016/07/07/4-top-voting-issues-in-2016-election/> (last visited Jan. 17, 2018).

15. See *Compare Proposals to Replace the Affordable Care Act*, KAISER FAMILY FOUND. (Sept. 25, 2017), <https://www.kff.org/interactive/proposals-to-replace-the-affordable-care-act/> (last visited Feb. 5, 2018).

16. See *id.*

delivery in the United States.¹⁷ One such change is the move toward Medicare and Medicaid reimbursement systems that incentivize providers to control costs and increase efficiency through collaboration with other providers along the continuum of care.¹⁸ This provision seeks to move away from traditional fee-for-service reimbursement that rewards volume over quality and efficiency.¹⁹ The ACA created the Innovation Center within the Centers for Medicare and Medicaid Services (CMS) to create, implement, and evaluate new care-delivery and payment models.²⁰ One broad category of such innovative models is defined as Episode-Based Payment Models (EPM).²¹ These models, generally speaking, hold providers accountable for the price of a course of treatment for some set period of time.²² This time period can include the days before a planned procedure, such as joint replacement, and continue through the procedure itself and subsequent skilled nursing care.²³

EPM, and in fact many of these innovative strategies, are aimed at incentivizing business and clinical practice habits that control cost and increase quality.²⁴ Unfortunately, the desired behaviors often run counter to practices that CMS has worked hard to eliminate, or at least control, in a fee-for-service environment.²⁵ The ACA foresaw this inherent tension and granted the Secretary of Health and Human Services (HHS) the ability to waive certain aspects of fraud and abuse regulation for CMS Innovation Center programs.²⁶

Providers across the health care continuum are faced with myriad uncertainties when operating in this new environment. EPMs and other CMS Innovation Center models tend to be quite complex and require coordination across numerous providers with varying levels of compliance sophistication. The very fact that these programs are experimental in nature adds to the

17. *See id.*

18. *See* KAISER FAMILY FOUND., *supra* note 13, at 10.

19. *Transitioning to Episode-Based Payment*, CTR. FOR HEALTHCARE QUALITY & PAYMENT REFORM (Apr. 12, 2009), <http://www.chqpr.org/downloads/TransitioningtoEpisodes.pdf>.

20. *About the CMS Innovation Center*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://innovation.cms.gov/About/index.html> (last visited Jan. 18, 2018).

21. For a complete list of models, *see Innovation Models*, CTR. FOR MEDICARE & MEDICAID SERVS., <https://innovation.cms.gov/initiatives/index.html#views=models> (last visited Feb. 8, 2018).

22. *Id.*

23. EPISODE-BASED COST MEASURE DEVELOPMENT FOR THE QUALITY PAYMENT PROGRAM, CTRS. FOR MEDICARE & MEDICAID SERVS. 8, 10–11, 14, 26 (2016).

24. CTR. FOR HEALTHCARE QUALITY & PAYMENT REFORM, *supra* note 19.

25. THE LEWIN GROUP, CMS BUNDLED PAYMENTS FOR CARE IMPROVEMENT INITIATIVE MODELS 24: YEAR 3 EVALUATION & MONITORING ANNUAL REPORT 4–5 (2017), <https://downloads.cms.gov/files/cmimi/bpci-models2-4yr3evalrpt.pdf>.

26. Social Security Act § 1115, 42 U.S.C. § 1315a(d)(1) (2012).

regulatory uncertainty.²⁷ In some cases, the unknown variable is how a particular relationship will evolve throughout the course of the project. Entering into a clinical and financial relationship across providers with any measurable degree of uncertainty is an anathema to legal and compliance professionals in an environment with increased consequences: both financial and potentially criminal.²⁸ Programs such as Bundled Payments for Care Improvement (BPCI, often referred to as *BIP-SEE*)²⁹ and Accountable Care Organizations (ACOs)³⁰ are voluntary and can be entered into with careful organization and regulatory planning. Other programs, such as the Comprehensive Care for Joint Replacement (CJR) model,³¹ are mandatory for providers in certain designated markets.

Adding to the complexity is the fact that relationships between providers may differ based on the Diagnosis-Related Group (DRG) of the patients they share.³² The relationship between an acute and post-acute provider may operate under very different sets of regulations at the same time for different patients. Finally, an almost constant stream of political rhetoric aimed at repeal of the ACA adds another dimension of uncertainty.

This article will examine the implications of EPMs generally, and the CJR model specifically, on fraud and abuse laws. The laws of particular interest are the following: Stark Law,³³ the Anti-Kickback Statute,³⁴ and the Gainsharing Civil Monetary Penalty Law.³⁵ The discussion will highlight areas where the CMS waivers fail to insulate participants from exposure to fraud and abuse liability for actual or intended conduct under the model. The article will also look at how this uncertainty surrounding the actual scope of CMS waivers and the overall uncertainty of the regulatory climate suppresses innovation in the

27. GLEN HEPBURN, ORG. FOR ECON. CO-OPERATION & DEV., ALTERNATIVES TO TRADITIONAL REGULATION 11 (2009), <http://www.oecd.org/gov/regulatory-policy/42245468.pdf>.

28. U.S. DEP'T. OF JUSTICE, OFFICE OF THE DEPUTY ATTORNEY GEN., MEMORANDUM TO ASSISTANT ATTORNEYS GENERAL, INDIVIDUAL ACCOUNTABILITY FOR CORPORATE WRONGDOING 2 (Sept. 9, 2015), <https://www.justice.gov/archives/dag/file/769036/download> (last visited Feb. 8, 2018).

29. Laura Dummit et al., *Association Between Hospital Participation in a Medicare Bundled Payment Initiative and Payments and Quality Outcomes for Lower Extremity Joint Replacement Episodes*, 316 JAMA 1267, 1267 (2016).

30. U.S. DEP'T. OF HEALTH & HUMAN SERVS., CTRS. FOR MEDICARE & MEDICAID SERVS., ACO PARTICIPANT LIST AND PARTICIPATION AGREEMENT 2 (2017).

31. *Comprehensive Care for Joint Replacement Model*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://innovation.cms.gov/initiatives/cjr> (last visited Feb. 5, 2018).

32. The DRG system is used by Medicare, as well as some private payors, to classify diagnosis for the purposes of reimbursement. Inke Mathauer et al., *Hospital Payment Systems Based on Diagnosis-Related Groups: Experiences in Low- and Middle-Income Countries*, 91 BULL. WORLD HEALTH ORG. 746, 746 (2013).

33. Also known as physician self-referral. 42 U.S.C. § 1395nn (2012).

34. *Id.* § 1320a-7b.

35. *Id.* §§ 1320a-7a(b)(1), (2).

delivery of care and run counter to the stated goal of the program. The article will begin with a brief discussion of the evolution of Medicare reimbursement from fee-for-service to the current innovation models. The discussion will then move to the operation of the CJR model and waivers of certain fraud and abuse provisions to allow for foreseeable relationships between providers.

This is an important topic to explore for several reasons. In order to be truly effective, bundled payment models need to foster collaboration and integrated delivery of care between and among providers. Although health system researchers, and most likely the majority of providers, understand on a conceptual level the importance of coordinated care, the realities of a decentralized and disjointed system make delivering integrated care difficult. Furthermore, fraud and abuse regulations in the United States, which can charitably be described as complex, are often suspicious of the types of activities undertaken in order to deliver this care. Secondly, the risk to providers is very high if they misjudge what is permitted under the demonstration project and create an impermissible relationship. This risk would not only be in the form of legal liability, but also in opportunity costs they would incur from not building stable relationships that would withstand scrutiny moving forward. Finally, it is important to understand as much as possible about the potential for liability because of the mandatory nature of the program. Unlike voluntary demonstration projects where providers can set aside, in advance, the resources necessary to build compliant programs, CJR takes a “ready or not” approach to participation. This clarity would be especially helpful for smaller providers, such as independent skilled nursing facilities (SNFs) who may not have the legal resources to make informed decisions regarding their participation.

