As of late, healthcare reform is not just in the headlines—it is the headline. As the nation’s leaders debate comprehensive reform, many issues have risen to the surface. Among others is the growing consensus that meaningful healthcare reform requires payment reform.

This outline addresses different aspects of payment reform, with Part I giving a general overview of innovative payment arrangements, including bundled or episode payments, performance-based payments, and gainsharing; Part II listing certain select laws that might impact innovative payment arrangements, such as Stark, federal and stack kickback prohibitions, and the Medicare patient inducement prohibition; Part III highlighting certain payment reform pilot projects currently underway; and Part IV briefly presenting some of the issues and barriers to implementation on the frontier of payment reform, including healthcare warranties and possible legal incentives for providers who practice evidence-based medicine.

In evaluating payment reform models and issues, a September 2008 white paper from the Healthcare Financial Management Association (HFMA), *Healthcare Payment Reform: From Principles to Action*,\(^1\) enunciates five useful principles of an “ideal” payment system (condensed as follows):

- **Principle 1—Quality.** Payments should encourage and reward high-quality care and discourage medical errors and ineffective care.

\(^1\) Available at [http://www.hfma.org/library/reimbursement/paymentreform/400618.htm](http://www.hfma.org/library/reimbursement/paymentreform/400618.htm). The paper includes statements of support from the American Hospital Association, The Commonwealth Fund, DMAA: The Care Continuum Alliance, the Medical Group Management Association, and the National Business Group on Health.
• **Principle 2—Alignment.** Payments should align incentives among all stakeholders to maximize the efficiency and coordination of health services based on accepted practice and evidence-based delivery models and protocols.

• **Principle 3—Fairness/Sustainability.** Payment systems should sufficiently balance the needs and concerns of all stakeholders, and should be sustainable (*i.e.*, provide a stable funding stream in the face of competing claims on public and private capital).

• **Principle 4—Simplification.** Payment processes should be simplified, standard and transparent.

• **Principle 5—Societal Benefit.** The resources needed to support broad societal benefits, such as medical and public education, medical research, and care for disenfranchised or uninsured persons should be identified and paid for explicitly. Payment systems should reward innovators who develop technologies, services, and processes that enhance safe, high-quality, and efficient care.\(^2\)

I. Types of Innovative Payment Arrangements

A. Bundled Payments

1. Bundled payments fall along a large continuum, and include:

   a) “episode” payments—a single price for all the healthcare services needed by a patient for an entire episode of care—to individual or multiple providers; and

   b) comprehensive care payments (also called condition-adjusted or condition-specific capitation)—a single price for all the services needed by a specific patient for a specific health condition.

2. Pros and Cons of Bundled Payments

   a) Episode payments reduce the incentive to overuse unnecessary services during the episode of care, and allow providers flexibility in how to deliver care, but do not provide any incentive to reduce the number of unnecessary episodes of care.

   b) Comprehensive care payments may help reduce the number of unnecessary episodes of care for a particular condition or group, but place a great deal of risk on providers to control the efficiency of, and appropriately coordinate, the delivery of care (thus increasing the risk of that too few services will be provided).

3. *Example*—PROMETHEUS Model—PROMETHEUS subdivides the risk financed by the current health care marketplace into insurance or probability risk, the risk due to health status or genetics not controllable by the provider, and technical risk which is under the control of the provider and related to their clinical action and skills. An Evidence-informed Case Rate (ECR) is developed

\(^2\) *Id.* at 15–19.
for each patient in accordance with their clinical condition. In addition, an allowance is made for potentially avoidable complications (PACs) such as rehospitalizations, infections or errors. The allowance is 50 percent of the total cost of PACs and is intended to create an incentive for providers to improve because they can keep the difference between the allowance and their actual costs. It also provides an amount to provide care for complications that may occur. An ECR is constructed beginning with clinical guidelines, adjust for regional variations in practice patterns, add 10% for margin and finish with the PAC allowance. An episode is triggered by an event such as a diagnosis or admission and continues until broken or terminated. For chronic conditions a calendar year is used as the episode period. By using the bundled payment approach, the hope is to see care coordination improved. By using ECRs, the goal is to realign payment incentives to reward high quality, efficient care.

B. Performance-Based Payments

1. Pay-for-performance (also known as “P4P”) generally refers to a payment relationship where providers that meet certain quality metrics are either (1) selected by payers over non-qualifying providers for payer contracts or more favorable contract or participation terms; or (2) paid additional amounts in comparison to why non-qualifying providers are paid.

