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Walking a Tightrope: Regulating Medicare Fraud and Abuse and the Transition to Value-Based Payment

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— Note —

WALKING A TIGHTROPE:
REGULATING MEDICARE FRAUD AND
ABUSE AND THE TRANSITION TO
VALUE-BASED PAYMENT

“The current legal environment has created major barriers to delivery system innovation. Innovation will not occur if each novel way to organize and pay for care needs to be adjudicated case-by-case or is threatened with legal proceedings.”¹

ABSTRACT

As the American health care system undergoes a fundamental shift from paying for health care on a fee-for-service basis to one based on value, providers are faced with the question of how to structure the business arrangements necessary to operate in a value-based market while simultaneously complying with the existing fraud-and-abuse regulatory framework. The passage of health care reform ushered in an era of rapid change in how health care is delivered, but the underlying regulatory structure within which health care business arrangements must reside has not kept pace with these changes. Consequently, providers are left to question whether their business arrangements comply with prior laws and regulations. While the government has recognized the inherent disconnect between the value-based care framework and the regulatory regime predicated on fee-for-service financial incentives, policy makers have not offered a permanent solution.

This Note addresses the fundamental conflict between paying for the value of care where providers assume risk for the management of a population's health in more tightly integrated care settings and the application of a fraud-and-abuse framework that came about because of perverse incentives in fee-for-service reimbursement. The discussion includes a review of the waiver authority granted by Congress as part of the Patient Protection and Affordable Care Act, which has facilitated certain innovative, value-based pilots, and evaluates the scope and long-term viability of this approach. While the waivers have, to a certain extent, permitted the development of the business relationships required to assume risk and receive value-based payments, they have left unanswered many questions that continue to cause providers to act cautiously. The resulting hesitation by

1. Timothy S. Jost & Ezekiel J. Emanuel, *Legal Reforms Necessary to Promote Delivery System Innovation*, 299 JAMA 2561, 2561 (2008).

providers to implement value-based reforms has chilled the pace of innovation. This Note argues for a new approach to regulating health care fraud and abuse in an era of expanded value-based payment and highly integrated provider relationships. This approach considers the role of the fee-for-service regulatory framework in light of new incentives to deliver high quality, value-based care and builds on the steps already taken to ensure integrity within the Medicare Shared Savings Program.

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INTRODUCTION

The portion of the United States economy devoted to paying for health care has more than doubled over the last forty years.² Efforts to curtail the rate of growth and reduce spending have a long history and have achieved varying degrees of success. The onset of large governmental payers like Medicare³ and Medicaid⁴ in 1965 and the corresponding increase in health care expenditures focused the attention of policymakers who sought to preserve the financial integrity of the programs.

Perhaps as a function of reimbursing providers on a fee-for-service basis, the problem of providers paying kickbacks in exchange for referrals became a significant threat to the financial health of the federal programs.⁵ In 1972, Congress realized the detrimental effect these improper payment arrangements could have on the solvency of the programs and made it a crime to knowingly offer or receive “remuneration” in exchange for the referral of health services financed by the Medicare and Medicaid programs.⁶ The anti-kickback statute and its associated safe harbors have since become one of the hallmark structural regulations aimed at mitigating fraud and abuse in the federal health care programs.

Throughout the 1980s, the effort to contain costs through managed care utilization controls, coupled with Medicare’s prospective payment system,⁷ created incentives for physicians to engage in entrepreneurial business practices that could take advantage of a reimbursement system based on payment for each separate service provided.⁸ These arrangements included the provision of in-

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2. See HENRY J. KAISER FAMILY FOUNDATION, HEALTH CARE COSTS: A PRIMER 4 (2012), <http://www.kff.org/insurance/upload/7670-03.pdf> (noting that the share of the United States economy “devoted to health care grew from 7.2% in 1970 to 17.9% in 2010”).
 3. 42 U.S.C. §§ 1395–1395hhh (2006).
 4. 42 U.S.C. §§ 1396–1396v (2006).
 5. See Richard P. Kusserow, *The Medicare & Medicaid Anti-Kickback Statute and the Safe Harbor Regulations—What’s Next?*, 2 HEALTH MATRIX 49, 69 (1992) (“Congress passed the anti-kickback statute because of its justifiably serious concern over the consequences that payment for referrals has on the Federal health programs . . .”).
 6. *Id.* at 49–53. The statute is commonly referred to as the anti-kickback statute and is codified at 42 U.S.C. § 1320a-7b(b) (2006).
 7. See discussion *infra* Part I.A.
 8. See Patrick A. Sutton, *The Stark Law in Retrospect*, 20 ANNALS HEALTH L. 15, 16–17 (2011) (describing various practice arrangements that physicians began to develop in response to cost containment, partially attributable to the Medicare prospective payment system); David Mechanic, *The Rise and Fall of Managed Care*, 45 J. HEALTH &

office ancillary and laboratory services, physician ownership of diagnostic imaging centers and durable medical equipment companies, and physician investment in outpatient surgery centers. Physicians were able to supplement the reduction in income that they experienced as a result of managed care by referring patients for treatment at a facility in which they had a financial interest.⁹

Seeking to curtail this practice, Representative Fortney “Pete” Stark sponsored legislation 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.¹⁰ The statute, by its very nature, presumed that all existing referrals made to entities with physician ownership interests or compensation arrangements were illegal unless the parties to such arrangements could satisfy one of the enumerated exceptions in the statute or those later promulgated by the Centers for Medicare and Medicaid Services (CMS).¹¹

Together, the anti-kickback statute and the Stark law, along with provisions of the False Claims Act¹² and the Civil Monetary Penalties (CMP) provision of the Social Security Act,¹³ formed the basis from which the federal government regulated the structural relationships within the health care sector. It is against this background that innovations in provider reimbursement gained traction in the early 2000s, as health policy experts began to question the effectiveness of paying providers for the volume of services provided with little consideration of the value or quality of care delivered.¹⁴ As experiments for value-based payment began to show signs of success, so too did they begin to highlight the restrictive nature of the underlying fraud-and-abuse regulatory scheme. In many instances,

SOC. BEHAV. 76, 81 (2004) (“As employee complaints increased and the public expressed dissatisfaction with restrictions on choice, both employers and health plans retreated by relaxing the utilization controls that gave managed care advantages in constraining costs [P]rivate plans and provider groups showed ingenuity in devising new types of practice arrangements that adapted to changing circumstances.”).

9. Sutton, *supra* note 8, at 16–17.

10. *Id.* at 24–25.

11. *Id.* at 25. At the time, CMS was referred to as the Health Care Financing Administration, or HCFA.

12. 42 U.S.C. § 1320a-7b(a) (2006). The Civil False Claims Act allows the government to recover civil penalties from individuals and permits “quitam” actions brought by individuals on behalf of the government. *See* 31 U.S.C. §§ 3729–33 (2006).

13. 42 U.S.C. § 1320a-7a (2006).

14. *See* discussion *infra* Part II.B.

these regulations either prohibited, or made very risky, a number of integrated provider relationships that were required to form successful value-based payment arrangements.

In 2010, the Patient Protection and Affordable Care Act (ACA)¹⁵ formally blessed several of the value-based payment initiatives that showed early success in pilot arrangements and encouraged broader adoption by providers. The regulatory framework within which these legally enshrined initiatives are to operate, however, has not changed. Perhaps realizing the difficulty in structuring the provider arrangements necessary for receiving value-based payments, Congress granted waiver authority to the Secretary of Health and Human Services, which provides for the waiver of various fraud-and-abuse laws and regulations—namely the anti-kickback statute, Stark, and several CMP provisions—for entities participating in various payment programs.¹⁶

This Note highlights the incongruity between the existing health care regulatory framework and modern forms of value-based payments. It argues that the fraud-and-abuse waivers are unduly narrow and do not provide sufficient guidance to providers who may at some point become technically noncompliant with a specific requirement of the value-based payment program. This Note goes on to explore ways in which legislators and policy makers can implement changes into the waiver program to facilitate the broader transition to value-based payments in the short term. The long-term challenge, however, involves making a more permanent transition from the structural approach to regulating fraud and abuse to an approach that obviates the need for blanket waivers. This approach would build on the quality reporting, transparency, and accountability requirements that CMS uses to protect against program abuse in the Medicare Shared Savings Program. The lingering issue for legislators is defining the future role of the underlying statutes from which a growing number of providers are receiving waivers to structure their business arrangements.

Part I provides an historical overview of the Medicare fee-for-service reimbursement system and the fraud-and-abuse provisions enacted in that era to combat the effects of essentially paying for the volume of services provided. Part II explains recent developments in the move to pay providers according to the value of care, including early value-based payment demonstration projects that were expanded in the ACA.

15. Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 42 U.S.C.).

16. *See id.* § 1899(f) (granting the Secretary of Health and Human Services the authority to waive fraud-and-abuse provisions to carry out demonstration projects under the ACA).

Part III elaborates on the disconnect between the current structural regulations concerning relationships among health care providers and the provisions of the ACA that encourage innovative payment-for-value models. Part IV then discusses the implications of this disconnect and critiques aspects of the regulatory waivers that have left many questions unanswered. Finally, Part V offers short-term proposals regarding the use of fraud-and-abuse waivers and contemplates the long-term application and viability of the structural regulations whose provisions are waived under the value-based payment approach.

I. MEDICARE REIMBURSEMENT AND STRUCTURAL REGULATION IN THE PRE-REFORM ERA

Before passage of the ACA in March 2010, the Medicare program had engaged in a handful of payment experiments but never implemented them on a larger scale.¹⁷ Up to that point, Medicare paid physicians and hospitals primarily on the volume of care they provided, with little or no emphasis on the quality or value of that care. Though the movement to pay providers based on the value of care had its followers,¹⁸ the unrestrained growth of Medicare expenditures without a corresponding increase in quality outcomes¹⁹ prompted an unambiguous embrace of the principles of value-based payment in the formulation of the ACA.²⁰ In order to better understand the movement toward paying for value, it is important to first understand the structure of Medicare fee-for-service payment and some of its inherent effects.

A. *Structure of Medicare Fee-for-Service Payments*

Hospitals that provide services to beneficiaries covered by Part A of the Medicare program receive payment through the Inpatient

17. See discussion *infra* Part II.

18. See, e.g., Meredith B. Rosenthal et al., *Paying for Quality: Providers' Incentives for Quality Improvement*, 23 HEALTH AFF. 127, 127 (2004) (noting the increasing use by individual purchasers, coalitions, and health plans of "pay-for-performance systems to reward providers for delivering high-quality care and to motivate quality improvement").

19. Instead of an increase in quality as a result of higher spending, the Dartmouth Atlas Project found that higher rates of spending in certain geographic locations of the country were associated with *lower* quality outcomes. Elliott Fisher et al., *Health Care Spending, Quality, and Outcomes: More Isn't Always Better*, DARTMOUTH INST. FOR HEALTH POL'Y & CLINICAL PRAC. 2 (2009), available at http://www.dartmouthatlas.org/downloads/reports/Spending_Brief_022709.pdf.