II. MEDICARE REIMBURSEMENT

Medicare as a source of revenue is extremely important for hospitals and physicians. Medicare averages 40.9% of the payor mix in American hospitals.³⁶ A survey of multispecialty physician practices found the average payor mix included thirty-one percent Medicare revenue.³⁷ Given the importance of Medicare to the financial health of providers, changes in its reimbursement schemes are impossible to ignore.

Medicare was created in 1965 when President Johnson signed the Title VII Amendment to the Social Security Act.³⁸ Originally intended solely for the

36. Results based on most recently available data from 2009. *60 Things to Know About the Hospital Industry / 2016*, BECKER'S HOSP. REVIEW (Jan. 14, 2016), <https://www.beckershospitalreview.com/lists/50-things-to-know-about-the-hospital-industry-2016.html> (last visited Feb. 6, 2018).

37. MED. GROUP MGMT. ASS'N, COST SURVEY: 2014 REPORT BASED ON 2013 DATA 4 (2014), <http://www.mgma.com/Libraries/Assets/Key-Findings-CostSurvey-FINAL.pdf?source>.

38. Sanaz Hariri et al., *Medicare Physician Reimbursement: Past, Present, and Future*, 89 J. BONE & JOINT SURGERY 2536, 2536 (2007).

elderly, Medicare expanded over the years to include other groups (e.g., those with end stage renal disease, those receiving disability payments from Social Security, and select public employees).³⁹ The range of covered services has also expanded to include broader home health services⁴⁰ and increased access to prescription drugs.⁴¹

In an effort to win the backing of wary health care providers, Medicare reimbursement was based on exiting fee-for-service models which dominated the industry.⁴² These models reimbursed physicians at a *reasonable* charge, which was defined as the lowest of three possible charges: the actual fee charged by the physician, the physician's customary charge, or some percentage of the prevailing charges by other physicians in the area.⁴³ Under this scheme, physicians had a financial incentive to raise fees⁴⁴ and provide more services.⁴⁵ Perversely, fee-for-service actually disincentives wellness initiatives as they reduce demand for more expensive health care down the road.⁴⁶

The cost of Medicare skyrocketed. During the 1980s, the cost of physician services rose 13.4% annually.⁴⁷ By contrast, the United States' GDP rose an average of 3.15% per year during the same time period.⁴⁸ First, Congress took action by pegging reimbursement rates to the actual cost of delivering the service.⁴⁹ Secondly, annual increases in reimbursement rates would be limited by a formula which measured the total volume of services provided in the previous year.⁵⁰ In 1997, Congress took further steps to limit the increase in physician reimbursement by enacting the Sustainable Growth Rate (SGR).⁵¹ The SGR attempted to tie the physician fee schedule directly to GDP and limped

39. *Id.*

40. *Medicare and Medicaid Milestones: 1937-2015*, CTRS. FOR MEDICARE & MEDICAID SERVS. 3 (2015), <https://www.cms.gov/About-CMS/Agency-Information/History/Downloads/Medicare-and-Medicaid-Milestones-1937-2015.pdf>.

41. *Id.* at 7.

42. Hariri et al., *supra* note 38, at 2537.

43. *Id.*

44. *Id.*

45. NETWORK FOR REG'L HEALTHCARE IMPROVEMENT, FROM VOLUME TO VALUE: TRANSFORMING HEALTH CARE PAYMENT AND DELIVERY SYSTEMS TO IMPROVE QUALITY AND REDUCE COSTS 1 (2009), <http://www.nrhi.org/uploads/nrhi-paymentreformprimer.pdf>.

46. *Id.* at 4.

47. Billy Wynne, *May the Era of Medicare's Doc Fix (1997-2015) Rest In Peace. Now What?*, HEALTH AFF. BLOG (Apr. 15, 2015), <http://healthaffairs.org/blog/2015/04/14/may-the-era-of-medicares-doc-fix-1997-2015-rest-in-peace-now-what/> (last visited Feb. 6, 2018).

48. Kimberly Amadeo, *The Strange Ups and Downs of the U.S. Economy Since 1929*, THE BALANCE (Jan. 26, 2018), <https://www.thebalance.com/us-gdp-by-year-3305543> (last visited Feb. 6, 2018).

49. Wynne, *supra* note 47.

50. *Id.*

51. Social Security Act § 1848(f), 42 U.S.C. § 1395w-4, *amended by* Pub. L. 105-33 111 Stat. 251 (1997).

along until 2003 when it became clear it did not offer sufficient incentive spread across a million providers to limit spending.⁵² At that point, Congress undertook a series of short-term, and sometimes shorter-term, patches to prevent physician reimbursement rates from falling off a cliff.⁵³ A resolution to this chaotic situation came in the form of the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA).⁵⁴ MACRA transitions physicians from fee-for-service to reimbursement systems that incentivize quality over volume of care.⁵⁵ Physicians can choose reimbursement through Merit-Based Incentive Payment System (MIPS)⁵⁶ or the Alternative Payment Models (APMs) discussed in this article.⁵⁷

Hospitals share a somewhat parallel history of Medicare reimbursement with physicians. Prior to 1983, hospitals were reimbursed retrospectively for services provided. The system amounted to fee-for-service with all of the associated drawbacks (e.g., cost increases in excess of inflation and limited focus on quality).⁵⁸ In that year, Congress passed the Social Security Amendments of 1983.⁵⁹ This legislation was actually one of several steps taken by Congress and HHS to move away from retrospective reimbursement.⁶⁰ What resulted was the Prospective Payment System.⁶¹ This system bases reimbursement on a DRG for inpatient hospital services.⁶² Each DRG is weighted based on the average

52. Wynne, *supra* note 47.

53. Had MACRA not been enacted in April 2015, physicians would have faced a 21.2% reduction in Medicare reimbursement. See Keith Fontenot et al., *A Primer on Medicare Physician Payment Reform and the SGR*, BROOKINGS (Feb. 2, 2015), <https://www.brookings.edu/blog/health/360/2015/02/02/a-primer-on-medicare-physician-payment-reform-and-the-sgr/> (last visited Feb. 6, 2018); Wynne, *supra* note 47; Joshua Hirsch et al., *Sustainable Growth Rate Repealed, MACRA Revealed: Historical Context and Analysis of Recent Changes in Medicare Physician Payment Methodologies*, 37 AM. J. NEURORADIOLOGY 210, 211 (2016).

54. Medicare Access and CHIP Reauthorization Act of 2015, 42 U.S.C. § 1305 (2015).

55. Khaled J. Saleh & William O. Shaffer, *Understanding Value-Based Reimbursement Models and Trends in Orthopaedic Health Policy: An Introduction to the Medicare Access and CHIP Reauthorization Act (MACRA) of 2015*, 24 J. AM. ACAD. ORTHOPEDIC SURGERY e136, e137 (2016).

56. Robert B. Doherty, *Goodbye, Sustainable Growth Rate—Hello, Merit-Based Incentive Payment System*, 163 ANNALS INTERNAL MED. 138, 138 (2015).

57. Saleh & Shaffer, *supra* note 55, at e139; STUART GUTERMAN & ALLEN DOBSON, IMPACT OF THE MEDICARE PROSPECTIVE PAYMENT SYSTEM FOR HOSPITALS 97 (1986).

58. GUTERMAN & DOBSON, *supra* note 57, at 97.

59. Social Security Amendments of 1983, Pub. L. No. 98-21, 97 Stat. 65 (codified as amended at 42 U.S.C. § 1395ww(d) (2012)).

60. *Id.* tit. IV; see also GUTERMAN & DOBSON, *supra* note 57, at 97.

61. *Prospective Payment Systems – General Information*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Sept. 6, 2017), <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ProspectivePaymentSystems/ProspectivePaymentSystems-Information/index.html?redirect=/ProspectivePaymentSystems-Information/> (last visited Feb. 8, 2018).