2. Pros and Cons of Performance-Based Payments

   a) P4P can help align incentives among different groups of providers, or between providers and payers. P4P is flexible and can be structured to offer incentive payments (“carrots”) or penalties (“sticks”).

   b) On the other hand, P4P does not fundamentally change what services are covered and, according to some critics, is not sustainable because after the initial savings have been achieved and shared, payers may not be able to continue P4P payments indefinitely. Likewise, providers may be discouraged from making large, multi-year investments in care improvements.

3. Legal Guidance— the OIG has approved one arrangement where a hospital would share with a physician owned entity certain performance based compensation available to the hospital under a quality and efficiency agreement with a private insurer.3

4. Example—PROMETHEUS Model—In response to the criticism that P4P does not go far enough to realigning incentives, PROMETHEUS examined six chronic diseases and, found that a substantial portion of the total cost of care is spent on PACs.

   a) As a solution, PROMETHEUS realigns incentives to encourage aggressive clinical care coordination around a practice built on evidence-based guidelines and solid patient decision support, with the goal of improving outcomes reducing costs.

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3 OIG Advisory Opinion 08-16 (Oct. 7, 2008).
b) PROMETHEUS Methodology—A patient-specific budget based on his or her condition and its relative severity is prepared. These budgets can be added across a specific patient population and serve as a global budget for the physicians caring for these patients irrespective of whether the physicians are incorporated in a system. The manner of payment may initially remain the same. Claims are accumulated against the prospective budget for each patient. At the end of the year, actual costs are reconciled to the budget and payments made accordingly. Because healthcare is complex and messy, unintended consequences of new ideas abound. For example, concern was expressed that there would be a tendency to under-deliver care or to “cherry pick” patients. In order to mitigate the first concern, a series of quality indicators tied to process and outcome measures has been included. In response to the second concern, the decision was made to rebase the PAC allowance in part to compensate providers for caring for patients with more complex decisions. It is important to note that quality thresholds must be met before any additional distributions are made.

5. Value-Based Purchasing (VBP)

a) Value-based purchasing (VBP) is another type of payment reform that links payment to performance. It goes beyond traditional P4P initiatives that offer incentives as reward for improved quality. VBP programs reward providers and suppliers for efficient as well as high quality service, and for publicly reporting performance information.

b) Under the mandate of the Deficit Reduction Act of 2005, CMS developed a VBP plan for hospitals and is in the process of creating a VBP plan for physicians and other professionals. VBP programs also include initiatives that prohibit paying hospitals for Hospital Acquired Conditions (HACs), and the National Coverage Determination that prohibits paying for other “Never Events.” VBP programs that are currently being discussed and explored nationally to correct the current misalignment of incentives include episode-based payments (discussed above).

C. Gainsharing or “Shared Savings”

1. Gainsharing generally refers to an arrangement in which a hospital gives its physicians a percentage share of any reduction in the hospital’s costs for patient care where such reductions result in part from the efforts of the physicians. “Shared savings” refers to similar arrangements between payers and providers.

2. Pros and Cons of Gainsharing

a) Like P4P, gainsharing and shared savings can help align incentives among different groups of providers, or between providers and payers.

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In addition, certain gainsharing arrangements have been blessed by the OIG through the advisory opinion process.

b) On the other hand, gainsharing does not fundamentally change what services are covered and might reward high spenders (who could waste fewer resources in order to benefit from gainsharing) rather than high performers (who might already have done everything possible to conserve resources).

3. Legal Guidance

a) On July 8, 1999, the OIG issued a Special Advisory Bulletin that first addressed the issue of gainsharing arrangements. Under federal law, gainsharing arrangements implicate at least three legal prohibitions (all discussed below): (1) the Stark Law; (2) the federal anti-kickback statute; and (3) the federal civil monetary penalty statute for reducing or limiting care to Medicare and Medicaid beneficiaries (“CMP Statute”).

b) Since that date, the OIG has issued a number of opinions examining various gainsharing arrangements. In each of these opinions, the OIG has mentioned both mitigating and aggravating features of the arrangements that might weigh for or against the permissibility of the arrangements under federal law.

II. Select Laws Applicable to Payment Reform

A. The Stark Law

1. Overview—the Stark Law prohibits physicians from referring Medicare and Medicaid patients for certain “designated health services” (“DHS”) reimbursable by the Medicare or Medicaid programs to entities with which the physicians (or their immediate family members) have a financial relationship. A financial relationship may be an ownership interest or a compensation arrangement, and may be direct or indirect. The Stark Law creates an absolute ban, unless the nature of the financial relationship or the venue and manner of delivering the service falls within one of the law’s exceptions.