20. For a discussion of value-based payments implemented since the passage of the ACA, see *infra* Part II.

Prospective Payment System (IPPS).²¹ The payment is based on the categorization of the patient's principal diagnosis upon discharge, along with up to eight comorbidities or complications, according to diagnosis-related groups, or DRGs.²² CMS sets the per-discharge payment rates for 746 of these groups based on the severity of the patient's case.²³ Different weights are assigned to DRGs based on the "relative intensity of resource consumption."²⁴ These weights are then multiplied by standardized amounts for labor, non-labor, and capital costs, the sum of which represents the cost of an average case treated in an efficient hospital.²⁵ Upon calculating the base payment, CMS makes a series of adjustments that apply based on the unique characteristics of the hospital and its patient population.²⁶

Physicians who provide care to patients covered by Part B of Medicare are paid according to the Resource-Based Relative Value Scale (RBRVS).²⁷ Like the DRG system used in Part A, the RBRVS is a prospective payment system that accounts for the resources used to deliver care to patients in settings outside of the hospital. The three components, called relative value units (RVUs), account for physician work, practice expense, and malpractice coverage, and they vary according to a geographic practice cost index. Each of the RVUs is summed and multiplied by a conversion factor approved by

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21. 42 U.S.C. § 1395ww (2006) (created by the Social Security Amendments of 1983, Pub. L. No. 98-21, § 601, 97 Stat. 65 as an alternative to cost-based reimbursement).
 22. BARRY R. FURROW ET AL., *HEALTH LAW: CASES, MATERIALS AND PROBLEMS* 786–87 (6th ed. 2008).
 23. *Hospital Acute Inpatient Services Payment System*, MEDPAC 1 (Oct. 2009) [hereinafter *MEDPAC, Payment Primer*], available at http://www.medpac.gov/documents/MedPAC_Payment_Basics_11_hospital.pdf.
 24. FURROW ET AL., *supra* note 22, at 787.
 25. *Id.*
 26. MEDPAC, *Payment Primer*, *supra* note 23, at 3–5. A series of adjustments are made to the base payment amounts. Hospitals that treat with cost-increasing technologies are eligible to receive add-on payments based on the technology's newness and clinical benefit. *Id.* at 3. Medicare will cover up to seventy percent of the bad debts incurred by hospitals as a result of Medicare beneficiaries not paying deductibles and copayments, if the hospitals made a reasonable effort to collect the unpaid amounts. *Id.* Other policy adjustments paid as per-case add-ons include indirect graduate medical education payments to assist hospitals that incur higher costs while training resident physicians, disproportionate share payments to offset the cost of treating large low-income populations, and outlier payments that provide extra reimbursement if a case is extraordinarily costly. *Id.* at 3–4.
 27. Passed as part of the Omnibus Budget Reconciliation Act of 1989, Pub. L. No. 101-239, 103 Stat. 2106 (codified at 42 U.S.C. §§ 1395w-4(a)–(j)).

Congress.²⁸ Perhaps recognizing the potential for unrestrained growth under a fee-for-service prospective payment model, Congress initially froze payment rates. The effort was futile, however, because physicians altered their practice behavior and increased the volume of services provided to patients to compensate for the reduction in revenue.²⁹ After several failed attempts to address physician volume increases, Congress developed the Sustainable Growth Rate (SGR) formula to calculate the increase (or decrease) in the conversion factor that ultimately determines RBRVS payments.³⁰ The formula seeks to keep Part B expenditures in line with overall economic growth and is based on, among other things, the estimated change in physician fees, the number of fee-for-service beneficiaries, and the estimated growth in real gross domestic product.³¹ In the early years after implementation of this formula, expenditures remained below the target, which allowed Congress to approve conversion factor increases.³² In 2002, however, Part B expenditures began to exceed SGR targets, and Congress reduced payments by 4.8%.³³ Every year since then, expenditures have exceeded the formula's target, but Congress has overridden the mandated reductions, or, in at least three instances, approved payment *increases*.³⁴ As a result of Congress's refusal to adhere to the formula, the 2012 SGR update mandated a 29.5% reduction in provider payments.³⁵

B. The Inherent Effects of Fee-for-Service Payment

The fee-for-service reimbursement system used to pay hospitals and physicians for providing care to Medicare patients encourages greater volume of care, regardless of its quality or necessity.³⁶ The

28. FURROW ET AL., *supra* note 22, at 790.

29. *Id.*

30. Balanced Budget Act of 1997, Pub. L. No. 105-33, § 4503, 111 Stat. 251, 433 (codified at 42 U.S.C. § 1395w-4(f)).

31. JIM HAHN & JANEMARIE MULVEY, CONG. RESEARCH SERV., R40907, MEDICARE PHYSICIAN PAYMENT UPDATES AND THE SUSTAINABLE GROWTH RATE (SGR) SYSTEM 3 (2010).

32. *Id.* at 4.

33. *Id.* at 5–6.

34. *Id.*

35. MEDPAC, REPORT TO THE CONGRESS: MEDICARE AND THE HEALTH CARE DELIVERY SYSTEM 183 (2011), http://www.medpac.gov/documents/jun11_entirereport.pdf.

36. Rick Mayes, *Moving (Realistically) from Volume-Based to Value-Based Health Care Payment in the USA Starting with Medicare Payment Policy*, 16 J. HEALTH SERVS. RES. & POL'Y, 249, 249 (2011); see also Meredith B. Rosenthal, *Beyond Pay for Performance—Emerging Models of Provider-Payment Reform*, 359 NEW ENG. J. MED. 1197, 1197

incentive to provide care according to volume is two-fold. First, increasing the number or the intensity of procedures is a rational response to cost-containment initiatives that result in reduced income to physician practices.³⁷ Studies dating back to the beginning of the DRG payment system have identified the phenomenon of “physician-induced demand,” which posits that physicians respond to reduced practice income by performing a greater volume of procedures.³⁸ Second, physicians respond to financial incentives present in the fee schedules by providing services for which they can obtain reimbursement and by minimizing procedures that are not reimbursed.³⁹ Since Medicare fee schedules do not reimburse providers for chronic care coordination, disease management, or other quality-improving activities, providers tend to perform more procedures for which reimbursement is possible, thus “fail[ing] to promote or even discourag[ing] optimal treatment.”⁴⁰

The encouragement that the fee-for-service reimbursement model provides physicians also has dramatic implications for cost containment. A recent article estimated that wasteful spending arising from providing care to patients that will not help them and from physician-induced demand was between \$158 billion and \$226 billion in 2011.⁴¹ This dramatic level of spending on care that does lead to better outcomes has been the primary driver of the shift to value-based payments.

C. *The Current Health Care Regulatory Structure*

The current regulatory structure in Medicare is largely a product of Congress’s response to the incentives created by the fee-for-service system. The statutes described below 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. These regulations embody Congress’s concern with the structural relationships of providers and focus on regulating their business arrangements and restricting compensation agreements,

(2008); Maria T. Currier & Morris H. Miller, *Medicare Payment Reform: Accelerating the Transformation of the U.S. Healthcare Delivery System and Need for New Strategic Provider Alliances*, HEALTH LAW., Feb. 2010, at 1.

37. Sandra Christensen, *Volume Responses to Exogenous Changes in Medicare’s Payment Policies*, 27 HEALTH SERVS. RES. 65, 66 (1992).
38. *Id.*
39. Mayes, *supra* note 36, at 249.
40. Rosenthal et al., *supra* note 18, at 127.
41. Donald M. Berwick & Andrew D. Hackbarth, *Eliminating Waste in US Health Care*, 307 JAMA 1513, 1514 (2012).

ownership interests, and referral patterns.⁴² While significant and ongoing academic debate continues regarding the efficacy of these statutes, this Note will focus primarily on the impact these provisions are having on the implementation and expansion of value-based payment initiatives currently being introduced to the Medicare program.

1. The Anti-Kickback Statute

In 1972, Congress enacted the anti-kickback statute to curb “certain practices which have long been regarded by professional organizations as unethical and which contribute appreciably to the cost of the [M]edicare and [M]edicaid programs.”⁴³ Prior to its enactment of the modern-day anti-kickback statute, the law prohibited only “misrepresentations to obtain Medicare and Medicaid payments rather than attacking kickback abuses head on.”⁴⁴ By enacting this new provision, Congress sought to broaden the scope of prohibited conduct to include knowing or willful payment or receipt of “any remuneration” in exchange for referring an individual, or in exchange for purchasing, leasing, or ordering an item financed by a federal health care program.⁴⁵

42. See Kristin Madison, *Rethinking Fraud Regulation by Rethinking the Health Care System*, 32 *HAMLIN J. PUB. L. & POL’Y* 411, 422 (2011) (“[P]ayers’ and patients’ inability to directly evaluate utilization and assess quality leads to a regulatory regime reliant on an indirect, structural approach that imposes high costs in terms of innovations foregone.”).

43. H.R. REP. NO. 92-231, at 107 (1972); see also Anne W. Morrison, *An Analysis of Anti-Kickback and Self-Referral Law in Modern Health Care*, 21 *J. LEGAL MED.* 351, 354 (2000) (quoting the House Report transcript).

44. Morrison, *supra* note 43, at 354.

45. A series of amendments in 1980, and again in 1987, resulted in the current language of the anti-kickback statute:

(b) Illegal remunerations

(1) 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—

(A) in return for referring an individual to a person for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

While the Statute requires a person to knowingly or willfully violate its provisions, some courts, namely the Eleventh Circuit, have interpreted the intent requirement more broadly to include conduct that a defendant knows any aspect of which is unlawful.⁴⁶ Other courts, however, have required the government to meet a higher standard by proving that the defendants knew the law “prohibit[ed] offering or paying remuneration to induce referrals” and that defendants “engage[d] in conduct with the specific intent to violate the law.”⁴⁷ Congress clarified the Statute’s intent requirement in the ACA by codifying the broad interpretation of the Eleventh Circuit.⁴⁸

After passage of such a broadly worded prohibition in 1972, providers hesitated to form new business and payment arrangements out of fear that they would face criminal liability or exclusion from Medicare.⁴⁹ This prompted Congress, in 1987, to grant authority to

(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—
(A) in return for referring an individual to a person for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than \$25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b) (2006).

46. See *United States v. Starks*, 157 F.3d 833, 838–40 (11th Cir. 1998) (noting that a defendant need not act with knowledge that he is violating a specific rule; knowledge of general illegality of conduct is sufficient).
47. Corrine Propas Parver & Allison Cohen, *The Affordable Care Act: Strengthening Compliance Through Health Care Fraud Provisions*, 5 HEALTH L. & POL’Y BRIEF, no. 1, 2011, at 5–6 (quoting *Hanlester Network v. Shalala*, 51 F.3d 1390, 1400 (9th Cir. 1995)).
48. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 6402(f), 124 Stat. 119, 759 (2010) (provision codified at 42 U.S.C. § 1320a-7b(h)). The amendment states that the government need not prove that an individual had actual knowledge of the statute or specific intent to violate its terms. *Id.*
49. See, e.g., Kusserow, *supra* note 5, at 51–52 (noting that the broad language of the statute created uncertainty, which caused providers to be reluctant to “engage in many arrangements which were not harmful to the programs and beneficiaries, and which may have even been helpful”); Morrison, *supra* note 43, at 355 (noting a “growing concern regarding the vagueness and ambiguity of important terminology” found in anti-kickback statutes enacted prior to 1987).

the Secretary of Health and Human Services (HHS) to promulgate safe harbor regulations that, if properly adhered to, would shield providers from criminal and administrative action.⁵⁰ Thus, in addition to avoiding liability for failing to act with the requisite intent, providers could minimize legal liability by ensuring that their business and payment arrangements met the enumerated requirements of a safe harbor.

The Office of the Inspector General (OIG) has issued twenty-five safe harbors;⁵¹ however, the safe harbor for personal services and management contracts is most relevant in the context of value-based payments. A statutory exclusion for bona fide employment relationships, while not a regulatory safe harbor, is also commonly used in the context of value-based arrangements. The safe harbor for personal services and management contracts exempts remuneration paid as compensation to providers acting as agents on behalf of principals⁵² and is commonly used for medical directorships⁵³ where directors receive a salary but are not employed by the hospital. In order to satisfy the requirements, the agreement between the hospital and the physician must, among other things, be in writing and signed by the parties, specify all of the services that the physician will provide over the term, be in place for more than one year, and provide compensation that is consistent with fair market value and not dependent on the “volume or value of any referrals.”⁵⁴

50. Kusserow, *supra* note 5, at 52.

51. See FURROW ET AL., *supra* note 22, at 1070–71.

52. 42 C.F.R. § 1001.952(d) (2012).

