



THE HEALTH LAWYER

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MEDICARE PAYMENT REFORM: ACCELERATING THE TRANSFORMATION OF THE U.S. HEALTHCARE DELIVERY SYSTEM AND NEED FOR NEW STRATEGIC PROVIDER ALLIANCES

Maria T. Currier, Esq.
Holland & Knight, Miami, FL

Morris H. Miller, Esq.
Holland & Knight, Tallahassee, FL

Unsustainable growth in Medicare spending and inefficiencies in the current Medicare fee-for-service payment system have prompted calls to transform the Medicare payment model from one based on rewarding volume to a system that pays for quality and favorable outcomes. Congress is hearing consistent messages from the Medicare Trustees,¹ the Medicare Payment Advisory Commission² and the Government Accountability Office³ that the fee-for-service model is flawed and that Medicare must rethink its payment methodology.

The 2009 Medicare Trustees Report paints a dire picture of Medicare’s fiscal state. The report estimates that the Hospital Insurance fund that supports Medicare Part A will become insolvent by 2017. The Trustees warn that addressing this problem will require significant changes to program income and expenses. The Trustees estimate that

expenses under Part B of the Supplementary Medical Insurance Trust Fund, which pays doctors’ bills and other outpatient expenses, will exceed projections, resulting in the need for increased beneficiary premiums and additional funding from general revenues. In the report the Trustees call on Medicare “to transform the program from being a passive bill-payer to an active purchaser of healthcare.”⁴

Recent Congressional action toward adoption of payment reform legislation has been influenced largely by the recommendations of the Medicare Payment Advisory Commission (“MedPAC”). MedPAC is an independent Congressional agency established by the Balanced Budget Act of 1997 (P.L. 105-33) to advise Congress on issues affecting the Medicare program.⁵ MedPAC has been critical of the fee-for-service system, which pays providers largely based on the volume of services provided. MedPAC holds the current model partially responsible for the fiscal challenges now facing Medicare. Specifically, MedPAC has concluded

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Today, as I write this, the tortured travails of healthcare reform continue. Will it pass or will it fail? The odds must have changed at least 20 times in the last six months. Now, in another ironic twist a special election in Massachusetts has substantially reduced the likelihood of passage. Somehow, it is in total keeping with the almost absurd

history of this legislation that the state which elected Ted Kennedy, perhaps the most consistent advocate of healthcare reform in the last 50 years, elected a replacement who may condemn Kennedy's final effort to failure. Additionally, the health insurance system espoused by the reform bill, which apparently many people in Massachusetts opposed in this election, is already in place in Massachusetts and is fairly popular. Elmore Leonard could not make this stuff up. The news from DC is full of conflicting rumors. Some Democrats are working behind the scene to get the Senate bill passed without change by the House. Others are ridiculing this idea and suggest pushing a pared down bill. Another scenario is finding parts of the bill which can pass and then moving them through Congress in individual bills. The drama continues with speculative guesses about what Olympia Snow or Susan Collins will do. Might they be persuadable if the bill is revised and reconsidered?

This uncertainty is nothing new for the healthcare lawyer. The last 30 years have been filled with twists and reversals. Managed care, physician practice management companies, capitation, and the dominance of primary care were passing trends, but required enormous new learning or healthcare lawyers. Whatever the outcome of this legislative episode, the contents of the bills are crucial information to the healthcare bar. If the legislation passes, healthcare lawyers must be prepared to negotiate what will be the most complex social reform in their lives. If, as is more likely, the bill fails, many provisions of this bill will likely become stand-alone legislation or will be part of a pared down bill that has a better chance of passing. Although there were many subtle differences in the Senate and the House versions, they are more alike than they are different. When these bills are examined closely one can quickly determine the most likely direction of healthcare legislation and regulation over the next five years.

The reform bills are an amazing cornucopia of ideas, programs and institutions. For example, did you know that there is a provision that requires employers to maintain a private place for women to nurse their babies? Did you know that both bills allow retainer medicine practices to participate in the insurance exchanges? (This is the first

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2009-2010 Officers and Council of the ABA Health Law Section are as follows:

Chair
David W. Hilgers
Brown McCarroll, LLP
 Austin, TX
 512/476-4716
 dhilgers@mailbmc.com

Chair-Elect
Linda A. Baumann
Arent Fox, LLC
 Washington, DC
 202/857-6239
 baumann.linda@arentfox.com

Vice Chair
David H. Johnson
Banerman & Williams PA
 Albuquerque, NM
 505/837-1900
 dhj@nmcounsel.com

Section Delegates to the House of Delegates
Gregory L. Pemberton
Ice Miller
 Indianapolis, IN
 317/236-2313
 gregory.pemberton@icemiller.com

Michael E. Clark
Hamel Bowers & Clark, LLP
 Houston, TX
 713/869-0557
 mclark@hbctrial.com
 clark@hal-pc.org

Thomas E. Dowdell
Fulbright & Jaworski LLP
 Washington, DC
 202/662-4503
 tdowdell@fulbright.com

Robert W. Friz
PricewaterhouseCoopers LLP
 Philadelphia, PA
 267/330-6248
 robert.w.friz@us.pwc.com

Young Lawyer Division
Christi Braun
Ober Kaler Grimes & Shriver
 Washington, DC
 202/326-5046
 cjbraun@ober.com

Board of Governors Liaison
R. Kinnan Golemon
KG Strategies, LLC
 Austin, TX
 512/479-9707
 kg@kgstrategies.com

William W. Horton
Haskell Slaughter Young & Rediker, LLC
 Birmingham, AL
 205/254-1448
 www@hsy.com

Priscilla D. Keith
Health & Hospital Corp. of Marion County
 Indianapolis, IN
 317/221-3136
 pkeith@hhcorp.org

Alexandra Hien McCombs
Pinnacle Partners in Medicine
 Dallas, TX
 972/663-8552
 amccombs@pinnaclepartnersmed.com

Section Director
Jill C. Peña
American Bar Association
 321 N. Clark Street
 Chicago, IL 60654-7598
 T: 312/988-5548 F: 312/988-9764
 jillpena@staff.abanet.org

Secretary
David L. Douglass
Shook Hardy & Bacon
 Washington, DC
 202/662-4861
 ddouglass@shb.com