62. *Id.*

resources expended to treat the condition.⁶³ Again, as with physician reimbursement, acute care is moving toward APMs that draw focus away from volume to value.⁶⁴

III. EPISODE-BASED PAYMENT MODELS

As with almost everything related to health care finance, EPMs defy a single, parsimonious definition. However, as a practical matter, they involve the payor setting a price, or target price, for all services rendered during a specific episode of care.⁶⁵ These models work best in situations where the episode has a clear onset and is expected to resolve in a fairly predictable period of time.⁶⁶ For example, complete joint replacement, which will be the subject of this article, is a well-defined episode of care. Chronic conditions, such as asthma or cancer, are less amenable to this payment scheme.

In a literal interpretation of the model, the payor would strictly limit reimbursement for the set price. Providers who were able to treat the patient for less than the price would profit directly from the episode and those who overran the set price would be in deficit. The current demonstration projects actually operate with somewhat more flexibility. Reimbursement occurs as usual with providers—hospitals in this case—receiving bonuses or penalties depending on quality, cost, and patient satisfaction.⁶⁷

There are several demonstration projects that fall into the broad class of EPMs which are sometimes referred to as bundled payment models. One example, the BPCI initiative, is composed of four separate models which test various permutations of reimbursement schemes.⁶⁸ Participation in BPCI is completely voluntary.

The CJR model was initiated under Section 3021 of the ACA.⁶⁹ The model tests the role of bundled payments in increasing the quality and lowering the cost

63. *Acute Inpatient PPS*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Aug. 2, 2017), <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/index.html?redirect=/acuteinpatientpps> (last visited Feb. 8, 2018).

64. *BPCI Advanced*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://innovation.cms.gov/initiatives/bpci-advanced> (last visited Jan. 21, 2018).

65. NETWORK FOR REG'L HEALTHCARE IMPROVEMENT, *supra* note 45, at 7.

66. *Id.*

67. Dave Barkholz, *Under Construction: Risk-Based Reimbursement*, MOD. HEALTHCARE (Jun. 18, 2016), <http://www.modernhealthcare.com/article/20160618/MAGAZINE/306189982> (last visited Feb. 8, 2016).

68. For example, retrospective bundled payments made for acute care only, retrospective bundled payments for acute and post-acute care, retrospective bundled payments made for post-acute care only, and prospective bundled payments made for acute care only. *See Bundled Payments for Care Improvement (BPCI) Initiative: General Information*, CTRS. FOR MEDICARE & MEDICAID SERVS., <https://innovation.cms.gov/initiatives/bundled-payments/> (last visited Feb. 8, 2018).

69. On September 29, 2016, a letter was sent to the Acting Director of CMS, signed by 179 Members of Congress, demanding this program be halted. Signatories argued CMS overstepped its

of care for Medicare beneficiaries undergoing hip and knee replacements.⁷⁰ These conditions were chosen in part because of their impact on the Medicare budget. Hip and knee replacements cost the system approximately seven billion dollars in hospital care alone each year.⁷¹ What makes CJR unique is the fact that, unlike BPCI, participation is required for providers in sixty-seven Metropolitan Statistical Areas (MSAs).⁷² The MSAs were purposefully selected by CMS to provide an adequate sample across differing sizes and historical spending patterns.⁷³

The demonstration project puts hospitals at the center of the triggering episode. Starting April 1, 2016, the cost-affected DRGs in selected areas will be compiled for all necessary care from admission to ninety days after.⁷⁴ All providers are paid in the normal manner.⁷⁵ Every year during the five year project, hospitals will be assigned a target price for each DRG.⁷⁶ These target prices will be stratified to account for the higher prices that naturally accrue to patients with fractures needing emergent, more expensive care, as opposed to elective cases.⁷⁷ The regional cost of treatment will account for one-third of the

authority by requiring providers in the designated markets to participate in the program, failed to adequately engage stakeholders in the design and implementation of the program, and that the program amounts to a medical experiment conducted without patient consent. As of the writing of this article, there has been no official response from CMS. It is important to note that the main author of that letter, Tom Price, later served as the Secretary of Health and Human Services. In that capacity he exercised enormous authority of how the program was administered. Letter to Andrew Slavitt & Patrick Conway, Ctrs. for Medicare & Medicaid Servs. (Sept. 29, 2016), https://c.y.mcdn.com/sites/www.clinicalresearchforum.org/resource/resmgr/docs/news_&_announcements/ccts/CMMI_Letter_Final.pdf.

70. MS-DRG 469 (Major joint replacement or reattachment of lower extremity with major complications or comorbidities) or 470 (Major joint replacement or reattachment of lower extremity without major complications or comorbidities). See *Comprehensive Care for Joint Replacement Model*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Dec. 22, 2017), <https://innovation.cms.gov/initiatives/CJR> (last visited Feb. 8, 2018).

71. See Melanie Evans, *Knee and Hip Bundled-Payment Challenge Is About to Start*, MOD. HEALTHCARE (Mar. 26, 2016), <http://www.modernhealthcare.com/article/20160326/MAGAZINE/303269996> (last visited Feb. 8, 2018).

72. *Id.*

73. *Id.*

74. See U.S. DEP'T OF HEALTH & HUMAN SERVS., PUB. 100-19 DEMONSTRATIONS, TRANSMITTAL 140 1 (Feb. 19, 2016).

75. See Doherty, *supra* note 56, at 138; CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 20.

76. See CTRS. FOR MEDICARE & MEDICAID SERVS., COMPREHENSIVE CARE FOR JOINT REPLACEMENT (CJR) MODEL: PROVIDER AND TECHNICAL FACT SHEET, THE CENTER FOR MEDICARE AND MEDICAID INNOVATION 4 (2015), <https://innovation.cms.gov/Files/fact-sheet/cjr-providerfs-finalrule.pdf>.

77. Social Security Amendments of 1983, Pub. L. No. 98-21, 97 Stat. 65 (codified as amended at 42 U.S.C. § 1395ww(d) (2012)); see Doherty, *supra* note 56, at 138; CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 20; Evans, *supra* note 71.

calculated target price in the first year of the demonstration but will solely determine the target in years three, four, and five.⁷⁸

At the conclusion of each performance year, the actual spending and quality metrics are compared to the targets.⁷⁹ If the aggregate episodes of care fell under targets (if they cost less), the hospital could receive a bonus.⁸⁰ However, if the episodes equaled more than the target price, the hospital could be forced to reimburse some portion of the difference.⁸¹ Hospitals are exempt from penalties during the first year.⁸² The program does place a cap on potential bonuses and penalties.⁸³ For the first program year, participants will be held harmless and excused from potential repayments if the aggregate cost of care exceeds the target price.⁸⁴ Beginning in the second year, repayment of overage will be capped at five percent.⁸⁵ That figure rises to ten percent in year three, and twenty percent in years four and five.⁸⁶ These caps limit the potential shock as providers make the necessary adjustments. Reconciliation payments from CMS to the provider are capped at five percent in years one and two.⁸⁷ These caps rise to ten percent in year three and twenty percent in years four and five.⁸⁸

Quality is measured using a complicated composite score consisting of measures of medical outcomes and patient satisfaction.⁸⁹ Medical complications within the ninety day window, such as acute myocardial infarction, pneumonia, sepsis, bleeding, pulmonary embolism, mechanical complications related to the prosthetic, and related infections, are factored into the measure.⁹⁰ The score includes patient satisfaction domains as captured by eleven measures of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey.⁹¹ The model also allows for the “voluntary submission of Patient Reported Outcomes (PRO)” data.⁹² Through a complicated scoring formula, individual hospital quality measures will be weighted and compared

78. Evans, *supra* note 71.

79. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 30.

80. *Id.*

81. *Id.*; *see also* CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 20.

82. Evans, *supra* note 71.

83. *Id.*

84. 42 C.F.R. § 510.305 (2016).