2. Penalties—the Stark Law requires a provider to timely refund payments received as the result of a prohibited referral, establishes civil money penalties of $15,000 for each instance in which a timely refund is not made or a claim is submitted for services that the provider knew or should have known were furnished pursuant to the prohibited referral. A $100,000 penalty may be

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7 42 U.S.C. § 1395.
assessed for circumvention schemes, and violators may be subject to exclusion from the Medicare and Medicaid programs.⁸

3. **Payment Reform Exceptions**—CMS has proposed a specific exception to the Stark Law for properly structured, non-abusive incentive payment and shared savings (i.e. “gainsharing”) programs. Of particular concern from a fraud and abuse perspective is the sharing of total (or global) savings for a particular department or service line without individually-tracked and measured performance measures, a cornerstone of the programs that have received favorable OIG advisory opinions to date.⁹ CMS sought comments on the extent to which “stand alone” exceptions for incentive payment and shared savings programs is necessary given the exceptions for personal service arrangements, arrangements involving fair market value compensation, arrangements involving indirection compensation, bona fide employment relationships and academic medical centers.¹⁰ CMS further sought comments on whether it would be preferable to modify aspect of the existing exceptions to protect a broader range of beneficial, non-abusive incentive payment and shared savings programs.¹¹

B. **Federal and State Anti-Kickback Statutes**

1. **Overview**—the federal anti-kickback statute prohibits the offer, payment, solicitation, or receipt of any remuneration, directly or indirectly, covertly or overtly, in cash or kind: (1) in return for the referral of patients, or arranging for the referral of patients, for the provision of items or services for which payment may be made under any federally-funded healthcare program other than the Federal Employee Health Benefit Program (“Federal Government Programs”); or (2) in return for the purchase, lease or order, or arranging for the purchase, lease, or order, of any good, facility, service, or item for which payment may be made under the Federal Government Programs.¹² The statute has been interpreted to cover any arrangement where even one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals.

2. **Safe Harbors**—under the federal statute, the OIG has promulgated “safe harbors” that define practices that are not subject to penalty.¹³ Although arrangements that fall outside a safe harbor are not necessarily unlawful, arrangements that satisfy all the conditions of a particular safe harbor protect the parties from criminal or civil penalties. One safe harbor that might be applicable to certain payment reforms is the personal services safe harbor. This safe harbor requires, among other things, that the compensation paid for the personal services be set in advance. In examining certain gainsharing arrangements, however, the OIG has concluded that the personal services safe harbor would not be applicable because the proposed arrangements paid the physicians on a percentage basis and thus compensation was not set in advance.

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⁸ Id. § 1395(g).
⁹ 73 Fed. Reg. 69,698 (November 19, 2008).
¹⁰ Id.
¹¹ Id.
¹² 42 U.S.C. § 1320a-7b(b).
¹³ See 42 C.F.R. § 1001.952.
3. **Penalties**—violation of the statute constitutes a felony punishable by a maximum fine of $25,000, imprisonment for up to five years, or both, as well as automatic exclusion from the Federal Government Programs.

4. **State Law**—some states also enacted an “all payer” anti-kickback prohibition. For example, the Texas statute prohibits any remuneration paid between parties for “the securing or soliciting [of] a patient or patronage for or from a person licensed . . . by a state healthcare regulatory agency.” Violation of the Texas statute is a Class A misdemeanor and grounds for disciplinary action by the state agency that issued the hospital’s license, certification, or registration. In addition, both parties to the prohibited arrangement are subject to civil penalties of not more than $10,000 for each day of violation and each act of violation. Importantly, the Texas statute defers to the standards of the federal statute and its safe harbors.

C. Medicare Patient Inducement Prohibition (CMP Statute)

1. **Overview**—the federal Civil Monetary Penalty (“CMP”) statute establishes a civil monetary penalty against any hospital that knowingly makes a payment directly or indirectly to a physician (and any physician that receives such a payment) as an inducement to reduce or limit items or services to Medicare or Medicaid beneficiaries under the physician’s direct care.

2. **Penalties**—hospitals that make, and physicians that receive, such payments are liable for penalties of up to $2,000 per patient covered by the payments.

### III. Select Payment Reform Pilot Projects

#### A. Medicare Acute Care Episode (ACE) Demonstration (Bundled Payments)

1. **ACE** is a new hospital-based demonstration that will test the use of a bundled payment for both hospital and physician services for a select set of inpatient episodes of care to improve the quality of care delivered through Medicare fee-for-service. In this demonstration, CMS announced in January 2009 that five hospitals will participate in a project in which they are paid global fees for cardiac and/or orthopedic procedures, meaning that they will be paid a single fee for the hospital facility fee and for all of the physician fees, including the surgeon, any consulting physicians, radiologists, anesthesiologists, and other physicians/practitioners included in the care of the patient.