Finance Officer
Daniel A. Cody
Reed Smith LLP
 San Francisco, CA
 415/659-5909
 dcody@reedsmith.com

Immediate Past Chair
Vickie Yates Brown
Frost Brown Todd LLC
 Louisville, KY
 502/779-8189
 vvbrown@fbtlaw.com

J. A. (Tony) Patterson, Jr.
Fulbright & Jaworski, LLP
 Houston, TX
 214/855-8036
 japatterson@fulbright.com

Robert R. Nelson
Avera Health
 Sioux Falls, SD
 605/322-4607
 robert.nelson@avera.org

Charity Scott
Georgia State University College of Law
 Atlanta, GA
 cscott@gsu.edu

Kathleen Scully-Hayes
Social Security Administration
 Baltimore, MD
 kathleen.scully-hayes@ssa.gov

Publication Chair
Lisa L. Dahm
South Texas College of Law
 Houston, TX
 713/646-1873
 ldahm@stcl.edu

The Health Lawyer Editor
Marla Durben Hirsch
Potomac, Maryland
 301/299-6155
 mdhirsch@comcast.net

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that the fee-for-service system discourages efficient use of resources because it rewards more care or a level of care that is more intensive or expensive than necessary and does not reward higher quality of care. Additionally, MedPAC views the Medicare design of separate payment systems for physicians, inpatient care, and post-acute care as discouraging efficiency.⁶ In its June 2009 Report to Congress, MedPAC encouraged Congress to implement reforms that address these deficiencies. MedPAC described an ideal payment system as one that would encapsulate multiple providers and procedures and cover specific periods of time rather than specific visits or interventions. This system also would hold providers accountable for the quality of care provided and the resources used.⁷

The fundamental Medicare payment reforms being considered today are unprecedented in scope and complexity. For the first time, policy makers are proposing a move away from the historically separate Medicare payment silos for physician, hospital, and post-acute care toward bundled payment models designed to improve coordination, quality, and efficiency of care. During the next few years, the Medicare program will complete pilot programs to test the efficacy of these proposed payment reforms.⁸ The passage of a healthcare reform bill by Congress will further encourage or require the testing and implementation of such reforms. Some of the proposed reforms will lead to the development of new business relationships among acute-care hospitals, physicians and other practitioners, and providers of post-acute care. Some of these business relationships will raise challenging issues under anti-kick-back, patient self-referral, antitrust, and other laws.

This article discusses some of the proposed Medicare payment reforms and demonstration projects that are receiving particular attention among policy makers and the Centers for Medicare and Medicaid Services (“CMS”). These

reforms include the bundling of Medicare payments for acute care with payments for post-acute and physician services, the use of accountable-care organizations (“ACOs”), the development of medical home delivery models, and shared savings arrangements. This article also discusses some of the organizational and legal implications of such reforms on healthcare providers.⁹

Bundling Payments – Moving from Volume to Value

A payment for healthcare services may be called “bundled” when a single payment covers multiple services. In one form or another, “bundling” of payments has long been used as a means of encouraging efficiency and containing costs. For example, under the Medicare Part A prospective payment system, a hospital receives a single payment for all Part A services provided during an inpatient stay, based on diagnosis-related groups, and a skilled nursing facility receives a single payment, based on resource utilization groups, for all routine and ancillary services provided to a skilled nursing resident. Medicare Advantage Plans and private payers under other managed care plans pay some providers periodic capitation payments to compensate for all covered services provided to plan enrollees, regardless of the volume of services provided.

Additional variations of bundling have been at the center of recent discussions of Medicare payment reform. For example, in its June 2008 Report to the Congress, entitled “Reforming the Delivery System,”¹⁰ MedPAC proposed that Congress should require the Secretary of the Department of Health and Human Services (“HHS”) to create a voluntary pilot program to test the feasibility of bundled payments for services provided during and within a defined period of time (such as 30 days)

after a hospital stay. The bundling of payments for short-term, acute-care hospital services and post-acute care services also was one of 115 options presented in the Congressional Budget Office (“CBO”) “Report on Budget Options”¹¹ for reducing (or in some cases increasing) federal spending on healthcare and for otherwise changing federal healthcare programs and the nation’s health insurance system. In a speech to the American Medical Association in June 2009, President Obama proposed the bundling of hospital and physician payments.¹² Proponents of such bundled payment arrangements believe that they would create incentives to reduce the volume of marginal or unnecessary services that do not improve patient care outcomes but drive up the cost of healthcare.

Bundling of Payments for Acute Care and Post-Acute Care Provider Services

Under the CBO’s proposal for bundling payments for acute-care and post-acute care services, acute-care hospitals would receive a single, bundled payment covering both the services provided during an acute-care hospital stay and post-acute-care services received or initiated during a period of time (the CBO proposes 30 days) following the patient’s discharge from the hospital.¹³ The single payment would cover such services in a variety of post-acute settings, including skilled nursing facilities, home health agencies, inpatient and outpatient rehabilitation facilities, and long-term care hospitals. The acute care hospital would receive the full bundled payment, regardless of whether the patient ever received post-acute care, and Medicare would not make separate payments for the post-acute services. The hospital receiving the bundled payment would provide the post-acute care directly or under contract with a post-acute care provider. Presumably, because the hospital retains whatever portion of the bundled

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payment it is not required to pay for post-acute care, the bundling of the payment would provide the hospital an incentive to limit the provision of care in a post-acute setting. The CBO report states that savings could occur through reductions in the volume or intensity of post-acute care or through the hospital's contracting with lower cost providers of such care.¹⁴

Under the CBO's model, it is not clear how the incentive created by a bundled payment to the hospital would translate into an incentive to treating physicians to avoid unnecessary referrals for post-acute care. Accordingly, to the extent that a patient's physician, rather than the hospital, controls or influences decisions concerning the patient's need for post-acute care, it is unclear how the hospital could effectively control the volume of post-acute services unless the hospital's and referring physicians' incentives were closely aligned or the hospital were able to establish and enforce, through contracts with post-acute providers, clinical protocols and standards to determine whether post-acute care is necessary or appropriate and whether, on that basis, a post-acute care provider would be entitled to share in the bundled payment with respect to a particular patient's episode of care.