53. Medical directors typically oversee clinical departments within the hospital or supervise the entire medical staff. See, e.g., HARRY A. SULTZ & KRISTINA M. YOUNG, HEALTH CARE USA 82–83 (6th ed. 2009) (describing the structure commonly found in the medical divisions of many hospitals).

54. 42 C.F.R. § 1001.952(d)(5). Additional requirements include a schedule of exact intervals for services, if they are provided on a sporadic or part-time basis. It should describe the exact length and charge for such intervals. Compensation must be consistent with amounts in arms-length transactions. *Id.* § 1001.952(d)(3). Lastly, the agreement must be commercially reasonable, which OIG interprets as having “intrinsic commercial value” to the purchaser that is “reasonably calculated to further the business of the . . . purchaser, and must be . . . services that the . . . purchaser needs, intends to utilize, and does utilize in furtherance of its commercially reasonable business objectives.” Linda A. Baumann, *Navigating the New Safe Harbors to the Anti-Kickback Statute*, HEALTH LAW., Feb. 2000, at 1, 6 (quoting 64 Fed. Reg. 63,518, 63,525 (Nov. 19, 1999)).

Providers seeking to avoid anti-kickback liability have also relied on the exclusion for bona fide employment.⁵⁵ By employing physicians, hospitals are able to structure referrals and payments in ways that would not otherwise be protected by a safe harbor. It is important to note that independent contractors are not protected by the employment exception, and payments to independent contractors would need to meet protections of another safe harbor, such as the provision for personal services arrangements.⁵⁶ OIG has adopted the same definition of “employee” used by the Internal Revenue Service, which is “any individual who would be considered an employee under the usual common law rules applicable in determining the existence of an employer-employee relationship.”⁵⁷ While this exception provides broad immunity from anti-kickback liability, the option to employ physicians to minimize liability is not currently feasible for many health care organizations. As Part III.A discusses, hospitals seeking to structure financial arrangements for participation in a value-based reimbursement program face the difficult task of trying to minimize liability under a statute that was designed, at least in part, to prohibit such arrangements.

2. The Stark Law

In the late 1980s, Congress turned its attention to the problem of physician referrals to entities, especially clinical laboratories, with which physicians had an ownership interest or a compensation arrangement. A study ordered by Congress found that a sizable number of physicians who sought Medicare reimbursement referred patients to entities with which they had financial relationships.⁵⁸ Because the Medicare Part B program paid physicians according to a fee-for-service fee schedule, the prospect of physicians referring patients for unnecessary procedures in order to bill Medicare was a real threat to the program’s long-term solvency. Indeed, the OIG

55. Instead of appearing in OIG’s safe harbor regulations, the employment exemption appears in the statute itself, thus not technically constituting a “safe harbor.” The prohibition “shall not apply to any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services.” 42 U.S.C. § 1320a-7b(b)(3)(B) (2006).

56. Kusserow, *supra* note 5, at 60–61.

57. *Id.* at 60 (quoting 56 Fed. Reg. 35,952, 35,987 (July 29, 1991)).

58. OFFICE OF INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUMAN SERVS., OAI-12-88-01410, FINANCIAL ARRANGEMENTS BETWEEN PHYSICIANS AND HEALTH CARE BUSINESSES: REPORT TO CONGRESS iii (1989) [hereinafter OIG REPORT], *available at* <https://oig.hhs.gov/oei/reports/oai-12-88-01410.pdf> (finding that twelve percent of Medicare physicians have a financial relationship with the entities to which they make patient referrals).

report noted that patients of physicians who owned or invested in outside clinical laboratories received 45 percent more services than other Medicare patients.⁵⁹ To combat this problem, the OIG Report identified six options for policymakers hoping to tackle the problem of physician self-referral.⁶⁰ Emboldened by the OIG report and the estimated \$28 million associated with physician self-referral to clinical laboratories,⁶¹ Congress, led by Representative Fortney “Pete” Stark, implemented the first prohibition on physician referrals for clinical laboratory services to entities with which the physician or a family member had a financial relationship.⁶² This prohibition, referred to as “Stark I,” paved the way for additional studies of physician referral behavior and resulted in additional prohibitions that were enacted in 1993.⁶³

In its current form, the Stark law prohibits physician referrals of Medicare or Medicaid patients for designated health services to entities with which the physician or a family member has a financial interest or compensation arrangement.⁶⁴ This broad prohibition does not require violators to act with a particular mental state. Instead, it adopts a “bright line” test for liability, which renders any such transaction unlawful unless it meets an exception.⁶⁵ Entities that

59. *Id.*

60. The report recommended (1) implementing “a post payment utilization review by carriers directed at physicians who either own or invest in other health care entities,” (2) requiring physicians to disclose their financial interest to patients, (3) improving enforcement of existing anti-kickback protections, (4) instituting a private right of action for kickbacks, (5) prohibiting physician referrals to certain entities to which they have a financial interest, or (6) prohibiting physician referrals to all entities to which they have a financial interest. *Id.* at iv; *see also* Sutton, *supra* note 8, at 19 (commenting on the results of the OIG Report).

61. OIG REPORT, *supra* note 58, at iii.

62. Sutton, *supra* note 8, at 19. The provision was passed as part of the Omnibus Budget Reconciliation Act of 1989 and took effect on January 1, 1992. *Id.*

63. The additional referral prohibitions, referred to as “Stark II,” were passed as part of the Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, § 13562, 107 Stat. 312, 596.

64. 42 U.S.C. § 1395nn(a) (2006). Designated health services include clinical laboratory services, physical therapy services, occupational therapy services, radiology services, radiation therapy services, durable medical equipment, parenteral and enteral nutrients and equipment, prosthetics, orthotics, and prosthetic devices and supplies, home health services, outpatient prescription drugs, and inpatient and outpatient hospital services. *Id.* § 1395nn(h)(6).

65. *See* FURROW ET AL., *supra* note 22, at 1082. Stark’s exceptions are classified as those applying to ownership or investment financial

receive overpayments because of a failure to meet the criteria of one of the exceptions must follow the Self-Referral Disclosure Protocol that was established pursuant to the ACA in September 2010.⁶⁶ Penalties include repayment of the claims paid while the violation existed,⁶⁷ civil penalties of \$15,000 per service for knowing violations,⁶⁸ and exclusion from the Medicare and Medicaid programs with penalties up to \$100,000 per service where evidence indicates a regulatory circumvention scheme.⁶⁹ CMS has the authority to issue advisory opinions to entities requesting review of a specific transaction or business arrangement; however, the opinion is binding “as to the Secretary and the party or parties requesting the opinion.”⁷⁰

Two Stark exceptions play a significant role in the structure of compensation arrangements between hospitals and physicians attempting to implement value-based payment programs. These exceptions include the personal services exception⁷¹ and the bona fide

relationships, direct and indirect compensation arrangements, or are generic exceptions to all financial arrangements. The law is characterized as an “exceptions bill” that enacts a sweeping prohibition and then carves out specific exceptions. *Id.* at 1084–85.

66. See U.S. DEP’T OF HEALTH & HUMAN SERVS., REPORT TO THE CONGRESS: IMPLEMENTATION OF THE MEDICARE SELF-REFERRAL DISCLOSURE PROTOCOL i (2012) [hereinafter SRDP REPORT], available at <http://www.cms.gov/Medicare/Fraud-and-Abuse/PhysicianSelfReferral/downloads/CMS-SRDP-Report-to-Congress.pdf>. The disclosing parties must submit information detailing: the nature of the violation; the duration of the violation; the circumstances leading to the discovery of the violation and steps taken to address and prevent future issues; disclosure of any previous similar conduct or enforcement actions; the existence of any compliance program; if applicable, any notices provided to other government agencies; and whether the matter is under government investigation. *Id.* at 5. The disclosing party must also provide a legal analysis of the suspected violation and identify elements of the exception that were and were not satisfied, and, in addition, specify the time frame in which the violative arrangement existed. *Id.* The repayment must be accompanied by a financial analysis that includes “a total amount actually or potentially due . . . as a result of the disclosed violation,” a description of the methodology used to calculate the amount, the total remuneration that involved physicians (or their family members) received, and a “summary of audit activity and documents used in the audit.” *Id.* at 6.
67. 42 U.S.C. § 1395nn(g)(2).
68. § 1395nn(g)(3).
69. § 1395nn(g)(4).
70. § 1395nn(g)(6).
71. § 1395nn(e)(3). This exception is commonly used for compensation arrangements between hospitals and independent physicians occupying management or other hospital-affiliated positions. The exception requires the arrangement to be set out in writing, be signed by the

employment relationships exception.⁷² As this Note argues in later sections, these exceptions to the Stark law provide inadequate protections to providers seeking to re-align physician payments with value-based metrics.⁷³

3. Civil Monetary Penalties Statute

The Civil Monetary Penalties (CMP) statute,⁷⁴ while more straightforward than the anti-kickback and Stark laws, presents perhaps the most significant obstacle to the implementation of value-based payment initiatives and thus plays an important role in the discussion of the current regulatory framework. The statute prohibits any hospital from knowingly making a payment to a physician as an inducement to reduce or limit services provided to Medicare or Medicaid beneficiaries under the direct care of the physician.⁷⁵ Hospitals making such payments can be liable for civil penalties of up to \$2,000 for each beneficiary for which a payment is made.⁷⁶ Physicians who knowingly accept the payment may themselves be liable for up to \$2,000 for each beneficiary for which a payment is made.⁷⁷

The OIG has interpreted the statutory language broadly to prohibit any payment that is intended to influence the physician to reduce or limit items or services.⁷⁸ Further clarifying its reading of the

parties, and specify the services that will be covered. The services contracted for must not “exceed those that are reasonable and necessary for the legitimate business purposes of the arrangement[s].” *Id.* The arrangement must last for at least one year, and the compensation must be set out in advance, must not exceed fair market value, and must not take into account the volume or value of any referrals. *Id.*

72. § 1395nn(e)(2). This exception provides broad protection for hospital-physician transactions and compensation arrangements and its use has grown as hospitals and physician organizations align to form accountable care organizations. The exception requires employment to be for identifiable services, and remuneration must be consistent with fair market value and not be determined in a manner that takes into account the volume or value of any referrals. Productivity bonuses are not prohibited for services performed personally by the physician, and remuneration under the agreement must be commercially reasonable. *Id.*

73. See discussion *infra* Part III.

74. 42 U.S.C. § 1320a-7a (2006).

75. § 1320a-7a(b)(1).

76. *Id.*

77. § 1320a-7a(b)(2).