85. *Id.*

86. *Id.*

87. *Id.*

88. *Id.*

89. *CMMI Comprehensive Care for Joint Replacement Model: Quality Measures, Voluntary Data, Pub. Reporting Processes for Preview Reports*, CTRS. FOR MEDICARE & MEDICAID SERVS. 1 (2016), <http://www.wsha.org/wp-content/uploads/CJR-Medicare-Quality-Fact-Sheet.pdf>.

90. *Id.*

91. *Id.* at 2.

92. *Id.* at 4.

against national averages.⁹³ Those hospitals with better quality scores will be given a “discount” off of the overall cost of their procedures proportional to where they rank nationally.⁹⁴ This will have the practical effect of making those hospitals then appear more efficient from a cost standpoint.⁹⁵

As the hospital bears the exposure to cost overruns for physicians and skilled/home nursing care, it is imperative it find ways to curb these costs as well. Nursing homes in particular are fertile ground for finding new efficiencies. In a 2015 study of joint replacement costs using three years of Medicare data, researchers found a \$10,000 average difference between the highest and lowest cost providers in three northeast states. Nursing home spending accounted for sixty percent of this cost difference.⁹⁶ This finding demonstrated the variability in the cost of skilled nursing care in those markets.⁹⁷ As will be discussed later, hospitals are finding new ways to select and work with post-acute providers across the spectrum of services.

As post-acute care ideally represents the back end of the episode of care, physicians represent the front end. It is the physician (in this case, most likely an orthopedist) that orders the joint replacement and initiates the episode of care. Playing such a key role in the process, it would make sense that these clinicians have the ability to share in any potential reconciliation payments as well, beyond their normal Medicare Part B reimbursement. The CJR model allows for “collaborator[s]”⁹⁸ to enter into a Participation Agreement that allows for the sharing of cost savings and reconciliation payments made pursuant to the program.⁹⁹ Historically, these payments would have been prohibited by Section 1128A(b)(1) of the Social Security Act, which prohibited a hospital from “making a payment, directly or indirectly, to induce a physician to reduce or limit services to Medicare or Medicaid beneficiaries under the physician’s

93. *Id.* at 17.

94. *CTRS. FOR MEDICARE & MEDICAID SERVS.*, *supra* note 89, at 17–18.

95. *Id.* at 18.

96. Evans, *supra* note 71.

97. *Id.*

98. Hospital collaborators are not limited to physicians; they include “skilled nursing facilities (SNF),” “home health agencies (HHA),” “long-term care hospitals (LTCH),” “inpatient rehabilitation facilities (IRF),” and “physician group practices (PGP).” *See* 42 C.F.R. § 510.2 (2017). Non-physician practitioners, as well as providers and suppliers of therapy services, are also included. *Id.* It should be noted that hospitals may not enter into gainsharing arrangements with certain organizations that are neither providers nor suppliers. *See id.* § 510.500.

99. *Id.* § 510.2.

care.”¹⁰⁰ Hospitals and physicians involved in these payments are liable for a \$2,000 civil monetary penalty (CMP) per patient.¹⁰¹

One researcher pointed out the CMP could stand as perhaps the most significant regulatory hurdle to successful implementation of value-based payment models.¹⁰² The law did not distinguish between “medically necessary” and/or “medically *unnecessary* care.”¹⁰³ The CJR program did specifically waive restrictions on gainsharing payments that are spelled-out in sharing agreements.¹⁰⁴ It is worth noting that the CJR program requires that the decision of hospitals to enter into sharing agreements must be made, in part, on the quality of care to be delivered to the beneficiary during the episode.¹⁰⁵

In addition to specific waiver of gainsharing provisions in the CJR, an even larger development came when MACRA¹⁰⁶ inserted a key qualifier into the statutory language. MACRA inserted the words “medically necessary” into the CMP statute after “reduce or limit.”¹⁰⁷ This allows for payments to physicians to induce the limitation of unnecessary services. This provision is seen as an entrée for providers to enter into gainsharing agreements outside of waived demonstration projects.¹⁰⁸ The provision in MACRA does not completely render moot any discussion of the compliance implications of gainsharing in general, or in bundled payment programs specifically.¹⁰⁹ Commentators do see this as a move by CMS to reserve gainsharing enforcement to those instances where physicians are limiting *necessary* services.¹¹⁰ However, given its recency and

100. *Special Bulletin: Gainsharing Arrangement & CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries*, DEP’T OF HEALTH & HUMAN SERVS., OFFICE OF THE INSPECTOR GEN. (1999), <https://oig.hhs.gov/fraud/docs/alertsandbulletins/gainsh.htm> (last visited Feb. 9, 2018).

101. *Id.*

102. Corbin Santo, *Walking a Tightrope: Regulating Medicare Fraud and Abuse and the Transition to Value-Based Payment*, 64 CASE W. RES. L. REV. 1377, 1392 (2014).

103. *Change in CMP Law Affecting Gainsharing Arrangements*, STEVENS & LEE (May 4, 2015) (emphasis added), <http://www.stevenslee.com/change-in-cmp-law-affecting-gainsharing-arrangements/> (last visited Feb. 9, 2018).

104. CTRS. FOR MEDICARE & MEDICAID SERVS., NOTICE OF WAIVERS OF CERTAIN FRAUD & ABUSE LAWS IN CONNECTION WITH THE COMPREHENSIVE CARE FOR JOINT REPLACEMENT MODEL (Jan. 1, 2018), <https://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/Downloads/2017-CJR-Model-Waivers.pdf>.

105. *Id.*

106. Medicare Access and CHIP Reauthorization Act of 2015, 42 U.S.C. § 1305 (2015).

107. STEVENS & LEE, *supra* note 103.

108. *Revisions to the CMP Law Open the Door for Gainsharing Arrangements with Physicians*, KUTAK ROCK (May 6, 2015), <http://www.kutakrock.com/revisions-cmp-gainsharing-arrangement-physician/> (last visited Feb. 9, 2018); STEVENS & LEE, *supra* note 103.

109. KUTAK ROCK, *supra* note 108.

110. Thomas E. Dutton et al., *Congress Amends Gainsharing Civil Monetary Penalties and Commissions Further Study of Gainsharing Agreements*, JONES DAY 2 (2015), <http://www.jones>

the uncertainty surrounding how CMS will ultimately enforce the updated provision, it will not be addressed further in this article.

IV. COMPLIANCE IMPLICATIONS OF CJR MODELS

This section will examine the relationship between financial and treatment arrangements fostered by CJR and traditional health care compliance statutes. The analysis will begin with a discussion of the waivers put in place by CMS in order to prevent the program from violating fundamental provisions of the health care regulatory framework. A discussion of typical arrangements being put together by providers and where these waivers are proving to be ambiguous or failing to address these arrangements will follow. Finally, this article will examine the implications and impacts of CJR preferred provider networks on existing SNF steering regulations.

A. *CJR Compliance Waivers*

Congress has provided the Center for Medicare & Medicaid Innovation (CMMI) with the authority to waive select fraud and abuse laws in order to facilitate the implementation of payment model demonstrations that would violate those laws.¹¹¹ Such waivers will be discussed below in the context of the respective statutes.

It should be noted that each of the fraud and abuse laws discussed also have the possibility of implicating the federal False Claims Act (FCA), which makes it a crime to knowingly present, or cause to be presented, a false or fraudulent claim for payment or approval.¹¹² The FCA has a long history in United States law outside of health care. It was first enacted to punish war profiteers during the Civil War in 1863.¹¹³ Because the basis for a FCA violation is the underlying false or fraudulent claim, it is not subject to waiver.¹¹⁴ The scrutiny turns primarily to the legality of the underlying claim.¹¹⁵ If that claim is legal, either by its nature, or by effect of a waiver, the claim is not false or fraudulent and would not form the basis for an FCA action.¹¹⁶

day.com/files/Publication/a1d72edd-58e5-476b-a072-a611289dc63c/Presentation/PublicationAttachment/f426c3aa-386b-4a7e-85f1-b404234f158e/Congress%20Amends%20Gainsharing.pdf.