Absent effective integration of the referring physicians with the hospital and clear standards that are acceptable to the physicians and the hospital concerning the medical necessity or appropriateness of post-acute services, the effectiveness of bundling as a means of containing costs of post-acute services may depend on whether the hospital has the legal and contractual authority to deny payments to post-acute-care providers that provide services which, based on the hospital's standards, are not medically necessary or appropriate and would not contribute sufficiently to the patient's recovery.

Bundling of Payments for Acute Care and Physicians' Services

As an alternative or in addition to bundling of payments for acute and post-acute care, the CBO and MedPAC reports discuss the bundling of payments for acute-care hospital services and physician services provided to a patient during and after an inpatient hospital stay.¹⁵ Under this form of bundling, the hospital would receive a single payment to cover both hospital and physician services relating to a particular diagnostic related group ("DRG");¹⁶ a portion of the payment would be intended to cover the cost of physicians' services during the inpatient stay and, possibly, during a period of time following the inpatient stay. The goal of bundling payments would be to align hospital and physician incentives to encourage greater coordination of care, improve the quality of care, and contain costs by such avenues as reducing unnecessary usage of resources, eliminating unnecessary patient admissions and re-admissions, avoiding unnecessary physician consultations, and avoiding unnecessary or excessively expensive post-acute services.

CMS currently has underway the Acute Care Episode ("ACE") Demonstration, a three-year project to test the use of bundled payments covering all Part A and Part B services, including physician services, pertaining to an inpatient stay for certain cardiovascular and orthopedic procedures.¹⁷ CMS has selected five sites for the demonstration: two in Oklahoma and one each in Colorado, New Mexico, and Texas. The goal of the demonstration is to better align the incentives for hospitals and physicians, leading to better quality and greater efficiency in the care that is delivered.

Notwithstanding the quality improvement and cost containment goals that might be achieved through bundling, the implementation of

bundled payment systems would be complex and challenging for both the Medicare program and the hospitals that would be required to administer the bundled payment system, and the actual effect on cost is uncertain. A bundling system could create incentives to increase costs as well as incentives to reduce costs. For example, MedPAC has pointed out that a potential challenge to achieving cost savings through a bundled payment system is that it could create a new incentive for physicians to increase hospital admissions.¹⁸ In view of the unintended consequences that could result from bundling, MedPAC proposed that its recommended pilot program be conducted incrementally over a period of time, so that HHS can determine whether a bundling system could be implemented in a manner that would achieve its quality and cost-containment goals while avoiding unintended and undesirable consequences.¹⁹

Bundling Programs under the Health Reform Legislation

The separate healthcare reform bills recently adopted by the Senate and the House of Representatives contain bundling provisions similar to those contained in the MedPAC and CBO proposals. The Patient Protection and Affordable Care Act²⁰ (the "Senate Bill") calls for the Secretary of HHS to establish, by January 1, 2013, a five-year pilot program for integrated care in order to improve the coordination, quality, and efficiency of healthcare services. The bill authorizes the Secretary to use bundled payments covering the costs of "applicable services" and other appropriate services (such as care coordination, medication reconciliation, discharge planning, transitional care services, and other patient-centered activities as determined appropriate by the Secretary) furnished to a Medicare beneficiary during an episode of care.²¹ An "episode

of care” is defined, with respect to an “applicable condition” and an applicable beneficiary, as the period that includes (a) the three days prior to the admission of the applicable beneficiary to a hospital for the applicable condition; (b) the length of stay of the applicable beneficiary in the hospital; and (c) the 30 days following the discharge of the applicable beneficiary from the hospital.²²

The Senate Bill defines “applicable condition” as one or more of eight medical or surgical conditions selected by the Secretary. The term “applicable services” means (i) acute care inpatient services; (ii) physicians’ services delivered in and outside an acute care hospital setting; (iii) outpatient hospital services, including emergency department services; (iv) post-acute care services, including home health services, skilled nursing services, inpatient rehabilitation services, and inpatient hospital services furnished by a long-term care hospital; and (v) other services the Secretary determines appropriate. The bill calls for the Secretary to establish quality measures related to care provided by entities participating in the pilot program and to conduct an independent evaluation of the pilot program, including the extent to which the pilot program (1) improves quality measures; (2) improves health outcomes; (3) improves access to care; and (4) reduces spending.²³

The Affordable Health Care for America Act²⁴ (the “House Bill”) calls for the Secretary to develop a detailed plan to reform payment for post acute care services under the Medicare program, including detailed specifications for a bundled payment for post acute services. Although the House Bill focuses on bundling of payment for acute and post-acute care services, it calls for the Secretary to consider whether payment for services of physicians and other categories of providers should be included in the bundle. The House Bill also calls for the Secretary, by January 1, 2011, to convert the ACE demonstration program to a pilot program and to expand that

program to include post acute services and other services that the Secretary determines to be appropriate.²⁵ This provision of the bill authorizes the Secretary to apply bundled payments with respect to hospitals and physicians; hospitals and post-acute care providers; hospitals, physicians, and post-acute care providers; or combinations of post-acute providers.²⁶

Accountable-Care Organizations – The New Integration Model

MedPAC’s Report on ACOs

Another new delivery model that expands on the Medicare payment bundling concept can be found in the use of ACOs. In its June 2009 Report to Congress, MedPAC reported on ways that ACOs could affect the growth in volume of healthcare services through incentives for providers to produce high-quality, well-coordinated healthcare while containing growth in the cost of such services.²⁷ As presented in the MedPAC report, an ACO consists of primary care physicians, specialists, and at least one hospital and can be operated under a variety of organizational forms, such as an integrated delivery system, a physician-hospital organization (“PHO”), an academic medical center, a hospital plus multi-specialty groups, and a hospital teamed with independent practices.²⁸ The defining characteristic of an ACO, under the MedPAC model, is that a set of physicians and hospitals “accept joint responsibility for the quality of care and the cost of care received by the ACO’s panel of patients.”²⁹