78. Anne B. Claiborne, Julia R. Hesse & Daniel T. Roble, *Legal Impediments to Implementing Value-Based Purchasing in Healthcare*, 35 AM. J.L. & MED. 442, 445 (2009).

statute with respect to gainsharing,⁷⁹ the OIG stated in 1999 that appropriately structured gainsharing arrangements were prohibited, without regard to necessity or prudence as informed by current medical practice, even though they may provide financial benefit to the provider without an adverse impact on the quality of care.⁸⁰ The CMP has complicated recent efforts by hospitals to implement gainsharing agreements as part of broader value-based reimbursement initiatives that would allow physicians to share in the overall cost savings they deliver to the hospital.⁸¹ Recently, however, the OIG signaled some willingness to relax its interpretation of the provision in a series of advisory opinions⁸² that approved “carefully-tailored” gainsharing agreements.⁸³

Another provision of the CMP statute relating to beneficiary inducement is applicable to value-based payment programs. The statute prohibits offering remuneration to any Medicare or Medicaid beneficiary that a person knows or should know is likely to influence the beneficiary to seek care from a particular provider for which payment is made under the Medicare or Medicaid programs.⁸⁴ Certain value-based delivery models conflict with this prohibition because they offer items or services for free or below fair market value in an attempt to influence patient behavior. As with the provision relating to the reduction or limitation of services, there have been recent

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79. Gainsharing refers to arrangements where hospitals give physicians a share of any reduction in the hospital’s costs that can be attributed to the physician’s clinical behavior. FURROW ET AL., *supra* note 22, at 1079.
80. Gainsharing Arrangements and CMPs for Hospital Payments to Physicians to Reduce or Limit Services to Beneficiaries, 64 Fed. Reg. 37,985 (July 14, 1999).
81. See FURROW ET AL., *supra* note 22, at 1079–80 (noting the government’s concern for “black box” gainsharing arrangements in which physicians receive money for overall cost savings without disclosing what specific actions were taken to generate those savings).
82. OFFICE OF INSPECTOR GEN., U.S. DEP’T OF HEALTH & HUMAN SERVS., ADVISORY OPINION NOS. 05-01 TO 05-06 (2005), *available at* <https://oig.hhs.gov/reports-and-publications/archives/advisory-opinions/index.asp#2005>.
83. FURROW ET AL., *supra* note 22, at 1080. Some narrowly targeted agreements have been permitted where hospitals seek to reduce the use of costly supplies and procedures, or where they seek to employ less expensive clinical practices that reduce costs. *Id.* at 1079. Such agreements have been carefully designed with significant safeguards, including identification of the specific actions physicians are taking to reduce costs, external medical review of each cost-savings measure, and case-by-case evaluations with physician independence to choose the most appropriate treatment. *Id.* at 1080.
84. 42 U.S.C. § 1320a-7a(a)(5) (2006).

developments with the CMP for beneficiary inducement and the OIG's application of the provision to newer forms of value-based payment. These developments are discussed in Part IV.

II. THE TREND TOWARD VALUE-BASED PAYMENTS

In recent years, Congress has become increasingly concerned with the unrestrained growth in Medicare expenditures. This has been attributed, at least in part, to a method of reimbursement that rewards providers for increasing the volume and intensity of medical procedures with little regard for their quality or value to the patient.⁸⁵ The Medicare Payment Advisory Commission, or MedPAC, which advises Congress on issues related to Medicare payment policy, has encouraged Congress to develop payment reforms that focus on the bundling of payments across care settings and providers.⁸⁶ In addition, the Commission recommended the development of integrated care delivery systems, commonly referred to as Accountable Care Organizations, or ACOs, which use incentives to produce “high-quality, well-coordinated health care while containing growth in the cost of such services.”⁸⁷ Congress accepted these recommendations and included authorizing language for their development in the ACA.⁸⁸

A. *How Value-Based Payment Differs from Fee for Service*

As discussed in the beginning of this Note, the chief criticism of the fee-for-service model is that it functions to reward providing a greater volume of care that tends to be more costly.⁸⁹ To move beyond blind reimbursement for services without any regard for their value, reform advocates have encouraged value-based alternatives. Paying for value attempts to realign the financial incentives of care delivery by tying physician compensation to achievement of evidence-based clinical standards.⁹⁰ While there has been significant praise for

85. See Currier & Miller, *supra* note 36, at 1 (noting that Medicare should transform “from being a passive bill-payer to an active purchaser of healthcare”) (citing Nancy McCall et al., *Rates of Hospitalization for Ambulatory Care Sensitive Conditions in the Medicare+Choice Population*, 22 HEALTH CARE FIN. REV. 127, 127 (2001)).

86. *Id.* at 3.

87. *Id.* at 5.

88. See 42 U.S.C. § 1395jjj(a) (Supp. V 2011) (establishing the Medicare Shared Savings Program and associated ACOs); 42 U.S.C. § 1395cc-4(a) (Supp. V 2011) (establishing the National Program on Payment Bundling). These provisions and their implementation are discussed *infra* Parts II.C–D.

89. See discussion *supra* Part I.B.

90. See Michael F. Cannon, *Pay-for-Performance: Is Medicare a Good Candidate?*, 7 YALE J. HEALTH POL'Y L. & ETHICS 1, 3 (2007)

the idea of linking Medicare payments to value and quality, considerable difficulties in defining and measuring “value” and “quality” have persisted.⁹¹ Despite these difficulties, CMS has been experimenting with various forms of quality measurement in value-based payment initiatives that began long before the ACA was even contemplated.

B. Value-Based Purchasing

One of the earliest Medicare value-driven demonstration projects was the Hospital Quality Incentive Demonstration (HQID), which began in 2003. CMS attempted to determine whether financial incentives could improve inpatient care measures in five high-cost areas: acute myocardial infarction, coronary artery bypass surgery, heart failure, community-acquired pneumonia, and hip and knee replacement.⁹² Each hospital received a score based on composite quality measures,⁹³ the majority of which were process metrics that indicated the percentage of patients who received a specified treatment. Using composite data from these metrics, CMS awarded two-percent bonus payments on hospital DRG payments for the condition for hospitals in the top decile of participants.⁹⁴ Hospitals in the second decile received a one-percent bonus.⁹⁵ In response to criticism that the poorest-performing hospitals were not being rewarded for their sustained improvement, payments were adjusted in the second phase, which lasted from 2007 to 2009, to reward hospitals that demonstrated year-over-year improvement.⁹⁶ In 2011, CMS

(describing how financial rewards can be used to affect the performance of a physician).

91. For an excellent discussion of the difficulties and implications associated with defining quality, see *id.* at 5–8. Cannon notes that quality can be measured in four ways: patient outcomes, processes, structural factors (facilities and equipment), and patient satisfaction. *Id.* at 5. These quality measures are each associated with a unique set of benefits and drawbacks and are likely to be impacted by the availability and quality of the data used to calculate them. See *id.* at 7–10 (discussing the numerous upsides and downsides likely to result from quality measures).
92. DAVID MECHANIC, *THE TRUTH ABOUT HEALTH CARE: WHY REFORM IS NOT WORKING IN AMERICA* 122 (2006).
93. *Id.*
94. *Id.*
95. *Id.*
96. See *CTRS. FOR MEDICARE & MEDICAID SERVS., PREMIER HOSPITAL QUALITY INCENTIVE DEMONSTRATION REWARDING SUPERIOR QUALITY CARE: FACT SHEET 3* (2011), <http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/HospitalQualityInits/Downloads/HospitalPremierPressRelease-FactSheet.pdf> (noting that incentive payments were given to hospitals based on quality score improvement over the past few years). The project extension also

indicated that, among the 216 participating hospitals, the composite quality score improved by an average of 18.6 percent across each of the five measured areas.⁹⁷

The results of this demonstration informed the design of the new Value Based Purchasing (VBP) Program, which went into effect for all Medicare-participating hospitals on October 1, 2012.⁹⁸ Under the new VBP Program,⁹⁹ Medicare will withhold one percent of regular DRG reimbursements, and, over the course of a year, money will be paid to hospitals based on their adherence to clinical guidelines and their performance on patient satisfaction surveys.¹⁰⁰ Seventy percent of the hospitals' ratings correspond to clinical process measures, while the remaining thirty percent is derived from satisfaction survey responses from discharged patients.¹⁰¹

C. Shared Savings Programs and the Development of ACOs

The Medicare Physician Group Practice (PGP) Demonstration¹⁰² represented the first large-scale attempt to pay physicians according

imposed a one percent DRG penalty on hospitals that did not score above the ninth decile in any clinical area in year four. A two percent reduction was imposed for hospitals failing to score above the tenth decile in any clinical area in year four. *Id.*

97. *Id.* at 2.

98. Jordan M. VanLare & Patrick H. Conway, *Value-Based Purchasing—National Programs to Move from Volume to Value*, 367 NEW ENG. J. MED. 292, 293 (2012); Jordan Rau, *Medicare's Pay for Performance Effort Begins, Targeting Quality and Readmissions*, CAPSULES: THE KHN BLOG (Oct. 1, 2012, 6:06 AM), <http://capsules.kaiserhealthnews.org/index.php/2012/10/medicares-pay-for-performance-effort-begins-targeting-quality-and-readmissions/>.

99. The VBP Program was created by the ACA and appears at 42 U.S.C. § 1395ww(o)(1) (Supp. V 2011).

100. Rau, *supra* note 98. A hospital's performance may allow it to recoup some of the DRG payment reduction, and hospitals that achieve higher ratings can potentially receive extra. Hospitals that underperform will likely fail to recoup the one percent DRG reduction. Over time, Medicare will increase the amount initially withheld from DRG payments, and new quality measures will be added. *Id.*

101. *Id.*

102. Medicare, Medicaid, and State Child Health Insurance Program Benefits Improvement and Protection Act of 2000, Pub. L. No. 106-554, 114 Stat. 2763 (codified at 42 U.S.C. § 1395cc-1(a) (2006)). The demonstration began in April 2005 and concluded in March 2010. All ten physician groups are participating in a two-year transition demonstration, which began in January 2011. CTRS. FOR MEDICARE & MEDICAID SERVS., MEDICARE PHYSICIAN GROUP PRACTICE DEMONSTRATION: PHYSICIANS CONTINUE TO IMPROVE QUALITY AND GENERATE SAVINGS UNDER MEDICARE PHYSICIAN PAY-FOR-PERFORMANCE DEMONSTRATION 9 (2011), <https://www.cms.gov/>

to value using a shared savings model. The demonstration used shared savings to encourage cost efficiency and quality improvement by allowing participating physician groups to retain a portion of the savings generated by reducing the cost of managing the health of a defined population of Medicare patients and improving quality.¹⁰³

The demonstration was structured to compare the annual expenditure growth of the PGP-participating patient population to that of the local nonparticipating patient population. Patients who received the largest share of their services from the participating group practice were assigned to the PGP for expenditure comparison.¹⁰⁴ If the group practice successfully held expenditures for its assigned patients more than two percent below the target, the practice was eligible for a performance payment of a percentage of the total savings.¹⁰⁵ Medicare received the remaining amount.¹⁰⁶ An additional quality performance payment was determined, based on the group's achievement of thirty-two quality measures.¹⁰⁷ If all targets were met, the PGP received the maximum quality performance payment; however, Medicare retained a portion of the payment if the PGP did not meet all targets.¹⁰⁸ Data for these quality measures were derived from claims submissions and patient record abstractions.¹⁰⁹

Building on the shared savings approach in the PGP demonstration, Congress created the Medicare Shared Savings Program in the ACA.¹¹⁰ The program encourages providers to develop accountable care organizations, or ACOs, which bring together disparate groups of providers to assume responsibility for the medical

Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/
PGP_Fact_Sheet.pdf.

103. John Kautter et al., *Medicare Physician Group Practice Demonstration Design: Quality and Efficiency Pay-for-Performance*, 29 HEALTH CARE FIN. REV., no. 1, 2007, at 15, 16. The project required a higher level of administrative and clinical capability, which limited participation to ten large physician groups viewed as having the capacity to respond to the incentives and track the necessary quality measures. *Id.* at 17.
104. *Id.* at 18. Patients who received a plurality of their outpatient evaluation and management services from the participating PGP during a given year were eligible for assignment. *Id.*
105. *Id.* at 21.
106. *Id.* Initially, the group practice retained eighty percent of the savings, while Medicare retained twenty percent. In the third, and final, year of the demonstration, both parties shared in the savings equally. *Id.*
107. *Id.* at 24.
108. *Id.* at 21.
109. *Id.* at 25.
110. 42 U.S.C. § 1395jjj(a) (Supp. V 2011).

care delivered to a population of patients.¹¹¹ The providers who assume responsibility for the care of the population are encouraged to coordinate care, reduce costs, and improve quality.¹¹² ACOs can take on a variety of organizational forms,¹¹³ but a series of statutory requirements apply to all participating entities.¹¹⁴

The shared savings payment structure still relies on the Medicare fee-for-service system, but the value-based element of shared savings encourages providers to meet cost reduction benchmarks and rewards them if they hold down costs.¹¹⁵ To establish a relative baseline against which the ACO's performance will be measured, the ACO and Medicare will agree on the historic costs of providing medical care to the patient population assigned to the ACO, taking into account the anticipated changes in health care costs for factors like age and health

111. DAVID NEWMAN, CONG. RESEARCH SERV., R41474, ACCOUNTABLE CARE ORGANIZATIONS AND THE MEDICARE SHARED SAVINGS PROGRAM 8 (2010).