2. The five participating hospitals are: (1) Baptist Health System in San Antonio, Texas; (2) Oklahoma Heart Hospital LLC in Oklahoma City, Oklahoma; (3) Exempla Saint Joseph Hospital in Denver, Colorado; (4) Hillcrest

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15 Id. § 102.010.
17 42 U.S.C. § 1320a-7a(b)(1).
18 Id. § 1320a-7a(b)(2).
Medical Center in Tulsa, Oklahoma; and (5) Lovelace Health System in Albuquerque, New Mexico.

B. Medicare Physician Group Practice (PGP) Demonstration (P4P)

1. The PGP Demonstration is Medicare’s first pay-for-performance initiative for physicians. The five-year demonstration created incentives for physician groups to coordinate the overall care delivered to Medicare patients, rewarded them for improving the quality and cost efficiency of health care services, and created a framework to collaborate with providers to the advantage of Medicare beneficiaries.

2. CMS rewards participating physician groups for improving patient outcomes by proactively coordinating their patients’ total health care needs, especially for beneficiaries with chronic illness, multiple co-morbidities, and transitioning care settings. Participating physician groups are paid under regular Medicare fee schedules and may share in savings by earning performance payments of up to 80% of the savings they generate. Performance payments are divided between cost efficiency for generating savings and performance on 32 quality measures phased in during the demonstration. As quality measures were added in performance years two and three, the quality portion has increased so that in the third performance year 50% of any performance payment is for cost efficiency and 50% is for achieving national benchmarks or improvement targets on quality.

3. In August 2009, CMS announced that all 10 of the participating physician groups achieved benchmark performance on at least 28 of the 32 measures reported in year three of the demonstration. As a result, five of the groups will receive performance payments totaling $25.3 million as part of their share of $32.3 million of savings generated in performance year 3.

4. The 10 participating physician groups are: (1) Billings Clinic, Billings, Montana; (2) Dartmouth-Hitchcock Clinic, Bedford, New Hampshire; (3) The Everett Clinic, Everett, Washington; (4) Forsyth Medical Group, Winston-Salem, North Carolina; (5) Geisinger Clinic, Danville, Pennsylvania; (6) Marshfield Clinic, Marshfield, Wisconsin; (7) Middlesex Health System, Middletown, Connecticut; (8) Park Nicollet Health Services, St. Louis Park, Minnesota; (9) St. John’s Health System, Springfield, Missouri; and (10) University of Michigan Faculty Group Practice, Ann Arbor, Michigan.

C. Medicare Premier Hospital Quality Incentive Demonstration (VBP)

1. This demonstration is a CMS partnership with Premier, Inc., a nationwide organization of not-for-profit hospitals, and rewards participating top performing hospitals by increasing their payment for Medicare patients.20

2. The demonstration began in 2003 to improve the quality of inpatient care for Medicare beneficiaries by paying financial incentives to approximately 250

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20 Fact Sheet, Centers for Medicare and Medicaid Services, Premier Hospital Quality Incentive Demonstration (July 2009), available at http://www.cms.hhs.gov/HospitalQualityInits/downloads/HospitalPremierFactSheet200907.pdf.
hospitals for high quality care measured using quality measures related to five clinical conditions (acute myocardial infarction, coronary artery bypass graph, heart failure, pneumonia, heart, and knee replacement). Hospitals scoring on the top ten percent for a given set of quality measures receive a 2 percent bonus payment on top of the standard DRG payment for the relevant discharges. Those scoring in the next highest 10 percent receive a 1 percent bonus.

3. In August 2009, CMS announced that participating hospitals had raised overall quality by an average of 17 percentage points over four years, based on their performance on more than 30 nationally standardized and widely accepted care measures for patients in the five clinical areas. CMS awarded incentive payments totaling $12 million in year four to 225 hospitals for top performance, top improvements and overall attainment in the five clinical areas. After the initial three years of the demonstration, CMS extended the project for three additional years to test new incentive models and ways to improve patient care.