Medicare would agree to pay the ACO a bonus for achieving quality goals while reducing the volume of unnecessary services, thereby reducing overall cost to the Medicare program. An ACO that achieves both quality and cost-saving goals would receive a bonus. In some cases, an ACO that failed to achieve such goals could be penalized. The presumption is that, by making providers jointly responsible for the

achievement of quality and cost goals and by centralizing authority to make decisions on behalf of all the participating providers, an ACO would improve coordination of care and reduce duplication of services, thereby improving quality while containing growth in cost.³⁰

Although MedPAC concluded that ACOs had the potential to address some of the limitations of the fee-for-service payment system, during public discussions held prior to the release of its report MedPAC acknowledged that the actual implementation of an ACO was fraught with significant technical challenges. A major design challenge identified by MedPAC was barring beneficiaries from going outside the ACO to access care. Aligning an ACO with a medical home (discussed below) may address this problem, but MedPAC concluded that an ACO operating independently would be difficult to implement.³¹

According to MedPAC, an effective ACO would need to be relatively large – including at least one hospital and 50 physicians serving at least 5,000 patients – and would need an organizational structure that allowed joint decisions on behalf of the organization as a whole so that the ACO could implement quality-improvement and cost-containment strategies.³² Obviously, existing integrated delivery systems, PHOs, and similar highly-integrated organizations of hospitals and physicians would have a head start over independent physicians and physician groups in positioning themselves to operate successfully as an ACO. To participate in an ACO, individual physicians and small group practices that are not already a part of a large, integrated organization would need to affiliate in some way with a larger organization and likely would lose some of their autonomy in doing so.

The 2009 MedPAC report considers both voluntary and mandatory ACOs. In a voluntary ACO, providers voluntarily join together to form the ACO, or an existing organization, such as an integrated delivery system or

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PHO that already comprises a hospital and a large multi-specialty physician group becomes an ACO. Under a voluntary ACO arrangement, there would be no penalty for failing to achieve the ACOs quality or cost goals. According to MedPAC, bonuses would be funded by constraining growth in fee-for-service reimbursement rates,³³ although it is not clear whether this would reduce costs.³⁴ The payment of bonus compensation for achievement of quality goals, by itself, would tend to increase costs,³⁵ although reduction of hospital readmissions and other follow-up services resulting from improved outcomes would tend to mitigate the overall increase.³⁶ Achievement of cost savings while improving quality would require a reduction in the volume of services provided (particularly high-cost services paid for on a fee-for-service basis) or the performance of those services by lower-cost providers (or both), without withholding medically necessary services.³⁷ Incentives to reduce volume and to use lower-cost providers would have to outweigh the incentives under a fee-for-service system to increase service volumes.³⁸

Under MedPAC's mandatory ACO model, Medicare would assign hospitals and physicians to an ACO and implement a system of bonuses (for achieving quality and cost goals) and penalties (for failing to achieve the goals) that would apply to the ACO, even if the hospitals and physicians assigned to the ACO did not formally agree to organize themselves as an ACO. As in the case of the voluntary model, the incentive to earn a bonus for achievement of quality and cost goals would tend to encourage the ACO and its participants to coordinate care, eliminate the provision of unnecessary services, and use lower-cost practitioners and providers to save costs. The penalty element would provide an additional incentive beyond that provided under the voluntary model. Penalties might be implemented

through withholding of fee-for-service payments, which would be lost if the ACO failed to achieve certain goals. The penalties, as well as savings achieved through the implementation of cost-saving practices, would fund the bonuses.³⁹

ACO Programs under the Health Reform Legislation

The pending healthcare reform bills, if finally reconciled and adopted, would pave the way for comprehensive testing of voluntary ACO models. The Senate Bill would require the Secretary of HHS, by January 1, 2012, to establish a shared savings program under which groups of providers work together to manage and coordinate care for Medicare fee-for-service beneficiaries through an ACO.⁴⁰ An ACO could consist of physicians and certain other healthcare professionals in group practice arrangements, networks of practitioners, partnerships or joint ventures between hospitals and practitioners, hospitals employing practitioners, and such other groups or providers and suppliers as the Secretary determines appropriate.

To participate, an ACO would have to have a mechanism of shared governance and meet the following requirements: (a) be willing to become accountable for the quality, cost, and overall care of the Medicare beneficiaries assigned to it; (b) enter into an agreement with the Secretary to participate in the program for a term of not less than three years; (c) have a formal legal structure that would allow the organization to receive and distribute payments for shared savings to participating providers; (d) include primary care physicians or other practitioners that are sufficient for the number of Medicare beneficiaries assigned to the ACO (at a minimum, the ACO would have to have at least 5,000 such beneficiaries assigned to it); (e) provide the Secretary with such information regarding physicians and other practitioners participating in the

ACO as the Secretary determines necessary; (f) have in place a leadership and management structure that includes clinical and administrative systems; (g) define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies; and (h) demonstrate to the Secretary that it meets patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans.⁴¹

The Senate Bill requires the Secretary to determine appropriate measures and performance standards to assess the quality of care furnished by the ACO, and it requires that participating ACOs submit data in a form and manner specified by the Secretary on measures the Secretary determines necessary for the ACO to report in order to evaluate the quality of care furnished by the ACO. A participating ACO would be eligible to receive payments for shared savings if it achieved the quality performance standards established by the Secretary and certain cost containment standards specified by the Secretary (based on the percentage by which estimated average per capita Medicare expenditures for Medicare beneficiaries for parts A and B services is below the ACO's benchmark).⁴²

Section 1301 of the House Bill requires the HHS Secretary to conduct a pilot program to test payment incentive models designed to reduce the growth of expenditures and improve health outcomes in the provision of items and services by qualifying ACOs.⁴³ A qualifying ACO that enters into an agreement with the Secretary to participate in the pilot program and that meets annual quality and performance standards established by the Secretary could qualify to receive an incentive payment.