112. *Id.* at 2.

113. While hospitals are not a necessary part of an ACO, the government believes they will be central to their creation because hospitals are better positioned to provide capital for increased staffing, health information technology investments, and electronic health records deployment. In addition, hospitals have the legal resources to contract with the government and other providers, and they are better positioned to develop integrated care processes. *See id.* at 7–8 (discussing reasons why ACO integration is likely). These hospitals could employ physicians directly through an integrated delivery system, or they could enter into joint ventures with independent physician practices and operate a non-employee medical staff. *See id.* at 4 (comparing the characteristics of various models of hospitals). Other forms of ACOs do not require hospitals at all. Instead, they rely either on associations of independent physician practices that contract jointly with health plans to coordinate care and improve quality, or they involve virtual physician networks led by individual physicians or local foundations capable of providing leadership and infrastructure to coordinate care. *Id.*

114. All ACOs must agree to: (1) become accountable for the quality, cost, and care of the Medicare beneficiaries assigned to them, (2) participate in the program for at least three years, (3) have a formal legal structure to allow for the receipt and distribution of shared savings payments to providers and suppliers, (4) include sufficient primary care professionals to provide care to the beneficiaries assigned to ACO, (5) have at least 5,000 fee-for-service beneficiaries assigned to the ACO, (6) create a leadership and management structure that includes administrative and clinical systems, and (7) define processes to promote evidence-based medicine, patient engagement, quality and cost measures, and care coordination. 42 U.S.C. § 1395jjj(b)(2)(A)–(G) (Supp. V 2011).

115. *See* NEWMAN, *supra* note 111, at 9 (describing the benefits of using an ACO in Medicare fee for service).

status.¹¹⁶ ACOs that enroll in the traditional Shared Savings Program will assume no risk for failing to achieve savings, and providers will still receive the full Medicare fee-for-service rate regardless.¹¹⁷ Those ACOs that achieve savings relative to the baseline will retain a portion of that amount to be distributed to providers according to the organization's individual business arrangement with ACO stakeholders.¹¹⁸ Performance based on Medicare-defined quality measures will also affect the portion of savings retained by the ACO.¹¹⁹

The government believes the prospect of sharing in any savings generated creates an incentive to reduce the volume and intensity of medical procedures, while the potential to receive a bonus for achieving quality performance measures reduces the likelihood that providers will stint on care. And, while most quality measures will likely consist of simple process metrics initially, CMS is expected to continue developing more sophisticated, evidence-based quality measures and reporting requirements for future implementation.¹²⁰ As providers continue to adopt electronic health record (EHR) systems and conform to the meaningful use regulations,¹²¹ the Medicare program will be positioned to take advantage of providers' clinical monitoring capabilities and use abstracted EHR data to assure quality of care. The implications of this capability regarding the development of a new Medicare regulatory structure are discussed in Part V.

116. *Id.* These beneficiaries will be assigned based on where they receive the majority of their primary care in the prior year. *Id.*

117. *Id.* More advanced integrated care providers participating in the Pioneer ACO model will face downside risk by being held accountable for a portion of the losses relative to the benchmark. *See* CTRS. FOR MEDICARE & MEDICAID SERVS., PIONEER ACCOUNTABLE CARE ORGANIZATION (ACO) MODEL PROGRAM: FREQUENTLY ASKED QUESTIONS 3 (2012), <http://innovations.cms.gov/Files/x/Pioneer-ACO-Model-Frequently-Asked-Questions-doc.pdf>. In the third year of the program, Pioneer ACOs will transition to a population-based payment model, which replaces a significant portion of the fee-for-service system with a per-beneficiary per-month payment that resembles capitation. *Id.* The results of this model will be used to inform future rulemaking related to the Shared Savings Program. *Id.* at 1.

118. NEWMAN, *supra* note 111, at 9.

119. *Id.*

120. *Id.* at 10.

121. To receive incentive payments under the Medicare and Medicaid Incentive Programs, which help offset the cost of implementing new EHR systems, providers must certify that they are "meaningfully using" EHR technology by meeting objectives established by CMS. The requirements for eligible professionals and hospitals appear at 42 C.F.R. § 495.210 (2012).

D. Bundling Payments by Episode of Care

Episodic payment bundling is an alternative to fee-for-service payment that packages the payments of multiple providers into a single lump sum payment corresponding with the treatment of a patient's condition.¹²² Instead of Medicare reimbursing hospitals under Part A and physicians and other professionals under Part B, the program encourages all providers to coordinate treatment across multiple specialties and deliver more efficient care, while ensuring quality through monitoring and improvement protocols.¹²³ CMS has developed a series of payment bundling models as part of a demonstration project established by the ACA.¹²⁴ While the models have subtle differences, each of them attempts to bundle all services associated with inpatient care with those services needed for a defined period after discharge from the hospital. Since the bundled payment establishes a target for a given condition, all providers, including hospitals, physicians, and related health practitioners involved in the patient's treatment and recovery up to 30-90 days post-discharge, have an incentive to hold costs below the bundled amount and share the savings.¹²⁵ If costs for treating the patient for the condition exceed the target, the provider must pay the difference back to Medicare.¹²⁶

While there may be consensus among policymakers that the Medicare program can no longer pay for medical services using a reimbursement model that encourages overtreatment and poor

122. See CTRS. FOR MEDICARE & MEDICAID SERVS., BUNDLED PAYMENTS FOR CARE IMPROVEMENT INITIATIVE: FREQUENTLY ASKED QUESTIONS 4 (2012) [hereinafter BUNDLED PAYMENT FAQs], available at <http://innovation.cms.gov/Files/x/Bundled-Payments-FAQ.pdf> (describing how various models of payment function).

123. CTRS. FOR MEDICARE & MEDICAID SERVS., BUNDLED PAYMENTS FOR CARE IMPROVEMENT INITIATIVE: FACT SHEET 1 (2011) [hereinafter BUNDLED PAYMENT FACT SHEET], available at http://www.phprwi.com/Partner_Resource_Docs/Fact-Sheet-Bundled-Payment-FINAL82311.pdf.

124. See 42 U.S.C. § 1395cc-4(a)(1) (Supp. V 2011). Each of the three retrospective payment models use agreed-upon targets calculated using the historical costs of providing care for specified conditions and then discounting those costs to arrive at a bundled payment for the episode. Providers still bill using the fee-for-service system, but the final amount paid by Medicare is reconciled with the target. When providers remain below the target, they are permitted to retain the excess payment; however, providers do not receive additional payments if costs exceed the target. The prospective model uses established payments that are automatically distributed to the hospital, which then has the responsibility of distributing the bundled payment across involved providers. See BUNDLED PAYMENT FACT SHEET, *supra* note 123, at 3.

125. BUNDLED PAYMENT FACT SHEET, *supra* note 123, at 3.

126. BUNDLED PAYMENT FAQs, *supra* note 122, at 4.

coordination of care,¹²⁷ significant regulatory barriers remain. As Part I discussed, the regulatory framework currently in existence is highly complex and was structured to combat fraud and abuse in the fee-for-service system.¹²⁸ The difficulties imposed by the current regulatory structure on the implementation of new value-based payment methods and care delivery reforms are significant. Part III examines these difficulties and begins to critique the approach that CMS has taken to alleviate some of the restrictions posed by the fraud-and-abuse regulations.

III. VALUE-BASED REIMBURSEMENT AND THE EXISTING REGULATORY FRAMEWORK

Provider efforts to implement value-based reimbursement models will almost certainly be met with an array of conflicts related to the existing fraud-and-abuse regulatory framework. As mentioned above, the existing regulatory structure was designed to combat abuse of the fee-for-service reimbursement system. To preserve the financial health of the federal health care programs, legislators and regulators focused on indirect control over financial relationships and ownership interests among providers. Now, in an era of integrated care delivery and changed financial incentives, physicians must begin to develop relationships in ways that conflict with these existing regulations. While it remains possible to implement value-based reimbursement programs under current regulations, doing so curtails the scope of the program, and it requires innovative providers to assume the risk that their arrangement could become the first example of what is not permitted under existing regulations. As a result, providers have moved forward, if at all, with an abundance of caution that could chill innovation and impact the timeline for adopting cost-reducing payment models.

A. *Conflicts with the Anti-Kickback Statute*

Currently, the anti-kickback statute does not provide a safe harbor for the gainsharing-type arrangements found in shared savings payment models. Though the statute is intent-based, and thus requires the government to prove that a payment was made with knowledge to induce referrals, providers would still seek to minimize liability by fitting the gainsharing payments into an existing safe harbor or by requesting an advisory opinion from the OIG. The most

127. See Ezekiel Emanuel et al., *A Systematic Approach to Containing Health Care Spending*, 367 NEW ENG. J. MED. 949, 950 (2012) (noting the views of several prominent health policy experts and their support for the accelerated adoption of fee-for-service alternatives in Medicare).

128. See discussion *supra* Part I.C.

avored safe harbor under the statute, however, is not even a safe harbor at all. As noted in Part I, the statute does not define “remuneration” to include money paid as compensation to bona fide employees.¹²⁹ This broad exception has led many large integrated care providers to employ physicians to avoid scrutiny under the statute.

Another option available to providers seeking to shield gainsharing-type payments from anti-kickback scrutiny is the safe harbor for personal service arrangements and management contracts. As discussed in Part I, the requirements for the safe harbor are complex.¹³⁰ The most difficult requirements, however, are that aggregate compensation paid to the physician over the term of the agreement be set out in advance, consistent with fair market value, and not take into consideration the volume or value of referrals.¹³¹ For hospitals attempting to make shared savings payments to physicians, these requirements present risks because hospitals may not know the aggregate dollar figure of payments at the beginning of the agreement. Additionally, determining the fair market value for shared savings payments presents problems because the payments are outside the “existing paradigm of fair market value fees being measured in terms of hours of service provided.”¹³² Because of these difficulties and uncertainties, providers are often unwilling to rely on the purported protection of the safe harbor. Providers who choose to rely on the incomplete protection of the safe harbor cite the intent requirement as a primary justification. With contemporaneous documentation and a business justification for the payments, some providers are willing to proceed without any greater protection on the basis that knowledge to pay remuneration to induce referrals could not be proven in any enforcement action.¹³³

One remaining option for providers who have sought a greater level of protection has been to request an advisory opinion from OIG. OIG has issued several advisory opinions approving gainsharing arrangements between hospitals and identifiable groups of

129. *See supra* notes 55–57 and accompanying text.

130. *See supra* notes 52–54 and accompanying text.

131. *See* 42 C.F.R. § 1001.952(d) (2012) (establishing all of the requirements that must be met in order to exclude payments that would otherwise constitute remuneration under the statute).

132. Robert F. Leibenluft et al., *Hospital-Physician Collaborations: Antitrust and Health Care Fraud and Abuse Considerations*, in HEALTH LAW HANDBOOK 251, 270 (Alice G. Gosfield ed., 2009).

133. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-355, MEDICARE: IMPLEMENTATION OF FINANCIAL INCENTIVE PROGRAMS UNDER FEDERAL FRAUD AND ABUSE LAWS 20 n.68 (2012) [hereinafter GAO FINANCIAL INCENTIVE REPORT].

physicians.¹³⁴ Approved gainsharing plans have included payments made by hospitals to cardiology and radiology groups at a rate of fifty percent of the annual savings achieved by physician implementation of cost-saving recommendations.¹³⁵ Providers opting for an advisory opinion face significant costs—and risks—as the requesting party must pay OIG to evaluate the proposal and prepare an advisory statement.¹³⁶ Furthermore, the requesting party must seek review of an existing or proposed financial arrangement, since OIG will not respond to hypotheticals or general questions of interpretation.¹³⁷ Any advisory opinions issued by OIG are binding only between the requesting party and the Secretary of HHS.¹³⁸ While many organizations and their legal counsel look to these advisory opinions for guidance in structuring their financial incentive programs, the opinions do not provide an absolute shield from liability, and the slightest difference in circumstances could affect the applicability of the advisory opinion to the relying party's arrangement.¹³⁹

B. Conflicts with the Stark Law

The potential for liability under the Stark law is much broader. As mentioned in Part I, the statute imposes strict liability on violators unless their conduct falls within one of the recognized exceptions. In the context of shared savings and ACOs, the Stark law would be easily implicated because of the compensation arrangements involving physicians who make referrals to the hospital for designated health services.¹⁴⁰ Similar to the anti-kickback statute, there is no Stark exception that applies directly to shared savings or other incentive payments. The absence of explicit protection under the strict liability statute leaves providers with a patchwork of existing exceptions that provide only limited protection to value-based payment programs.

Perhaps the most comprehensive protection offered by the Stark law as it relates to gainsharing is the exception for bona fide employment relationships. Under this exception, the agreement must

134. Claiborne et al., *supra* note 78, at 489.

135. *Id.* at 489 n.249.

136. GAO FINANCIAL INCENTIVE REPORT, *supra* note 133, at 12–13, 13 n.49.

137. *Id.* at 12 n.46.

138. *Id.* at 12.

139. *Id.*

140. Carrie Valiant, *Stark Law Implications for ACOs: Fitting a Square Peg into a Round Hole*, ACCOUNTABLE CARE NEWS, Jan. 2011, at 1, 7, available at http://www.ebglaw.com/files/42796_Valiant-Accountable-Care-News-Stark-Law.pdf.

show that employment is for identifiable services, the amount paid is consistent with fair market value, the amount does not take into consideration the volume or value of any referrals, and the amount paid is commercially reasonable.¹⁴¹ In large part, this exception protects the distribution of shared savings between hospitals and employed physicians. Lingering risks include ensuring that payments to physicians remain consistent with fair market value and that payments are commercially reasonable; however, the measurability of fair market value for services meeting a “clinically based outcome measure for a financial incentive program to improve quality” is unclear.¹⁴² To overcome this difficulty, some agreements ensure that total physician compensation, including all incentive payments and other sources of income, remains consistent with fair market value.¹⁴³ To meet the requirement that payment not depend on volume or value of referrals, some incentive payment plans are structured to pay physicians the same amount of money, regardless of their contribution to the savings generated.¹⁴⁴ The effects of rewarding physicians equally for making an unequal contribution to achieve savings may have adverse effects on changing physician habits and improving the quality of care;¹⁴⁵ however, such a review is beyond the scope of this Note.

More complex issues arise when the relationship between coordinating parties does not involve an employment relationship protected by the broad bona fide employment exception. Hospitals seeking to distribute shared savings payments to non-employed physicians have sought protection under the personal services arrangement exception¹⁴⁶ and fair market value compensation exception.¹⁴⁷ While some minor differences exist between the exceptions, parties seeking to meet the requirements of either

141. 42 U.S.C. § 1395nn(e)(2) (2006).

142. GAO FINANCIAL INCENTIVE REPORT, *supra* note 133, at 21.

143. See KEVIN G. MCANANEY, KIM MOBLEY & CLAIRE TURCOTTE, AMERICAN HEALTH LAWYERS ASSOCIATION ANNUAL MEETING: GOVERNANCE BEST PRACTICES FOR PHYSICIAN COMPENSATION AND CONTRACTING 34–38 (June 28–29, 2011) [hereinafter AHLA BEST PRACTICES], available at http://www.healthlawyers.org/Events/Programs/Materials/Documents/AM11/mcananey_mobley_turcotte_slides.pdf (presentation describing some of the issues associated with the fair market value and “set in advance” requirements under Stark and noting that fair market value analysis should be performed on total compensation, including incentive-based components).

144. GAO FINANCIAL INCENTIVE REPORT, *supra* note 133, at 21.

145. *Id.*

146. 42 C.F.R. § 411.357(d) (2012).

147. § 411.357(l).

exception have faced similar difficulties. Both exceptions require that compensation under the agreement: (1) be set out in advance; (2) be consistent with fair market value; (3) not take into account the volume or value of referrals or other business generated by the referring physician; and (4) be commercially reasonable.¹⁴⁸ Unlike with the employment exception, the personal services exception often is not applied in situations where hospitals can bundle the physician's base salary and the incentive-based compensation received from a gainsharing arrangement together to perform a fair market value analysis. In the employment context, hospitals receive greater protection from errors in fair market value calculations because a sizable portion of the compensation (the base salary) can be verified by third party surveys. The personal services arrangement and fair market value exceptions, in contrast, are typically reserved for physicians who are not employed by the health system, and thus a significant portion, if not the entirety, of the physician's payment from the health system is derived from shared savings payments for which no objective third party fair market value survey exists.

Structuring compensation arrangements in ways that have not been explicitly approved by CMS creates a significant risk for providers. Performing fair market value analysis on incentive-based payments, as alluded to above, is difficult, if not impossible, and CMS has not provided certainty in this area. Additionally, it is difficult for hospitals and health systems to know at least one year in advance what the total compensation under the agreement will be; however, CMS has been receptive to the inclusion of formulas that will be used to calculate incentive-based compensation that is subject to outcome metrics.¹⁴⁹ As with the anti-kickback statute, providers have the option of seeking an advisory opinion from CMS. While the published opinion binds only the requesting party and the Secretary of HHS,¹⁵⁰ other parties have relied on the language to craft incentive payment programs consistent with what CMS has previously sanctioned. Some parties cite the statistic that CMS and OIG have not taken any Stark or anti-kickback enforcement actions regarding pay-for-performance or gainsharing arrangements from 2005 to 2010.¹⁵¹ The threat of becoming the first provider targeted by such an enforcement action, however, has caused providers to implement programs with caution.¹⁵²

148. *Id.*; § 411.357(d).

149. *See* AHLA BEST PRACTICES, *supra* note 143, at 34 (noting that quality-based payments to independent contractor physicians may meet the "set in advance" requirement for Stark if the formula is set forth in the agreement).

150. GAO FINANCIAL INCENTIVE REPORT, *supra* note 133, at 12.

151. *Id.* at 23.

152. *Id.*

As discussed below, the lack of clarity and protection offered to providers attempting to implement value-based payment models using a regulatory framework directed toward fee for service has a chilling effect that could unnecessarily delay innovation.

In an early attempt to address these issues, CMS, in 2008, issued a proposed rule¹⁵³ outlining an exception for incentive payment programs and shared savings programs.¹⁵⁴ The 16-element exception adopted many of the safeguards that were adopted in favorable OIG advisory opinions related to gainsharing under the anti-kickback statute.¹⁵⁵ The rule was never finalized, and HHS later 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.”¹⁵⁶ Providers have since relied on favorable advisory opinions issued by CMS that contain many of the provisions of the proposed rule; however, parties relying on advisory opinions that are not binding between themselves and the Secretary of HHS will not likely receive any legal immunity.¹⁵⁷

C. *Conflicts with the CMP Statute*

The CMP statute creates a straightforward prohibition on gainsharing initiatives in which providers receive a share of the savings generated from reducing or limiting care in any way, regardless of medical necessity.¹⁵⁸ Unlike with the anti-kickback statute and the Stark law, the CMP statute does not provide a measure of protection in the form of a safe harbor or exception if

153. Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Revisions to E-Prescribing Exemption Amendment, 73 Fed. Reg. 38,502, 38,604 (proposed July 7, 2008).

154. Claiborne et al., *supra* note 78, at 487.

155. *Id.* The proposed rule would have guarded against some of the risks associated with gainsharing, including: “limitations on costly services (‘stinting’); favoring of healthier or cheaper patients (‘cherry picking’); disfavoring of sicker or more expensive patients (‘steering’); inappropriately limiting length of stay (‘quicker and sicker discharge’); or generating abusive referrals through improperly increased percentage payments to physicians or manipulating outcomes data.” *Id.* The proposed rule allowed gainsharing programs to last up to three years and required that: at least five physicians participate in each quality measure, all physicians in a given department be permitted to participate, and all physicians be on the medical staff at the outset of the program. *Id.* at 487–88.

156. Notice of Meeting, 75 Fed. Reg. 57,039, 57,041 (Sept. 17, 2010); *see also* Valiant, *supra* note 140, at 8 (quoting the notice in the Federal Register).

157. Claiborne et al., *supra* note 78, at 488.

158. *See supra* notes 74–83 and accompanying text.

certain requirements are met. Providers attempting to create narrow gainsharing arrangements are instead left to rely on nonbinding statements from the OIG that offer no guaranteed protection from penalties, except as between the Secretary and the entity to which the opinion is addressed.¹⁵⁹

Recently, the OIG has allowed for “carefully tailored” gainsharing agreements that meet certain requirements.¹⁶⁰ While this measure of relief allowed for some gainsharing arrangements to proceed, nearly all of them have been limited to individual service lines,¹⁶¹ particularly in the form of clinical co-management agreements. Even where other providers attempt to strictly replicate a gainsharing arrangement that OIG has explicitly approved, the impact the programs have on achieving high quality and value is limited because of the constraints that OIG places on the program.¹⁶² Without changing the way in which the CMP statute is applied and enforced, however, the statute would continue to present the “most direct constraints on the financial and clinical integration between physicians and hospital[s] where the goal of integration is efficiency.”¹⁶³ As a result of this limitation on the expansion of high-value care, the broad applicability of the CMP statute was a prime candidate for reform when Congress was contemplating the transition from fee-for-service to value-based payment.

IV. THE LEGISLATIVE RESPONSE: FRAUD-AND-ABUSE WAIVERS

As part of the ACA, Congress granted waiver authority to the Secretary of HHS that would allow for provisions of the anti-kickback statute, the Stark law, and the CMP statute to be waived in connection with approved demonstration projects.¹⁶⁴ CMS exercised

159. *See supra* notes 74–83 and accompanying text.

160. FURROW ET AL., *supra* note 22, at 1080; *see also supra* note 83 (describing the characteristics of approved gainsharing arrangements).

161. *Id.*

162. *See* GAO FINANCIAL INCENTIVE REPORT, *supra* note 133, at 31 (noting that permissible gainsharing arrangements are narrow and permit specific cost-saving limitations, for instance limits on use of certain surgical supplies and product substitutions). Another limitation in approved gainsharing arrangements is that payments for financial incentives must also be distributed equally per capita, regardless of the level of effort by the physician. *Id.*

163. Leibenluft et al., *supra* note 132, at 267–68.

164. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3022(f), 124 Stat. 119, 398 (2010) (provision codified at 42 U.S.C. § 1395jjj(f) (2012)).

this new waiver authority and promulgated an interim final rule with comment (IFC) that specified five waivers applicable to the Medicare Shared Savings Program.¹⁶⁵ These waivers are self-executing, broad in their applicability, and provide specific protection for ACO pre-participation activity,¹⁶⁶ participation in approved ACOs,¹⁶⁷ distribution of shared savings payments,¹⁶⁸ compliance with the Stark

165. 76 Fed. Reg. 67,992, 67,993 (Nov. 2, 2011) (to be codified at 42 C.F.R. ch. IV–V).