111. Social Security Act § 1115, 42 U.S.C. § 1315a (2012).

112. 31 U.S.C. § 3729(a)(1) (A-C) (2006).

113. AMY BAILEY ET AL., HEALTH CARE COMPLIANCE LEGAL ISSUES MANUAL 216 (Harry R. Silver & Cynthia F. Wisner eds., 4th ed. 2014).

114. *Does a Release Signed by an Employee Preclude Whistleblowing?*, MCELDREW YOUNG, <https://www.mceldrewyong.com/whistleblower/release/> (last updated Feb. 8, 2018); see generally BAILEY ET AL., *supra* note 113, at 223–26.

115. See generally BAILEY ET AL., *supra* note 113, at 223–26; MCELDREW YOUNG, *supra* note 114.

116. See generally BAILEY ET AL., *supra* note 113, at 215.

One important aspect of the FCA to discuss is the liability that attaches not only to the person submitting the false or fraudulent claim, but to anyone who *causes* a false claim to be presented.¹¹⁷ This aspect of the law has been applied in a wide variety of ways. For example, pharmaceutical companies that promote off-label¹¹⁸ use of their drugs may *cause* a pharmacy to file fraudulent cost reports for prescriptions filled to Medicare patients because Medicare does not pay for off-label use.¹¹⁹ A widely-known example is a medical device manufacturer who advised hospitals to perform the device implantation as an inpatient procedure rather than as a medically acceptable, and less expensive, outpatient service.¹²⁰ Almost 100 hospitals in the United States have settled FCA cases with the Department of Justice (DOJ) over inpatient claims they submitted.¹²¹ The device manufacturer itself settled the case for seventy-five million dollars.¹²²

Again, assuming that CMS waivers are sufficient and providers adhere to the strictures, the FCA should not be implicated. However, as this is a demonstration project, the idea is to push the boundaries of common practice. One of the most attractive and promising ways to implement bundled payment models is to increase collaboration among and between agencies. Providers, especially smaller organizations without sophisticated legal departments or the resources to pay large settlements, may be somewhat reticent to enter into novel, untested, payment arrangements for fear of being caught in a stream of FCA liability. In fact, there is a general climate of uncertainty following the decision in *Universal Health Services v. United States ex rel. Escobar* in which the Supreme Court affirmed the theory of implied certification of Medicare claims.¹²³ While a thorough discussion of *Escobar* is outside the scope of this

117. 31 U.S.C. § 3729(a)(1)(A-B) (2006) (emphasis added).

118. Off-label use is the use of a prescription drug for purposes other than that for which it has been approved by the Food and Drug Administration. Richard C. Ausness, “*There’s Danger Here, Cherie!*”: *Liability for the Promotion and Marketing of Drugs and Medical Devices for Off-Label Uses*, 73 BROOK. L. REV. 1253, 1254 (2007).

119. *Id.* at 1284–1326.

120. Steven W. Postal & Robyn Whipple Diaz, *DOJ’s Kyphoplasty Initiative: AHA Urges Greater Oversight in the Wake of Continuing Settlement Announcements*, ABA HEALTH ESOURCE (May 10, 2011), https://www.americanbar.org/content/newsletter/publications/aba_health_esource_home/aba_health_law_esource_2011_may_volume_7_issue_9.html (last visited Feb. 8, 2018); Press Release, U.S. Dep’t of Justice, Office of Pub. Affairs, 32 Hospitals to Pay U.S. More Than \$28 Million to Resolve False Claims Act Allegations Related to Kyphoplasty Billing (Dec. 18, 2015), <https://www.justice.gov/opa/pr/32-hospitals-pay-us-more-28-million-resolve-false-claims-act-allegations-related-kyphoplasty> (last visited Feb. 8, 2018); BAILEY ET AL., *supra* note 113, at 223–25.

121. U.S. Dep’t of Justice, *supra* note 120; BAILEY ET AL., *supra* note 113, at 223–25.

122. BAILEY ET AL., *supra* note 113, at 223–25.

123. *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 1995 (2016). Writing for a unanimous Court, Justice Thomas held “[FCA] liability can attach when the defendant submits a claim for payment that makes specific representations about the goods or services provided, but

thesis and its ultimate application by the DOJ and trial courts remains to be seen, it is seen by many as a lowering of the threshold to FCA liability.¹²⁴ It is therefore important that the legality of the CJR arrangements, as they relate to those regulations that could potentially form the basis of a FCA case, be understood as completely as possible.

B. *The Anti-Kickback Statute*

Initially enacted in 1972, the Anti-Kickback Statute (AKS) is a criminal statute that prohibits individuals or entities from knowingly and willfully offering, paying, soliciting, or receiving bribes, kickbacks, or other remuneration in order to induce business reimbursement from Medicare, Medicaid, and other federal health care programs.¹²⁵ AKS has been hailed as the hallmark of a federal effort to limit fraud and abuse in federal health care spending.¹²⁶ Originally a misdemeanor,¹²⁷ Congress amended the statute in 1977 making violation a felony that carries a maximum \$25,000 fine, imprisonment of up to five years, or both.¹²⁸ In addition to the criminal consequences, violation of AKS will cause an automatic exclusion from federally-funded health care programs and potential exposure to civil liability under the FCA.¹²⁹ The intent standard was revised in 1980 to require proof that the individual or entity acted “knowingly and willfully” when making the prohibited referrals.¹³⁰ In 1997 the statute was again modified to include the potential for CMPs which lowered the burden of proof¹³¹ and allowed for penalties up to \$50,000 for each act.¹³²

Because financial relationships between and among health care providers are extremely complex, it is quite possible that certain arrangements, although appearing to violate AKS, may in fact be quite proper and beneficial. Congress directed the Secretary of HHS to carve out these relationships from AKS scrutiny in the form of safe harbors.¹³³

An often used example of an AKS violation is one in which a medical laboratory pays the referring physician an “interpretation fee” for the physician’s

knowingly fails to disclose the defendant’s noncompliance with a statutory, regulatory, or contractual requirement.” *Id.* The Court further held that this liability is not contingent upon whether compliance was expressly designated by the government as a condition of payment, and the result of this decision is lowering the bar for potential FCA exposure. *Id.* at 1996.

124. See generally Robert Miller, *Escobar Appears to Open the Door to More “Materially” False Claims*, 10 J. HEALTH LIFE SCI. L. 1, 6 (2016).

125. 42 U.S.C. § 1320a-7b(b) (2012).

126. Santo, *supra* note 102, at 1379.

127. THOMAS S. CRANE ET AL., WHAT IS THE ANTI-KICKBACK STATUTE? 4 (2016).

128. BAILEY ET AL., *supra* note 113, at 231.

129. *Id.*

130. CRANE ET AL., *supra* note 127, at 4.

131. Preponderance of the evidence as opposed to beyond a reasonable doubt.

132. CRANE ET AL., *supra* note 127, at 6.

133. See 42 C.F.R. § 1001.952(a)-(y) (2016).

time spent explaining the results to the patient.¹³⁴ Because the physician has the obligation to explain diagnostic results to the patient as part of the standard of care, this payment is unnecessary.¹³⁵ The payment basically serves as an incentive, or reward, for referring patients to that particular lab.¹³⁶ These arrangements have the potential to color the physician's judgement into making a referral based on the potential kickback, rather than on medical necessity.¹³⁷ This skewed judgment can encourage overutilization of services, which ultimately increases the cost of providing care.¹³⁸

Gainsharing involves a hospital knowingly making a payment to a physician for the purpose of inducing the physician to reduce or limit services furnished to Medicare and Medicaid beneficiaries under the doctor's care.¹³⁹ These type of arrangements are not included in any of the AKS safe harbors.¹⁴⁰ An argument has been made that AKS concerns in bundled payment models could be obviated by simply hiring physicians as bona fide employees.¹⁴¹ For physicians to abandon private practice and for hospitals to take on expensive clinical employees seems like a drastic step in order to satisfy regulatory requirements of a narrowly-drawn demonstration project. A less dramatic step would be to use an existing safe harbor that allows for personal service contracts.¹⁴² Unfortunately, the requirements for the employment safe harbor are quite complex.¹⁴³ Furthermore, these contracts must be for a year or more and set in advance the compensation to be paid.¹⁴⁴ Given the experimental nature of the CJR program, it would be almost impossible to set the value of the compensation in advance.¹⁴⁵ Providers and physicians might be handcuffed by overly-specific contracts that do not take into account the innovative relationships contemplated under the program.