A “qualifying ACO” is defined, generally, as a group of physicians, or an organization under which physicians enter into agreements with other providers for the purposes of participating in the pilot program, that is organized at least in part for the purpose of providing physicians’ services. A qualifying ACO could include one or more hospitals and other providers or suppliers of services that are affiliated with the ACO under an arrangement structured so that each such provider or supplier participates in the pilot program and shares in any incentive payments under the pilot program. In order to qualify as an ACO for purposes of the pilot program, an organized group of physicians would have to satisfy the following criteria as well as any other criteria determined to be appropriate by the Secretary:

- (a) The group has a legal structure that would allow the group to receive and distribute incentive payments;
- (b) The group includes a sufficient number of primary care physicians for the beneficiaries for whose care the group is accountable (as determined by the Secretary);
- (c) The group reports on quality measures in such form, manner, and frequency as specified by the Secretary;
- (d) The group reports to the Secretary (in a form, manner and frequency as specified by the Secretary) such data as the Secretary determines appropriate to monitor and evaluate the pilot program;
- (e) The group provides notice to applicable beneficiaries regarding the pilot program (as determined appropriate by the Secretary);
- (f) The group contributes to a best practices network or website maintained by the Secretary for

the purpose of sharing strategies on quality improvement, care coordination, and efficiency that the group believes are effective; and

- (g) The group utilizes patient-centered processes of care, including those that emphasize patient and caregiver involvement in planning and monitoring of ongoing care management plan.⁴⁴

The House Bill calls for the Secretary to establish annual quality targets that qualifying ACOs must meet to receive incentive payments, based on clinical care and outcomes, care coordination, and patient experience of care. The bill prescribes two specific payment incentive models to be tested through the pilot program and authorizes the Secretary to develop other payment models that meet the goals of the program to improve quality and efficiency. The two specific models are referred to as the “performance target model” and the “partial capitation model.”

Under the performance target model, a qualifying ACO that meets the applicable quality standards would qualify to receive an incentive payment if expenditures for items and services for applicable beneficiaries are less than a target spending level or a target rate of growth established by the Secretary for the ACO. Under the partial capitation model, a qualifying ACO would be at financial risk for some, but not all, of the items and services covered under Medicare parts A and B (and part D, if the Secretary determines to include part D services). Under either model, payments to a qualifying ACO are to be established in a manner that would not result in spending that exceeds the amount that would be expended if the pilot program were not implemented.⁴⁵ The bill authorizes the Secretary to issue regulations to implement, on a permanent basis, one or more payment incentive models if, and to the extent that, such models are beneficial to the

Medicare program, as determined by the Secretary, and provided that the Chief Actuary of CMS certifies that the models would result in estimated spending that is less than what it would be in the absence of the permanent implementation.

The House Bill calls for the pilot program to begin no later than January 1, 2012. An agreement with a qualifying ACO under the pilot program may cover a multi-year period of between three and five years. The Secretary is authorized to extend the duration of the agreement for an ACO that consistently meets the applicable quality standards and earns incentive payments during any of the first four years of the pilot agreement or that consistently exceeds the quality standards and is not increasing spending under the program. The Secretary may terminate an agreement with a qualifying ACO under the pilot program if the ACO does not receive incentive payments or consistently fails to meet quality standards in any of the first three years under the program. The bill requires the Secretary periodically to submit to Congress reports on the use of ACO payment models under the pilot program, addressing the impact of the use of those models on expenditures, access, and quality.

Medical Homes – A Patient-centered Primary Care Focused Delivery Model

The term “medical home” is used to describe a method of delivering health-care focused on primary care and prevention. At the center of this model is the personal relationship between the physician and the patient, and when appropriate, the patient’s family. This patient-centric model stresses a coordinated team approach facilitated by information technology. Typical providers expected to participate include physicians who specialize in internal medicine, family practice, geriatrics and general practice. This model is designed to decrease the rate of healthcare

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expenditure and improve the management of chronic illness.

The basic goal of the medical home is to keep patients with chronic illnesses healthy enough to avoid hospital stays, preventable readmissions, and expensive treatments. Not to be confused with a “gatekeeper” model, a medical home aims to reduce barriers and facilitate the ability of patients to get the right care at the right time and in the right setting. These goals are supported by the Medical Home accreditation standards of the National Committee for Quality Assurance (“NCQA”) which require the medical home to deliver care through a team led by the patient’s personal physician who is responsible for integrating the patient’s care at all stages (e.g. acute care, chronic care, preventive services and end of life care) and in all settings (e.g. hospitals, home health agencies, nursing homes and community based services).⁴⁶

A key feature of the medical home model is reforming physician payment systems to adequately compensate physicians for patient-centered services. Ideally, Medicare would like to see the investments in these patient care management fees help reduce inpatient expenses for these patients. Through payment reform that compensates physicians for these type of services, physicians are encouraged to communicate regularly with their patients, spend more time getting to know them, provide patients with enhanced access to care (24-hour coverage and timely appointments), and serve as advocates in coordinating their patients’ care across the healthcare system. To reward such behavior, providers in a medical home model would receive a separate fee for providing “patient care management services” – unlike the existing Medicare payment model which pays for health-care services and tests. This new care coordination reimbursement mechanism would encourage prevention of acute episodes in chronically ill patients. The

enhanced coordination care payment could also be linked to bundled or other shared savings payment models so that the provider is rewarded and made accountable for actual care outcomes.

The House Bill includes medical home pilot programs aimed at evaluating the impact of this type of innovative payment initiative on delivery system reform.⁴⁷ Two types of medical home models would be tested. The first, referred to as an “independent patient-centered model” is a physician-directed or nurse-practitioner directed practice that would receive risk adjusted per member per month fees for providing “medical home services” such as direct and ongoing access to primary care, health team care coordination across all care settings, patient self-management activities and evidenced-based care capable of identifying patient needs over time. Another non-profit or state-based model referred to as the “community-based model” would focus on chronic care management activities such as teaching self-care skills, providing medication therapy management services and helping patients access local health-care and community-based resources.