166. *Id.* at 68,000. The ACO Pre-participation Waiver waives applicability of the anti-kickback statute, the Stark law, and the CMP statute for ACO activity that pre-dates the effective date of the ACO participation agreement, so long as certain requirements are met. Parties must make a good faith attempt to develop an ACO that will participate in the Shared Savings Program, as evidenced by contemporaneous documentation of diligent steps to create a governance structure, leadership, and management. A description of the arrangement must be publicly disclosed. The Pre-participation Waiver protects start-up activity that would otherwise violate the three fraud-and-abuse provisions for the one-year period preceding the application's due date with the Secretary. *Id.*

167. *Id.* at 68,000–01. The ACO Participation Waiver waives the three fraud-and-abuse provisions for all ACO activities related to an ACO's participants or any combination of its providers and suppliers, if certain requirements are met. The ACO must have entered into a participation agreement and remained in good standing; the ACO meets governance, leadership, and management requirements; the ACO's governing body has made a bona fide determination that the arrangement is reasonably related to the Shared Savings Program purposes; and all such determinations are contemporaneously documented and made available to the Secretary for a period of ten years following completion of the arrangement. The waiver becomes effective on the start date of the participation agreement and ends six months following the expiration of the agreement. If CMS terminates the agreement, however, the waiver period will end on the date of termination notice. *Id.*

168. *Id.* at 68,001. The Shared Savings Distribution Waiver applies to all three fraud-and-abuse provisions, if all of the conditions are met. The ACO must be in good standing with a participation agreement; shared savings must be earned by the ACO pursuant to the Shared Savings Program; and shared savings must be earned by the ACO during the term of the participation agreement, even if distribution occurs after the agreement expires. Distributions must be paid to providers/suppliers or participants who were a part of the ACO during the year in which shared savings were earned, or distributions must be used for activities that are reasonably related to the purpose of the Shared Savings Program. *Id.* Additionally, with regard to the CMP statute, the waiver applies to payments made directly or indirectly from hospital to physician but not knowingly to induce the physician to “reduce or limit *medically necessary* items or services to patients under the direct care of the physician.” *Id.*

law,¹⁶⁹ and protection for patient incentive payments.¹⁷⁰ The ACA also permits the Secretary to waive application of the fraud-and-abuse provisions to pilot programs on payment bundling, which would include the Bundled Payments for Care Improvement Initiative;¹⁷¹ however, CMS has not yet issued comprehensive language on what these waivers will require.

While the scope of the waivers provided under the Shared Savings Program is significant and may provide a measure of relief to providers who were previously unwilling to take risks by structuring value-based arrangements under the existing regulations, the evidence shows that many more questions exist regarding long-term reliance on these waivers. This Note argues that the reliance on regulatory waivers functions as the government's admission that the current regulatory structure is at odds with the ACA's focus on delivering high-value health care through ACOs. Though this is an important realization for the government, there are consequences to proceeding in a manner where CMS limits the use of waivers to providers participating in approved demonstration projects during only the period of participation. Without changes to the applicability and use of waivers, CMS will chill the adoption of these payment reforms by creating uncertainty about providers' long-term protection under the waivers and by creating two tiers of health care innovation.

One of the primary concerns that providers have under the ACO waiver program is the time-limited nature of the protection afforded to the financial relationships created as part of an ACO. The American Hospital Association (AHA) has expressed concern about potential future changes to the IFC without having the opportunity

169. *Id.* The Compliance with the Physician Self-Referral (Stark) Law Waiver waives application of the anti-kickback and CMP provisions to any financial relationship between an ACO and its participants or providers/suppliers that implicates the Stark law. The waiver requires a participation agreement in good standing, a financial relationship that is reasonably related to the purpose of the Shared Savings Program, and a financial relationship that fully complies with an existing Stark exception. *Id.*

170. *Id.* The Waiver for Patient Incentives protects ACOs who provide services to participants or its providers/suppliers that are free or below fair market value, if all requirements are met. The ACO must have a participation agreement in good standing; there must be a reasonable connection between the items or services and the care of the beneficiary; the services must be in-kind; the items or services are preventive care items, or they advance a clinical goal of adherence to a treatment regime, drug regime, follow up care plan, or management of a chronic disease. *Id.*

171. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, § 3023(d), 124 Stat. 119, 403 (2010) (provision codified at 42 U.S.C. § 1395cc-4(d) (2012)).

to comment further.¹⁷² Perhaps more concerning is the potential for CMS to modify the terms of the ACO waivers after the initial participation agreement between the provider and CMS expires. Under this scenario, the AHA fears that waiver protections could be subsequently altered or removed altogether, thus exposing providers to additional unexpected requirements at a minimum, and potential legal risks if CMS or the OIG choose to enforce existing regulations without regard for the provider's adherence to the previous waiver requirements.¹⁷³

The GAO's research on provider behavior validates the AHA's concerns regarding industry hesitance to structure financial relationships under the protections afforded by the waiver program. A recent report cites the time-limited nature of the protection as a major impediment to the broad-based formation of new integrated relationships.¹⁷⁴ Providers have instead chosen to rely on the "constraints of existing exceptions and safe harbors" and the advisory opinion process.¹⁷⁵ As a result of the continuing reluctance to seek an advisory opinion because of the time, cost, and uncertainty involved, providers are "more likely to implement only those programs that mirror already approved programs or none at all."¹⁷⁶ As noted above, the narrowness of the previously approved programs limits the scope that new programs can take.¹⁷⁷

The AHA has taken issue with another aspect of the ACO waivers related to the narrowness of their application and the potential effects that such exclusive application could have on the development of other "clinically integrated organizations."¹⁷⁸ The letter expresses a desire to provide all health programs the same opportunity to participate in care coordination improvements, so that all patients "have the same opportunity to benefit from quality and

172. Letter from Rick Pollack, Exec. Vice President, Am. Hosp. Assoc., to Marilyn Tavenner, Acting Adm'r, Ctrs. for Medicare & Medicaid Servs., & Daniel R. Levinson, Inspector Gen., U.S. Dep't of Health & Human Servs. Office of Inspector Gen. 1-2 (Jan. 3, 2012) [hereinafter AHA Letter], available at <http://www.aha.org/advocacy-issues/letter/2012/120103-cl-cms-1439-ifc.pdf>.

173. *Id.* at 4.

174. GAO FINANCIAL INCENTIVE REPORT, *supra* note 133, at 36-37.

175. *Id.* at 36.

176. *Id.* at 37. The GAO found that the average cost for obtaining an advisory opinion ranges from \$15,000 to \$50,000, can take over a year to get a final determination, and requires an actual or contemplated business arrangement that is more than a mere hypothetical. *Id.* at 30-31.

177. See discussion *supra* Part III.C.

178. AHA Letter, *supra* note 172, at 1.

care coordination.”¹⁷⁹ In addition to the above finding indicating that providers are hesitating to rely on time-limited waivers, the GAO noted that not all health systems are eligible for or even willing to participate in federal demonstration projects for which they could receive a waiver.¹⁸⁰ For providers opting to experiment with financial incentive arrangements with private payers outside of the Medicare Shared Savings Program, the GAO cited significant risks and complications with structuring such arrangements because of the inevitable spillover into the Medicare patient population.¹⁸¹ Thus, while providers seek to operate private value-based payment arrangements within the existing Stark, anti-kickback, and CMP framework, the potential for liability in areas previously discussed still remains, with no protection offered by the fraud-and-abuse waivers.¹⁸²

It is now clear that the American health care system is at a crossroads. The government’s decision, as embodied in the ACA, to move toward value-based payment for health services is likely to continue at a growing pace in the coming years.¹⁸³ While the government deserves credit for moving away from the costly and ineffective fee-for-service reimbursement model, serious conflicts with the underlying regulatory framework remain and must be addressed. Regulatory waivers are a clear recognition of the current regulatory framework’s incompatibility with value-based payment design, but

179. *Id.*

180. GAO FINANCIAL INCENTIVE REPORT, *supra* note 133, at 37.

181. *See id.* at 22 (noting that legal experts found it “difficult to separate commercial patients from Medicare patients for the purposes of financial incentive programs” and that programs “limited to commercial patient populations may ‘spill over’ to Medicare patients”). Providers implementing ACO-type arrangements with private payers rely on the existing safe-harbor and exception framework, often using the employment exception to protect from inadvertent inclusion of Medicare patients in the shared savings program. *Id.* The number of health care providers who are able to take advantage of this protection through direct physician employment is, however, comparatively limited. In such instances, providers must rely on other ill-suited safe harbors and exceptions, such as the requirements for personal services arrangements and management contracts. *See* discussion *supra* Part III.A–B.

182. *See* discussion *supra* notes 166–170 (noting that protection by each of the fraud-and-abuse waivers is limited to providers who have a Medicare Shared Savings Program participation agreement on file or under review by CMS).

183. An article written by leading health policy experts recommends converting at least seventy-five percent of payments in every region to fee-for-service alternatives within the next ten years. Emanuel et al., *supra* note 127, at 950. This will inevitably include payments under the shared savings and bundled payment models that conflict with the existing regulatory limitations.

the waivers do not present the comprehensive, long-term solution that is required to speed the adoption of innovative payment methodologies both within and outside the Medicare program. Part V begins by exploring some of the immediate changes that CMS should consider under its existing waiver authority. It then moves to a discussion on the long-term regulatory options that legislators and policymakers should consider as value-based payment models become the new normal.

V. A NEW APPROACH TO REGULATING HEALTH CARE IN THE VALUE-BASED PAYMENT ERA

Regulatory waivers may provide a temporary means to achieving the desired end of paying for value, but the government's reliance on waivers should be simply that—temporary. The discriminatory effect that the current waivers have on providers who do not qualify for or choose not to participate in CMS-sanctioned demonstration projects is counterproductive to the goal of achieving broad participation in value-based payment models. CMS's ability to waive fraud-and-abuse provisions in order to achieve the integrated payment and referral relationships functions as a recognition that the existing regulations inhibit the necessary formation of those relationships and no longer reflect the priorities of preventing fraud and abuse in the modern era.

While it is unlikely that a wholesale elimination of these regulations is likely anytime in the near future, CMS must explore long-term alternatives that can provide certainty in how health care organizations can structure future financial and care delivery relationships. Future regulations should build on the approach taken in the Shared Savings Program and focus on preventing fraud and abuse through accountability and transparency using the expanded capabilities of health information technology.

A. *Interim Reforms for Immediate Consideration*

The GAO has noted that CMS's authority to issue waivers under provisions of the ACA is broader than its authority to promulgate new exceptions under the Stark law.¹⁸⁴ In order to create an exception to Stark, the proposed arrangement must present “no risk” of “program or patient abuse.”¹⁸⁵ As CMS concluded in 2008 with the proposed gainsharing exception, the “no risk” standard for new Stark exceptions in an era of experimentation and uncertainty often prevents large-scale changes from taking place.¹⁸⁶ Realizing that

184. GAO FINANCIAL INCENTIVE REPORT, *supra* note 133, at 18.

185. *Id.*

exceptions and safe harbors for the underlying regulatory framework are unlikely in this period of transition from fee for service to payment for value, CMS should instead focus on correcting the shortfalls with the current waiver process.