134. CRANE ET AL., *supra* note 127, at 13.

135. Bryan Murray, *Informed Consent: What Must a Physician Disclose to a Patient?*, 14 AM. MED. ASS'N J. ETHICS 563, 564 (2012).

136. *See, e.g.*, Press Release, U.S. Dep't of Justice, Blood Testing Laboratory to Pay \$6 Million to Settle Allegations of Kickbacks and Unnecessary Testing (Apr. 28, 2017), <https://www.justice.gov/opa/pr/blood-testing-laboratory-pay-6-million-settle-allegations-kickbacks-and-unnecessary-testing> (last visited Feb. 9, 2018).

137. BAILEY ET AL., *supra* note 113, at 231.

138. *Id.*

139. *Id.* at 35.

140. Santo, *supra* note 102, at 1401.

141. *Id.* at 1402.

142. 42 C.F.R. § 1001.952(d) (2016).

143. Santo, *supra* note 102, at 1404.

144. *Id.* at 1388.

145. *Id.* at 1401.

In order to provide regulatory breathing space for CJR, CMMI used its authority to waive Sections 1128B(b)(1)¹⁴⁶ and (2)¹⁴⁷ of the Social Security Act related to the federal AKS.¹⁴⁸ The waiver is only applicable to the payment of gainsharing and alignment payments¹⁴⁹ pursuant to properly structured sharing agreements under the demonstration project.¹⁵⁰ It does not waive any other remuneration a physician might receive while participating in an innovative CJR model.¹⁵¹ For example, if a physician were provided with office space in a SNF in order to facilitate his seeing patients in the facility.¹⁵² This scenario is outside of the context of gainsharing and alignment payments and could very well violate AKS.¹⁵³

C. *Stark Self-Referral*

During the 1980s as congressional attempts to move away from fee-for-service models began to take effect,¹⁵⁴ physicians sought to replace lost revenue by investing in laboratories, diagnostic imaging centers, and outpatient surgery centers where they could still bill separately for individual services provided.¹⁵⁵ In the Omnibus Budget Reconciliation Act (OBRA) of 1989, Congress pushed back against this conduct by including language which prohibited a physician¹⁵⁶ from referring certain “designated health services (DHSs)”¹⁵⁷ in which they, or

146. 42 U.S.C. § 1320a-7b(b)(1) (2012) (“Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind.”).

147. *Id.* § 1320a-7b(b)(2) (“Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person.”).

148. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 104.

149. Alignment payments flow from the CJR collaborator (e.g., physicians’ group practice) to the hospital in cases where the episode of care exceeded the target price and the hospital made a reconciliation payment back to CMS. In short, alignment payments are the opposite of gainsharing payments. 42 C.F.R. § 510.500(b) (2017).

150. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 104.

151. *Id.*

152. *Id.*

153. *Id.*

154. For example, the Inpatient Prospective Payment System discussed earlier. *See supra* Part II.

155. Santo, *supra* note 102, at 1379–80.

156. 42 C.F.R. § 411.351 (2017) (“Physician means a doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatric medicine, a doctor of optometry, or a chiropractor.”).

157. *Id.* (“[DHS] means any of the following services (other than those provided as emergency physician services furnished outside of the U.S.), as they are defined in this section: (1)(i) Clinical laboratory services. (ii) Physical therapy, occupational therapy, and outpatient speech-language pathology services. (iii) Radiology and certain other imaging services. (iv) Radiation therapy services and supplies. (v) Durable medical equipment and supplies. (vi) Parenteral and enteral nutrients, equipment, and supplies. (vii) Prosthetics, orthotics, and prosthetic devices and supplies.”).

an immediate family member,¹⁵⁸ had a financial relationship.¹⁵⁹ The basic premise behind this law is that physicians who stand to benefit financially from a referral will be more likely to make that referral without respect to actual medical necessity. The eponymous legislation was championed by Congressman Pete Stark.¹⁶⁰ Originally focused on clinical laboratory services, the legislation was expanded in 1993 to include the current list of DHSs.¹⁶¹

Stark Law allows for a variety of penalties including denial of payment, refunds of payments already made in violation, and CMPs of up to \$15,000 for each improper bill or service and three times the amount of the improper payment itself.¹⁶² A CMP of \$100,000 may also be imposed for each violative arrangement scheme that the physician or entity knows, or should know, is designed to assure improper referrals.¹⁶³ There are a number of exceptions to Stark which are generally beyond the scope of this thesis.¹⁶⁴

Although seemingly straightforward, the definition of a “financial relationship” can be somewhat more complicated. At its most black-and-white, a direct financial relationship is one in which the parties share an actual ownership or investment interest.¹⁶⁵ More difficult to define are prohibited compensation arrangements between the physician and the entity providing the DHS. A compensation agreement is defined as “any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind.”¹⁶⁶ Given the interdependent nature of physicians and health care providers such as hospitals, the term “benefit” could be any number of seemingly innocuous items or benefits provided for the physician during the course of their practice.¹⁶⁷

(viii) Home health services. (ix) Outpatient prescription drugs. (x) Inpatient and outpatient hospital services.”).

158. *Id.* (“[I]mmediate family member [means] husband or wife; birth or adoptive parent, child, or sibling; stepparent, stepchild, stepbrother, or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law, or sister-in-law; grandparent or grandchild; and spouse of a grandparent or grandchild.”).

159. 42 C.F.R. § 411.354(a)(1) (2016) (meaning a “direct or indirect ownership or investment interest,” or a “compensation arrangement” with an entity that provides designated health services).

160. Steven D. Wales, *The Stark Law: Boon or Boondoggle? An Analysis of the Prohibition on Physician Self-Referrals*, L. & PSYCHOL. REV., 2013, at 1, 2.

161. BAILEY ET AL., *supra* note 113, at 235.

162. Social Security Act § 1877, 42 U.S.C. § 1953nn(g)(3) (2012) (Physician Self-Referral Law).

163. *Id.*

164. 42 C.F.R. § 411.355 (2012) (providing information on exceptions).

165. *Id.* § 411.354(a)(1).

166. *Id.* § 411.351.

167. See Susan O. Scheutzow, *Challenges to Employed Physicians' Compensation: Direct, Indirect, or Unintelligible Compensation*, J. HEALTH & LIFE SCI. L., Feb. 2014, at 6–7; Debbi M. Johnstone, *Illegal Remuneration and Stark Law Issues Raised by Physician Recruitment Agreements* (Am. Health Lawyers Ass’n, Paper No. P02110416, 2004).

Assuming the referring physician and the hospital had in place a gainsharing agreement, the CJR program would, absent a waiver, violate Stark Law. The referring physician would receive remuneration in the form of the reconciliation payment as a result of the referral. There is some nuance in that the remuneration in the case of CJR would not be a strict one-for-one for each referral. The payments would be dependent on the quality of care, patient outcomes, and the performance of many other actors in the episode of care. However, given the broad application of Stark in the past, it is unlikely that such an arrangement would withstand scrutiny absent an affirmative waiver. As with AKS, CMMI used its authority to waive Section 1877(a) of the Social Security Act relating to physician self-referral for the CJR model.¹⁶⁸

Given the similarities in the provisions of Stark and AKS, the potential effects on CJR implementation will be discussed together. There are several potential sources of liability in CJR, and other EPMS, as it relates to Stark and AKS liability. Experts have noted the sheer complexity of the sharing agreement, quality requirements, and the amount of documentation that must be kept puts participants at risk for not satisfying the conditions of the waiver.¹⁶⁹ While the program is complex, the real risk comes from the program's novelty. Health care providers operate in a daily environment of complex legal and regulatory guidelines. The real limiting factor is uncertainty regarding how these regulations will be enforced and the lifespan of the program.