None of these medical home services is currently reimbursed by Medicare. If these pilot programs demonstrate that these models result in improved quality and care for complex patients, reduce preventable hospitalizations, improve patient functional status, limit duplicative diagnostic testing and reduce healthcare expenditures, the medical home model will play a key role in a reformed health-care delivery system.⁴⁸

The Shared Savings Model – Adding to Delivery Reform

There is growing interest in using shared savings as an approach to health-care payment and delivery reform. A good example of this shared savings, which is often referred to as “gainsharing,” is used in the Medicare Physician

Group Practice (“PGP”) Demonstration. CMS selected ten physician groups to participate in this five-year demonstration.⁴⁹ The groups were selected based on organizational structure, operational feasibility, geographic location and current use of mature clinical and management information systems.⁵⁰

In addition to other measures, CMS rewards physician groups in the PGP demonstration for improving patient outcomes by proactively coordinating total healthcare needs of patients across care settings. At the end of a performance year, the total Medicare Part A and Part B per capita spending is calculated for assigned Medicare beneficiaries and compared to a base year period to determine spending growth. Any financial savings that result from improved quality and cost efficient care for a particular group of patients – through better management of chronic disease complications and avoidable hospitalizations – are shared with the physicians. Physician groups whose Medicare spending growth rate is more than two percent lower than their comparison population may share up to 80 percent of the Medicare savings.

Based on performance results for the first three years, five physician groups shared in savings under the PGP demonstration. These groups earned \$25.3 million as their share of the total \$32.3 million in Medicare savings.⁵¹ Key to the success of these groups was investment in care management initiatives and redesigning care processes that focused on maintaining health and avoiding further illness and admissions to the hospitals. For example, redesigning primary care practices by greater use of non-physicians and implementing expanded care management using daily telemonitoring programs and telephonic nurse management interventions have promising opportunities for substantially reducing costs and patient morbidity.⁵²

The shared savings approach is being proposed as a key mechanism for

encouraging the creation of ACOs, as evidenced by the shared savings/ACO pilot program called for by the Senate Bill. However, the concept of reducing total healthcare spending alone is not sufficient, because there are key primary care services that are not paid for under a shared savings approach. For example, this approach does not compensate physicians or ancillary practitioners for spending time with patients. Although creating incentives for providers to control costs is needed, even more important perhaps is payment reform that rewards physicians for doing what is needed to control such costs, including the “care coordination services” that are inherent in the medical home models. However, the ability to implement a medical home coordination model requires upfront spending to implement the necessary processes and internal structures to manage patient care across settings to keep patients healthy and reduce hospitalizations.

Shared savings are also commonly used in the new “co-management” arrangements used to integrate physician and hospital input in developing and managing specialty service lines. In this model, the hospital and physician organization as “co-managers” take on the responsibility for the management of both hospital and physician services within a particular specialty clinical services line, such as orthopedics or cardiology. The service line co-management model is typically implemented through the creation of a separate joint venture entity owned by the hospital and the physician group or by using a direct contractual model with a designated operating committee comprised of both hospital and physician representatives. The co-management venture assumes responsibility for the clinical service line by developing an infrastructure that integrates hospital and physician interests with the ability to collect and manage Part A and Part B services, payment structures such as bundled payments and shared savings aimed at targeted populations can be effectively used to control costs and monitor outcomes.

Although the organizational structure of the old physician hospital organizations (or PHOs) could serve as the basis for forming this new physician – hospital integration model, the goals of the co-management model differ from PHOs. The primary focus of PHOs is to represent physicians and hospitals in negotiating rates and financial risk arrangements with managed care payers. Conversely, the purpose of the co-management venture is to integrate and coordinate a particular hospital clinical service (which may cover inpatient, outpatient, ancillary and/or multisite services) and appropriately reward participating physicians for their efforts in developing, managing and improving the quality and efficiency of the hospital service line. Therefore, use of an existing PHO structure to develop a clinical co-management arrangement would likely require substantial contractual and operational changes.⁵³

Participants in the ACE demonstration project⁵⁴ may elect to participate in a shared savings program as a part of the bundling demonstration. In creating the framework for the shared savings element of the ACE demonstration project, CMS established several requirements with which the participants must comply. The requirements reflect CMS’s sensitivity to the public policies sought to be achieved by the Stark, civil monetary penalties, and anti-kickback laws (discussed further below). For example, CMS requires that incentive payments must not induce a physician to reduce or limit services that are medically necessary; incentives must not be based on the volume or value of referrals or business otherwise generated between the hospital and physicians; and payments to physicians may not exceed 25 percent of the amount that is normally paid to physicians for such cases.⁵⁵

Also, CMS requires a definite link between the incentive payment and the physician’s actions that contribute to cost savings and quality improvement. For example, CMS requires that incentive payments to physicians be made in such a manner as to assure a reasonable balance between the incentives and the

demonstration objectives. The incentive program must clearly and separately identify the actions that are expected to result in cost savings, and incentive payments must be linked to actions that improve overall quality and efficiency and result in cost savings. Each participant is required to provide a detailed explanation of the timing and method of distribution of savings to participating physicians, the proportion of those gains to the demonstration participant that is shared with physicians, how the portion of the gains shared with physicians is allocated among physicians, and how quality, patient safety, and internal efficiency measures influence that allocation. To address the concern that bundling may result in mixed incentives, CMS requires that the provider incentive program be based on *net* savings (reductions in overall patient care costs attributable to the program activity, minus any corresponding increases in costs associated with the same patients).⁵⁶

Organizational Structures to Implement New Payment Models

The new payment models described above are best suited to highly integrated healthcare organizations that have in place acute-care, primary and specialty physician care, ancillary care, and post-acute care capabilities. The implementation of these kinds of payment reforms likely will encourage consolidation and integration, including combinations of physicians into larger groups, closer affiliations of independent physician groups with hospitals, and combinations or affiliations of post-acute care providers with hospitals. Physicians, hospitals, and post-acute care providers will need to acquire new information technology and develop new protocols to permit greater sharing of medical information in a manner that complies with information privacy and security laws, and they may increasingly integrate into a single organization or under a unified organizational structure with

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centralized decision making. Hospitals and physician groups may increase their hiring, training, and use of physician assistants, nurse practitioners, and other practitioners who can increase physician productivity by delivering high quality and cost-effective services.

As Medicare moves beyond fee-for-service based compensation paid to separate providers operating within a highly fragmented system to one that pays for managing quality care that is coordinated among various closely affiliated providers and delivery sites, the fundamental question is: What organizational structures for strategic provider alliances are needed? There is no one provider organizational structure that automatically guarantees successful implementation of a bundling, ACO, medical home, or shared savings model. There may be several workable paths, and many organizational structures that currently exist could be adequate. For example, physician affiliations structured through existing independent practice association (“IPA”) models or the more highly integrated staff model structures could be used to operate a medical home. However, these organizations will need to function substantially differently from how they did in the past.