First, CMS should provide more certainty to providers participating in alternative payment models covered by fraud-and-abuse waiver authority by extending the waivers' coverage indefinitely, so long as providers continue to meet obligations specified in the participation agreement and the objectives set by CMS at the outset of the program. This was the position taken by the hospital industry¹⁸⁷ in response to CMS's promulgation of the IFC in November 2011,¹⁸⁸ however, CMS has not released any updated waiver language in response to these concerns.

Second, CMS should expand the coverage of waivers to other alternative payment programs and provide immediate guidance to providers through rulemaking. As of March 2013, CMS has not promulgated waiver language through rulemaking with respect to other demonstration programs that could potentially run afoul of the fraud-and-abuse regulations currently in force.¹⁸⁹ Providing guidance to organizational leaders contemplating participation in these innovative care delivery programs could minimize uncertainty without undue risk to the Medicare program. As part of the waiver language promulgated by CMS, the agency should provide guidance to providers who treat Medicare patients and are participating in value-based payment arrangements not sanctioned by CMS. As noted in Part IV, the risk that nonparticipating providers will run afoul of the Medicare fraud-and-abuse regulations while participating in private ACO-type arrangements has chilled the formation of innovative relationships across a large swath of organizations that may not be

186. *See id.* at 18–19 (noting that the “no risk” requirement for new Stark exceptions presented a “challenge in providing broad flexibility for innovative, effective programs while at the same time protecting the Medicare program and patients from abuses”).

187. *See* AHA Letter, *supra* note 172, at 2, 4 (noting that the Shared Savings Program waivers should be finalized in their current form and that changing the rules for organizations that seek to renew their contracts after meeting performance standards could undermine innovation and the development of new delivery models).

188. 76 Fed. Reg. 67,992 (Nov. 2, 2011) (to be codified at 42 C.F.R. ch. IV–V).

189. With respect to the Bundled Payments for Care Improvement Initiative, CMS has indicated that the Secretary may choose to exercise waiver authority provided in the ACA and that such waivers would be included in individual agreements with CMS. *See* BUNDLED PAYMENT FAQs, *supra* note 122, at 8–9. Broadly applicable and self-executing waivers similar to those in the Shared Savings Program promulgated through rulemaking, however, have not been published.

participating in the Medicare Shared Savings Program and subject to the expansive waivers it provides.

Third, after extending the scope of coverage under the waivers as recommended above, CMS should finalize the IFC and protect providers' reliance by indicating that future changes will proceed through notice and comment rulemaking and that changes will not retroactively apply to participation agreements already in effect. CMS should, however, retain the authority to modify the waiver with respect to individual entities if objectives of the Shared Savings Program are not met, or if fraud-and-abuse concerns necessitate modification or termination of the organization's participation agreement. Upon the expiration of participation agreements after the initial three-year ACO term, CMS should refrain from imposing changes on participating providers who were operating under the initial waiver language, unless individual circumstances require changes in the participation agreement to protect program integrity. As the AHA noted, seeking to impose changes on ACOs who have successfully achieved CMS's objectives could undermine the efforts providers have made to structure incentives and provider relationships.¹⁹⁰

These recommendations are, of course, only a temporary solution that will bridge the gap between a health care system moving toward value-based payments and a regulatory structure tailored to an antiquated fee-for-service model. As paying for value continues to gain traction, the government must recalibrate its approach to regulating fraud and abuse.

B. Ideas for Long-Term Regulatory Reform

As policy experts and government regulators contemplate future fraud and abuse protections, special consideration should be given to the effectiveness of the safeguards put in place during the initial phase of the Shared Savings Program. As part of their agreements with CMS, entities participating in the demonstration projects must agree to stringent reporting and compliance requirements that exceed the requirements placed on nonparticipating providers, likely as a result of the relaxed application of the fraud-and-abuse provisions. If this alternative to the existing regulatory framework is successful, Congress should consider, and CMS should provide guidance on, ways in which this alternative form of regulation could be expanded to all providers once value-based payments become the predominant form of health care reimbursement.

In order to maintain a participation agreement in good standing with CMS and benefit from the broadly worded regulatory waivers, providers must agree to expansive new quality reporting,

190. AHA Letter, *supra* note 172, at 4.

accountability, and transparency requirements.¹⁹¹ First, ACOs must establish or designate a legal structure with a governing body that can ensure management accountability and transparent compliance with quality performance standards.¹⁹² Second, the ACO must develop patient centered processes using evidence-based medicine and beneficiary engagement and integrate those processes into the organization's health care teams.¹⁹³ Third, the ACO must furnish data demonstrating adherence to quality of care metrics established by CMS, subject to a medical record audit and data validation.¹⁹⁴ Fourth, CMS is permitted to employ a range of methods to “monitor and assess the performance of ACOs,” including analysis of quality measurement data and beneficiary and provider complaints, coding audits, and electronic health record reviews.¹⁹⁵ Fifth, each ACO must publicly report information disclosing all joint venture agreements and members of the governing body, all shared savings and loss information, and aggregate data related to patient experiences and quality of care.¹⁹⁶ While ACOs are subject to many additional requirements, these major provisions are most instructive for discussing what policymakers should consider when formulating future fraud-and-abuse regulations.

The government's reliance on this form of regulation could be an important first step in moving away from the structural framework characterized by generally applicable safe harbors and exceptions to direct regulation of providers through contractual agreements requiring transparent and accountable care.¹⁹⁷ As increasing numbers

191. See GAO FINANCIAL INCENTIVE REPORT, *supra* note 133, at 33 (noting that an ACO's “continued participation in the Medicare Shared Savings Program is contingent on its performance” and CMS may “terminate an ACO's participation in the program based on the agency's findings”).

192. 42 C.F.R. §§ 425.104–425.106 (2012).

193. 42 C.F.R. § 425.112 (2012).

194. 42 C.F.R. § 425.500 (2012).

195. 42 C.F.R. § 425.316(a)(2) (2012). When read in conjunction with 42 C.F.R. § 425.506, where CMS strongly encourages providers to adopt electronic health record systems, the review of patient health records will require reviewing them in their electronic form. See 42 C.F.R. § 425.506 (noting that ACOs are “encouraged to develop a robust EHR infrastructure” and that “[p]erformance on [the quality measures regarding EHR adoption] will be weighted twice that of any other measure for scoring purposes and for determining compliance with quality performance requirements”).

196. 42 C.F.R. § 425.308 (2012).

197. This is an approach for which Professor Kristin Madison of the University of Pennsylvania Law School advocates. See Madison, *supra* note 42, at 422. Madison favors an approach that is less reliant on indirect structural regulation that attempts to micromanage the referral

of providers become “meaningful users” of electronic health record (EHR) technology, the prospect of adopting a framework of fraud-and-abuse regulation that relies on strict data reporting requirements becomes even more likely. Indeed, one of the provisions of the meaningful use regulations, which all providers must meet in order to qualify for federal financial assistance for EHR adoption under the HITECH Act,¹⁹⁸ is for providers to monitor a growing set of clinical quality measures (CQMs).¹⁹⁹ By expanding the quality reporting requirements under the meaningful use regulations and strongly encouraging the use of electronic health records going forward,²⁰⁰ the government can engage in a new form of fraud-and-abuse regulation that promotes the creation of integrated provider relationships yet still protects the Medicare program from fraud and abuse.

It is difficult to predict what role the anti-kickback statute, the Stark law, and the CMP statute will play in a health care system that relies on waivers from their expansive prohibitions in order to deliver coordinated and value-driven health care. Though it is difficult to predict the fate of these particular statutes, it is not impossible to glean some insight into how the government envisions the future of fraud-and-abuse regulation. In a recent article, Daniel Levinson, the Inspector General for HHS, hinted that certain provisions of these statutes might still be applicable for providers who violate the terms of the Shared Savings Program participation agreement and the associated waivers. Levinson mentioned that the government “retained authorities to redress identified problems,” that the “integrity requirements embedded into the SSP and the waivers would mitigate the risk of harm in the first instance, and that residual

relationships and compensation arrangements between providers. Instead, she favors expanding the use of information technology, especially electronic health record systems, to better discern the quality of care received by patients and tailoring payments to the value received by patients, as dictated by objective quality metrics. *Id.*

198. Health Information Technology for Economic and Clinical Health (HITECH) Act, Pub. L. No. 111-5, 123 Stat. 115 (2009) (codified as amended in scattered sections of 42 U.S.C.).
199. For fiscal year 2014, hospitals must begin to monitor twenty-four clinical quality metrics related to patient engagement, patient safety, care coordination, population and public health, efficient use of health care resources, and clinical processes and effectiveness using the electronic health record system. *See* Electronic Health Record Incentive Program Stage II, 77 Fed. Reg. 13,698, 13,759 (proposed Mar. 7, 2012) (to be codified at 42 C.F.R. §§ 412, 413, 495).
200. The HITECH Act mandates Medicare payment adjustments take effect in 2015 if providers have not become meaningful users of electronic health records, with exceptions for a narrow set of circumstances. *See id.* at 13,700–01 (describing payment adjustments and exceptions).

risk could be remediated through appropriate government action.”²⁰¹ For those who violate their contractual obligations, Levinson notes that the government may take action using “enforcement authorities that were not waived” and other “administrative tools”²⁰² to address “harms associated with kickbacks and referral payments, including overutilization, increased costs, and substandard or poor quality care.”²⁰³ Levinson’s comments indicate that the government may intend to rely on the safeguards in the participation agreements and waivers as a long-term policy solution. The statutes from which providers receive a waiver would seemingly remain in effect and, in conjunction with other non-waived provisions, namely the False Claims Act, function as a punitive backstop that applies once providers violate their participation agreement or the waiver requirements.

Parsing the words of government regulators may provide some indication of the future of the underlying statutes that comprise the fee-for-service regulatory framework, but little is known with certainty. Recent statements by the Inspector General indicate that the statutes will remain in place with undefined enforcement applicability. The extent to which the anti-kickback, Stark, and CMP statutes would serve a valuable purpose when other regulatory provisions, namely the False Claims Act, are capable of protecting against overutilization, increased costs, and substandard or poor quality care will certainly be debated in the future. What cannot be disputed now, however, is that waiving the applicability of these statutes more broadly in the short term is a necessary step during this period of transition. But, as the delivery model continues to shift toward integrated systems capable of delivering efficient, high quality care in the future, waivers will prove to be an increasingly inadequate and unreliable long-term policy solution. So, in contemplating post-fee-for-service fraud-and-abuse regulation, policymakers must recalibrate their approach by implementing a framework that reflects the incentives created by a value-based payment system and capitalizes on the new functionality of EHR data repositories.

CONCLUSION

The American health care system is undergoing rapid change that involves a shift from fee-for-service payment to value-based payment that depends heavily on care coordination and provider integration. Underlying this shift in payment methodologies is a regulatory

201. Daniel R. Levinson, *A New Era of Medicare Oversight*, 15 J. HEALTH CARE L. & POL’Y 249, 261 (2012).

202. *Id.*

203. *Id.* at 261 n.57 (quoting Final Waivers in Connection with the Shared Savings Program, 76 Fed. Reg. 67,992, 68,008 (2011)).

structure that was originally designed to tackle fraud-and-abuse schemes arising out of the fee-for-service payment system. The way Medicare pays for services is undergoing significant change, yet the fraud-and-abuse regulations inhibit developing integrated provider arrangements as part of value-based payment programs. Legislators provided some flexibility in the form of regulatory waivers that will allow for short-term experimentation and transition; however, the approach has several deficiencies that should be addressed in the near term. Going forward, the regulation of fraud and abuse in a health care system that is encouraging the development of larger, highly integrated care delivery systems must keep pace. A new regulatory framework must consider the changed incentives that have resulted from value-based payments and capitalize on the new capabilities that EHR systems offer in delivering high quality care.

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