As discussed above, the real opportunity for gains under the CJR program, both in terms of lower cost and higher quality care, is manifest in the ability of the program to encourage collaboration along a continuum of care.¹⁷⁰ Under existing models, it is tempting for participants in a patient's care to focus on only those aspects of the case in which they are ethically bound, legally liable, and financially invested. Once the patient progresses through the case to the point where they are being cared for by another entity, the previous provider may simply shuffle them along. Similarly, providers further downstream may not involve themselves in the patient's care until it becomes their instant responsibility. This disjointed system fosters poor coordination of care for the patient and poorer, more expensive, outcomes. The CJR has the potential of using market forces to foster increased collaboration.

A great example of the type of collaboration that is being discussed in the context of CJR involves attempts to limit hospital readmissions from SNFs following surgery.¹⁷¹ Such readmissions are extremely costly and would

168. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 104.

169. Robert D. Stone, *The Comprehensive Care for Joint Replacement Program: Bundle of Joy?*, 10 J. HEALTH & LIFE SCI. L. 12, 15–16 (2016).

170. *Id.* at 12.

171. This example is based on the author's participation in a Medicaid payment reform panel in the state of Ohio. Although CJP is a Medicare program, many lower extremity joint replacement patients are dual-eligible (that is, part of both the Medicare and Medicaid programs) and solutions

negatively impact gainsharing.¹⁷² As a result, hospitals have begun to work closely with SNFs to detect and correct the underlying causes of the readmissions.¹⁷³ Some causes are clinical. For example, due to the tight margins many nursing homes operate under, it is difficult to recruit and retain high quality registered nurses (RNs).¹⁷⁴ Many facilities rely on licensed practical nurses (LPNs) with less training and a higher rate of turnover. One area where this has been shown to affect patient outcomes is urinary catheter care. Without the correct training on proper procedures, a facility may experience higher rates of urinary tract infections, which in many cases lead to readmission to the hospital. Hospitals have experimented with providing training to SNF nursing staff on proper care.¹⁷⁵ It is hoped that this training will provide better care and reduce costs. The financial incentive for the hospital is higher gainsharing payments.¹⁷⁶

Another commonly reported cause for hospital readmission is SNF staff not being able to accurately communicate patient status to physicians. For example, patients often experience medical difficulties in the middle of the night or at other times when physicians are not physically available.¹⁷⁷ During these situations, nursing staff will contact an on-call physician by telephone to report the issue. If the SNF does not have twenty-four-hour RN coverage, it could be a LPN with less training making the phone call. If that nurse is not able to confidently respond to the physician's questions related to the patient's condition, the physician may simply order the patient readmitted rather than risk doing nothing and having the patient deteriorate. In order to mitigate this problem, select hospitals have experimented with training SNF nursing staff on

work to the benefit of both programs. *See, e.g.*, Robert Mechanic, *Post-Acute Care — The Next Frontier for Controlling Medicare Spending*, 370 *NEW ENG. J. MED.* 692, 692 (2014).

172. *Id.* at 692–93.

173. *Id.* at 693.

174. *Skilled Nursing Facilities Should Prepare for a Future of Challenges and Opportunities*, HEALTHSTREAM (Nov. 2, 2016), <https://www.healthstream.com/resources/blog/blog/2016/11/02/skilled-nursing-facilities-should-prepare-for-a-future-of-challenges-and-opportunities> (last visited Feb. 9, 2018).

175. *See, e.g.*, Jenna Libersky et al., *Value-Based Payment in Nursing Facilities: Options and Lessons for States and Managed Care Plans*, INTEGRATED CARE RESOURCE CTR. (Nov. 2017), http://www.integratedcareresourcecenter.com/PDFs/ICRC_VBP_in_Nursing_Facilities_November_2017.pdf; Joseph G. Ouslander & Robert A. Berenson, *Reducing Unnecessary Hospitalizations of Nursing Home Residents*, 365 *NEW ENG. J. MED.* 1165, 1167 (2011).

176. Libersky et al., *supra* note 175.

177. Eric Alper et al., *Hospital Discharge and Readmission*, WOLTERS KLUWER: UPTODATE (Dec. 19, 2017), https://www.uptodate.com/contents/hospital-discharge-and-readmission?search=hospital%20discharge%20and%20readmission&source=search_result&selectedTitle=1~150&usage_type=default&display_rank=1 (last visited Feb. 9, 2018); Sandra G. Boodman, *Shifting the Risks at Night*, *WASH. POST* (June 6, 2011), https://www.washingtonpost.com/national/health/shifting-the-risks-at-night/2011/05/03/AGuEQaKH_story.html?utm_term=.eb01cd8aefb0 (last visited Feb. 9, 2018).

how to communicate with physicians.¹⁷⁸ This training often involves role playing different scenarios, and aims to build clinical and interpersonal communication skills.¹⁷⁹ Some hospitals have even flirted with the idea of paying for physician coverage during overnight hours. Formal research related to the effectiveness of this intervention is just now getting underway, but colloquial accounts of success are promising.

On their face, these two examples of innovation collaborations do not seem to implicate the existing fraud and abuse statutes above.¹⁸⁰ The arrangements as presented do not include physicians referring patients in return for any remuneration. The models are merely health care organizations collaborating on initiatives to improve the quality of care. However, given that physicians are included in potential gain/risk sharing, should the hospital choose to build that model, it would make sense that they would be involved in the post-acute care quality improvement as well. This increased involvement may begin to implicate Stark and AKS.

Generally, a typical physician's¹⁸¹ relationship with a post-acute facility is somewhat limited. The doctors simply follow their patients to the post-acute settings and "round" on the them as they would in a hospital.¹⁸² There are generally no contractual or personal services agreements between the facility and the physician. SNFs typically do not peer review, credential, or offer formal privileges.¹⁸³ "The federal Stark Law does not impact the relationship between an attending physician and an LTC [Long Term Care] Provider unless there is a direct or indirect ownership or investment interest, or a direct or indirect compensation arrangement, between the attending physician and the LTC Provider."¹⁸⁴ One author noted ". . . Stark Law makes it difficult for providers to work together to voluntarily develop or implement various arrangements designed to improve health care quality and control costs, including arrangements such

178. Diane W. Shannon & Leigh Ann Meyers, *Nurse-To-Physician Communications: Connecting for Safety*, PATIENT SAFETY & QUALITY HEALTHCARE, Sept.–Oct. 2012, at 24.

179. *Id.* at 250.

180. 31 U.S.C. § 3729(a)(1)(A)–(C) (2012). Although outside the scope of this article, there are concerns that hospitals assembling preferred networks of skilled nursing facilities that agree to participate in these programs may implicate anti-trust statutes. Henry S. Allen, Jr. & George M. Sanders, *Chapter 6: Managing Antitrust Risks Associated with Accountable Care Organizations*, in ACOS AND OTHER OPTIONS: A "HOW-TO" MANUAL FOR PHYSICIANS NAVIGATING A POST-HEALTH REFORM WORLD 4 (Am. Med. Ass'n ed., 2013), https://www.aconline.org/system/files/documents/running_practice/delivery_and_payment_models/aco/physician_howto_manual.pdf.

181. This does not include medical directors employed by SNFs or other physicians who have a contractual relationship to provide patient care. James F. Miles, *Physician Integration and Long Term Care*, Am. Health Law Ass'n 1 (2012) (unpublished manuscript), https://www.healthlawyers.org/events/programs/materials/documents/phy12/papers/k_miles.pdf.