The physician integration models in the 1990s were formed primarily to gain market share and provide physicians with the ability to negotiate more favorable reimbursement rates in response to growing market share of managed care plans. In a newly reformed healthcare delivery system, the primary focus of these provider organizations must be coordination of care across the continuum and the ability to measure health outcomes and control costs. What will be critical is the organization’s capacity to “manage” a patient’s care, with the goal of preventing illness, in as cost-effective a manner as possible. For example, cost savings to fund the new fees paid for medical home coordination services could be accomplished

by using ancillary practitioners, such as nurse managers, who would contact patients through phone or email. For those models that pay bonuses (or charge penalties) based on avoidance of (or failure to avoid) unnecessary or preventable physician encounters, diagnostic tests, hospitalizations, emergency room visits, and hospital readmissions, what will be critical for their success is the organization’s ability to monitor patients by tracking tests for abnormal results, using data to identify patients with certain diagnoses, and providing ongoing patient health education.

Although many existing hospital and physician organizational structures could serve as an ACO or medical home and could implement a bundling or shared savings program, in order to deliver next-generation services these organizations must have the ability to coordinate care and measure outcomes across provider settings. Clearly, practices that have effective clinical information technology systems, trained teams of professional personnel, and continuous quality improvement initiatives in place will be better equipped to function under these new payment models.

Legal Challenges in Implementing Payment Reforms

Regardless of the organizational structure or level of integration of an entity or group of entities participating in a new payment model that involves bundling, bonuses, or shared savings arrangements, the participants must negotiate how fees and incentive payments will be allocated among them. These negotiations and allocation arrangements involve significant issues under the Stark law,⁵⁷ the Medicare anti-kickback statute (the “AKS”),⁵⁸ the civil monetary penalties statute (the “CMP”),⁵⁹ and antitrust laws.⁶⁰ Generally, managing these risks will be more challenging for loosely integrated groups than

for groups of practitioners and providers that are tightly integrated within a centrally governed and controlled organizational structure.

The issues presented under the Stark law, AKS, or CMP statute would be particularly challenging to the extent that incentive arrangements included payments to physicians that may induce the physicians to limit or withhold services, or to the extent that sharing of quality or cost containment bonuses with physicians is not based on specific actions by the physicians that measurably contribute to the achievement of the quality and cost-containment goals for which the bonus is paid. The effective implementation of these new payment models likely will require new exceptions under the Stark law,⁶¹ revised safe harbor regulations under the AKS, and a legislative relaxation of the CMP statute that are designed to permit and encourage providers and physicians to adopt the new payment models.

Stark Law

Participants in a bundling, ACO, or shared savings arrangement typically will include physicians and providers of inpatient and outpatient hospital services and other designated health services (“DHS”), as defined under the Stark law, and there likely will be referral relationships among the physicians and the participating hospitals and other providers. The implementation of a bundling, ACO, or shared savings arrangement will involve the creation of new financial relationships among the participants that might not have existed previously.

For example, a hospital that receives a bundled payment covering a DRG and related physician services will allocate a portion of the bundled payment to the physicians providing the physician services. Similarly, if a hospital operates as an ACO and receives a bonus based on achievement of quality and cost savings goals, it may be

required to allocate portions of the bonus among physicians who participate in the ACO.⁶² If the physician is employed by the hospital, the allocation can be addressed as part of the physician's compensation arrangement under his or her employment agreement, in which case the arrangement might rely on the Stark exception for employment arrangements. If the physician is not employed by the hospital, the allocation of a shared payment to the physician would have to be structured and implemented so that it satisfied another Stark law exception, such as the exception for personal service contracts.

Under current law, Stark compliance would be particularly challenging with respect to compensation arrangements that involve the allocation among hospitals and physicians of shared savings, bonuses, or similar payments made to the hospital for the achievement of quality or cost containment goals. Although those challenges would be less acute when they involve the sharing of such payments between a hospital and its employed physicians, a compensation arrangement that includes or consists of the sharing of payments between a hospital and a physician group may not fit squarely within any of the current Stark exceptions, particularly (for example) if each physician participating in the arrangement shares in a portion of a bundled payment for each patient and DRG, regardless of whether the physician actually becomes involved in the care of that particular patient, or if all of the participating physicians share in a bonus or shared savings payment regardless of their personal involvement in achieving the performance goals on which the bonus or shared payment is based.⁶³

Among the conditions to the Stark exception for bona fide employment arrangements is that the employment must be for "identifiable services" and the compensation must be consistent with the fair market value of those services.⁶⁴ The payment of a productivity bonus is permissible if it is based on identifiable services performed personally by the

physician.⁶⁵ It is questionable whether the current exception for employment arrangements would apply to a bonus allocation paid by an ACO or similar organization to an employed physician based on the organization's achievement of quality or cost containment goals if the allocation is not tied to the physician's performance of specific, identifiable services that contributed to the achievement of the goals.⁶⁶

If the physicians are not employed by the hospital or other entity receiving the bundled payment or other shared payment, the relationship between the entity and the physician would have to be structured to comply with another applicable exception under the Stark law, such as the exception for personal service arrangements. To comply with that exception, such arrangements must be set forth in a written agreement that specifies the personal services of the physician that are covered by the arrangement.⁶⁷

Similarly, under the exception for fair market value compensation, a compensation arrangement is protected only if the arrangement is set forth in a written agreement and covers only identifiable items or services, all of which are specified in the agreement.⁶⁸ To the extent that the entity receives a bonus or shared savings payment based on the entity's achievement of quality or cost containment goals, the exception for personal service contracts or fair market value compensation might not apply to the entity's payment of a portion of the bonus to the physician if the physician's share of the bonus were not tied to the physician's personal performance of specific, identifiable services that are set forth in the agreement.⁶⁹ Moreover, to meet the "set in advance" requirement under the exception for personal service arrangements, a formula for determining the physician's share of a quality or cost containment bonus would have to be set forth in the agreement in sufficient detail that it could be objectively verified.⁷⁰

The current Stark exception for certain arrangements with hospitals would be of limited utility. To qualify

under that exception, remuneration provided by a hospital to a physician must be wholly unrelated to the furnishing of DHS and must not take into account in any way the volume or value of the physician's referrals.⁷¹ Because of the "wholly unrelated" requirement, the scope of this exception would not be sufficient to cover most payment arrangements involving the sharing of bundled payments or bonuses received by the hospital.