D. Medicare Hospital Gainsharing Demonstration Program (Gainsharing)

1. Section 5007 of the Deficit Reduction Act of 2005 (DRA) authorizes a gainsharing demonstration program to test and evaluate arrangements between hospitals and physicians designed to improve the quality and efficiency of care provided to beneficiaries. The demonstration will allow hospitals to provide gainsharing payments to physicians that represent solely a share of the savings incurred as a result of collaborative efforts to improve overall quality and efficiency. The demonstration will determine if gainsharing aligns incentives between hospitals and physicians in order to improve the quality and efficiency of inpatient care, and to improve hospital operational and financial performance.

2. This project began October 1, 2008 and will end as mandated on December 31, 2009. CMS is operating two projects, each consisting of one hospital located in New York and West Virginia. Hospitals receiving payment under the Medicare prospective payment system are eligible to participate in this project.

E. Medicare Physician-Hospital Collaboration Demonstration (Gainsharing)

1. In 2006, CMS announced a three-year Physician-Hospital Collaboration Demonstration to examine the effects of a gainsharing program where the hospital would be paid its usual inpatient rate for the patient’s care, but would pay to the physician a portion of the savings resulting from quality improvement and efficiency initiatives taken by the physician. Such incentive payments would only be allowed for documented, significant improvements in quality of care and savings in the overall costs of care.

2. The program is intended to focus on the entire scope of healthcare for a surgical episode or other episode of illness involving hospital care. It will

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encompass physician groups and up to 72 hospitals in a limited number of geographic areas across the country, and will test whether financial incentives from hospital payments to their physicians for quality and efficiency improvement can increase quality while reducing hospitals’ and Medicare costs. For example, incentive payments to surgeons for achieving lower infection rates and fewer readmissions with complications could both improve patient outcomes and lower overall hospital and Medicare costs.

IV. Select Related Issues and Barriers to Implementation

A. Barriers to Implementation of Payment Reform

1. Bundled Payments

   a) What would be included in a bundled payment?

      (1) Bundled payments can include different periods of time.

      (2) Bundled payments can include varying ranges of providers and services.

   b) How would a transition to bundled payments work?

      One proposed sequence of transitions includes: paying all providers a single fee for an episode of care (such as one fee for a hospitalization event), including a “warranty” with each episode payment (see IV.B below), allowing gainsharing between providers during an episode of care, bundling payments for a particular phase of an episode, combining payments for different providers in different phases.23

   c) Potential Challenges—just a few of the challenges raised in the payment reform context include:

      (1) assigning responsibility for preventive care and coordination of care;

      (2) disincentives for complicated cases;

      (3) infrastructure needed for proper care coordination;

      (4) agreement on evidence-based standards; and

      (5) non-compliant patients.24

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24 Healthcare Payment Reform, supra note 1, at 23–25.
B. Healthcare Warranties

1. Could healthcare come with a warranty?
   
a) Traditionally, warranty law is limited to consumer products. For example, the Magnuson-Moss Warranty Act, the federal law governing warranties on consumer products, does not extend to warranties on services.

   b) In addition, if you do not offer a written warranty, the law in most states allows you to disclaim implied warranties (such as the implied warranties of merchantability or fitness for a particular purpose).

2. In the context of payment reform, bundled payments would be one form of creating a healthcare warranty. For healthcare warranties to be viable, the payment reform system will have to carefully separate those failures for which providers should be responsible for (and thus covered by the warranty) and those failures which should be beyond the scope of the warranty.25

C. Malpractice Reforms

1. Some have proposed malpractice reform in conjunction with payment reform. For example, perhaps physicians that adhere to evidence-based guidelines could be offered a statutory defense to malpractice.

2. In his September 9 speech to Congress, President Obama acknowledged that fear of malpractice could be contributing to rising healthcare costs, and promised to move on medical malpractice reform. Specifically, the president has authorized the Health and Human Services Department to set up a grant program for state pilot projects that focus on ways to reduce costs stemming from patients’ lawsuits against medical professionals, including early disclosure programs (that encourage physicians to reveal mistakes sooner and apologize if appropriate) or certificate-of-merit programs (to evaluate the merit of individual suits).

3. Is malpractice a sufficient cost driver for malpractice reform to be an effective motivator? The Congressional Budget Office has estimated that medical malpractice costs—which include defensive medicine—amount to less than 2% of overall healthcare spending.26

25 See Pauline W. Chen, New York Times, Can Health Care Come With a Warranty? (June 25, 2009); see also Francois de Brantes et al., Should Health Care Come With a Warranty?, 28 Health Affairs 678 (June 2009); Francois de Brantes et al., Building a Bridge from Fragmentation to Accountability—The Prometheus Payment Model, New England Journal of Medicine (Sept. 10, 2009);

26 http://www.cbo.gov/doc.cfm?index=4968&type=0.