182. *Id.*

183. *Id.*

184. *Id.* at 2 (citing 42 U.S.C. § 1395nn (2006); 42 C.F.R. § 411.350 (2007)).

as integrated delivery systems, pay for performance arrangements, gainsharing arrangements, or bundled payments.”¹⁸⁵ While the CMS fraud and abuse statute waiver specifically includes payments related to the gainsharing provision of CJR, it does nothing to protect against liability for other potentially innovative arrangements.¹⁸⁶ What if a SNF offered a referring physician free office space in the facility to facilitate interaction with staff and patients? Office rental has been a much-scrutinized target of anti-kickback enforcement and should be a red flag to any physician.¹⁸⁷

D. SNF Referral

As discussed above, the SNF into which a patient transitions after a complete joint replacement can have a significant impact on the cost of the overall episode. In an EPM, this cost difference can have very real financial ramifications for the hospital.¹⁸⁸ As such, hospitals have an interest in seeing that patients are referred to SNFs that meet certain quality and care parameters that will produce a better, more economical outcome for the patient.¹⁸⁹ Hospitals, and the care coordinators who work with patients and patients’ families to select a post-acute placement, have long been thought to “steer” patients into certain facilities.¹⁹⁰ There are several reasons for why a care manager would guide patients to choose certain facilities. On an individual level, the care manager may just feel that one facility is simply better than others. If this opinion is based on objective measures, particularly where a patient has a unique set of needs such as Alzheimer’s care, that guidance would be within the professional judgment of the care manager. However, it could be that a particular nursing facility simply has a strong marketing department. It is also possible that the care manager receives gifts or other gratuities from the nursing home in exchange for favorable referrals. From an institutional level, hospitals may encourage care managers to refer patients to facilities that are owned by the hospital.

To limit the practice of steering patients, federal law provides that the referring discharge plan “shall not specify or otherwise limit the qualified

185. Nita Garg, *Hospital Value Based Purchasing and the Bundled Payment Initiative Under the Affordable Care Act: A Good Start, But is it Enough?*, 22 ANNALS HEALTH L. 171, 189 (2013).

186. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 104.

187. *Special Fraud Alert: Rental of Space in Physician Offices by Persons or Entities to Which Physicians Refer*, OFFICE OF INSPECTOR GEN. (Feb. 2000), <https://oig.hhs.gov/fraud/docs/alertsandbulletins/office%20space.htm> (last visited Feb. 10, 2018).

188. James Hegyj et al., *Evaluating the Selection Process of Post-Acute Preferred Provider Relationships*, CARE MGMT., Aug.–Sept. 2016, at 1, 8.

189. *Id.*

190. Public Meeting, Medicare Payment Advisory Comm’n 21, 29 (Oct. 9, 2014), <http://www.medpac.gov/docs/default-source/meeting-materials/october-2014-meeting-transcript.pdf?sfvrsn=0> (last visited Feb. 9, 2018).

provider which may provide post-hospital home health services.”¹⁹¹ Many providers took this to mean that the patient was simply to be provided with an alphabetical list of facilities and left to make a decision alone.¹⁹² In fact, many care managers took it as a matter of professional duty that they not appear to favor one SNF over another or risk subverting the patient’s autonomy in care decisions.¹⁹³ The statute went on to say that care managers must inform patients if they are being referred to a facility “in the hospital has a disclosable financial interest.”¹⁹⁴ As a response to CJR and EPMs in general, hospitals have begun to form preferred networks of post-acute providers in order to exercise some control over the quality and cost of facilities into which their patients are referred.¹⁹⁵ The question is whether the creation of “preferred networks” is tantamount to patient steering.

Providers are being given very mixed messages on the legality of this practice. The notice of waivers associated with the program simply reinforces the existing prohibition against steering and refers readers to the Final Rule.¹⁹⁶ The Final Rule itself does not provide a definitive response. Language in the Federal Register discussion of the Final Rule states:

Nothing in this final rule alters the [Conditions of Participation] CoPs and similar requirements for providers and suppliers that furnish services to CJR beneficiaries. If a participant hospital or its CJR collaborator is found to have taken any action that threatens the health or safety of patients, including but not limited to...*steering beneficiaries to certain providers or suppliers*, this final rule allows CMS to take action against the participant hospital that is noncompliant or has a collaborator agreement with the noncompliant entity.¹⁹⁷

However, that same entry in the Federal Register also tacitly condones the practice:

Physicians and hospitals may *identify and recommend* “preferred providers,” a term used to include both providers and suppliers, which may include but are not limited to CJR collaborators with sharing arrangements with the participating hospital, as long as such recommendations do not result in violations of current laws or regulations.¹⁹⁸

191. Social Security Act of 1935 § 1861(ee)(2)(H)(i), 42 U.S.C. § 1395x (2012).

192. Hegyi et al., *supra* note 188, at 8–9.

193. Medicare Payment Advisory Comm’n, *supra* note 190, at 21, 29.

194. 42 U.S.C. § 1395x.

195. *See* Hegyi et al., *supra* note 188, at 9.

196. CTRS. FOR MEDICARE & MEDICAID SERVS., *supra* note 104, at 4–5 (referring to 42 C.F.R. pt. 510 (2016)).

197. Medicare Program; Comprehensive Care for Joint Replacement Payment Model for Acute Care Hospitals Furnishing Lower Extremity Joint Replacement Services, 80 Fed. Reg. 226, 73,274, 73,463 (Nov. 24, 2015) (to be codified at 42 C.F.R. pt. 510) (emphasis added).

198. *Id.* at 73,516.

It is “sheer torture of the English language”¹⁹⁹ to suggest there is a discernable difference between the prohibited “steering” and the permitted “identify and recommend.” This difference becomes even murkier when one considers that patients and families look to care managers for guidance in these situations and are very likely to defer to their advice.²⁰⁰ The ambiguity between these terms was given voice at a meeting of the Medicare Payment Advisory Commission (MEDPAC) with a rather protracted discussion of what was referred to as “soft steering,” which was acknowledged to take place.²⁰¹

V. CONCLUSION

There is a distinction between the legacy fee-for-service payment models of Medicare reimbursement and the emerging value-based payment models. Concomitant to that discussion was an examination of fraud and abuse statutes that were designed to control waste of federal health care dollars by limiting financial relationships between providers. These limitations were necessary safeguards as providers sought to make up revenue lost through cuts to reimbursement rates. The theory was that providers would form relationships as a way of increasing the volume of services that they themselves could not provide and bill for individually.

Although found under a variety of names (e.g., bundled payment, EPM, fee-for-value, value-based care), the emerging reimbursement models turn traditional fraud and abuse concerns upside down. Instead of being wary of provider relationships, the field has come to understand that fostering these relationships may be the key to actually reducing health care spending. In fact, these models actually provide financial incentives to form relationships.

Left in the middle of this revolution are providers as diverse as large, multi-state integrated health care networks and small primary care providers. They face widely divergent rules based on the type of patient they see, type of procedure they perform, and geographic market they serve. Although CMS has attempted to selectively waive fraud and abuse provisions as they deem is appropriate, the wide variety of providers and approaches have demonstrated areas where these waivers have fallen short. These gaps should not be viewed as a failing on the part of regulators. They themselves face a daunting challenge of encouraging innovation on the part of providers while at the same time prohibiting the creation of practices that would encourage fraud, waste, and abuse. Just as providers are trying to guess what CMS will allow, CMS is trying to guess where providers may try to game the system. The uncertainty around these programs will most likely increase as health care reform continues to be politicized.

199. *Terry v. Ohio*, 392 U.S. 1, 16 (1968) (quoting Chief Justice Warren).

200. Medicare Payment Advisory Comm’n, *supra* note 190, at 22.

201. *Id.* at 55–57.

The best-case scenario for the future of EPMs is that their efficacy be determined by independent, thorough, and rigorous research. Assuming they are, as many say, the future of federal health care payment, they should be introduced across the system in a deliberate and thoughtful manner allowing for the system to react appropriately. Once this transition is in progress, Congress and the executive branch agencies need to take a close look at fee-for-service fraud, waste, and abuse regulations and adjust those in a manner that guards against improper relationships for private-pay clients but still allows for innovative programs to flourish out of the public fisc.