Under some limited and specific circumstances, a shared payment arrangement might satisfy some other Stark exception. For example, an ACO might contract with a physician-controlled management services organization ("MSO") to implement quality and cost saving practices that do not involve the personal services of the physicians, and share cost savings with the MSO. In that case, the ACO might be able to rely on the Stark provisions applicable to indirect compensation arrangements.⁷² Also, the Stark exception for risk-sharing arrangements might apply to an IPA that enters into a risk-sharing arrangement with a physician group that includes withholds and bonuses relating to services provided to enrollees of a health plan.⁷³

In sum, the current exceptions under the Stark law are insufficient to permit and encourage the kinds of new organizational structures and compensation arrangements that will be necessary to implement payment models like those that policy makers are proposing. The purpose of the proposed new Stark exception for incentive payment and shared savings programs⁷⁴ is to provide additional flexibility for such new arrangements. However, the proposed exception, which contains 16 separate requirements or sets of requirements, is complex and narrowly drawn, and falls short of providing a "bright line" test by which the participants in an incentive payment or shared savings program can know with reasonable certainty whether they comply with the exception.⁷⁵ In its commentary to the proposed new exception, CMS explained that its approach

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to drafting the proposed exception was cautious and stated, "Our proposal is relatively narrow, and we acknowledge at the outset that it is unlikely to cover as many arrangements as interested stakeholders would like."⁷⁶ Fortunately, CMS stated that it was considering various ways to expand the proposed exception and that its goal was to promulgate an exception that is as broad as possible, consistent with the requirement that any Stark exception must pose no risk of patient or program abuse.⁷⁷

Section 1301 of the House Bill, which provides for an ACO pilot program, recognizes that an ACO arrangement could give rise to issues under the Stark law. The bill requires that the HHS Office of Inspector General ("OIG") provide for monitoring of the operation of ACOs under the pilot program with regard to violations of the Stark law.⁷⁸ Significantly, however, the bill also authorizes the HHS Secretary to waive provisions of the Stark law (as well as other provisions of the Medicare statutes) in the manner the Secretary determines necessary in order to implement the pilot program.⁷⁹

Anti-Kickback Statute and Civil Monetary Penalties Statute

A payment model under which an acute care hospital receives payments from Medicare and is responsible for contracting with and compensating physicians and providers of post-acute care could invite financial relationships that are problematic under the AKS. For example, suppose Medicare implements a post-acute care bundling system through a PHO from which a particular nursing home, home health provider, or other provider of post-acute care receives a substantial volume of referrals. Under the bundling arrangement, the post-acute care provider would lose direct access to Medicare reimbursement during the period (30 days, under the MedPAC bundling proposal) following each patient's transfer from

the hospital during which the bundled payment to the hospital covers post-acute care. To avoid losing its referral stream, the post-acute care provider would need to negotiate an agreement with the hospital, and likely compete with other potential post-acute care providers, to participate in the bundling arrangement.

Rather than risk a potentially catastrophic loss of business, the post-acute care provider might be motivated to provide its services during the bundling period at a substantially reduced fee, or for no fee, in order to protect its referral stream and ensure its ability to receive reimbursement at its full rates following the bundling period. Because the hospital would be able to retain whatever portion of the bundled fee is not paid to post-acute care providers, the hospital might be motivated to choose the post-acute care provider based more on cost than on quality of care or convenience for the patient, particularly if the bundling arrangement is not combined with patient readmission or other service quality standards that would penalize the hospital for substandard quality. Although a particular discount arrangement with a post-acute care provider might satisfy the AKS safe harbor for discounts, the bundling arrangement could result in unintended financial inducements.

On the flip side, in negotiating the allocation of a bundled hospital payment that is intended to cover physicians' services during and for a period of time following an inpatient stay or a physician's share of a quality or cost containment bonus or shared savings payment, a hospital might be tempted to favor physicians from whom the hospital receives substantial patient referrals. If "one purpose" of a payment allocation arrangement is to induce the referral of Medicare reimbursable business from physicians or to reward them for such referrals, then the arrangement potentially violates the AKS.⁸⁰ The rules

governing the shared savings component of the ACE demonstration project⁸¹ recognize this risk and specifically prohibit incentives to physicians that are based on the volume or value of referrals.

Under the CMP statute, bonus arrangements based on cost containment or other payment arrangements that may directly or indirectly have the effect of reducing or limiting services furnished with respect to Medicare beneficiaries would involve additional compliance risks. A hospital participating in an ACO or bundling arrangement would be prohibited from making payments to a physician or physician group, directly or indirectly, as an inducement to reduce or limit medically necessary services provided with respect to Medicare beneficiaries, and physicians would be prohibited from accepting such payments.⁸²

To achieve the objectives of the payment reform initiatives, including adoption of payment models other than fee-for-service, allocations of shared payments among providers and physicians would need to take into account such variables as success in reducing the volume of medically unnecessary services and hospital readmissions, achieving quality standards, and achieving revenue and expense based performance standards. Such allocation arrangements between a hospital and its employed physicians probably are achievable within the framework of the current AKS safe harbor for employment arrangements. However, the current safe harbor for personal services contracts probably would not protect most allocation arrangements between a hospital and physicians who are not employed by the hospital.⁸³ For example, a payment allocation that may vary based on achievement of such goals likely would not satisfy the personal service contract safe harbor standards requiring that the aggregate compensation to be paid to the physician over the entire term of the arrangement be set in

advance or the standard requiring that the agreement set forth the exact schedule of service intervals and the exact compensation for each such interval for arrangements that call for the physician's services on a periodic, sporadic, or part-time basis.⁸⁴

The OIG has issued numerous Advisory Opinions that address the OIG's enforcement position under the AKS and the CMP statute with respect to certain shared savings or gainsharing arrangements.⁸⁵ Although these opinions offer providers some guidance concerning the OIG's enforcement position, an Advisory Opinion protects only the persons requesting the opinion; other persons may not rely on the opinion to protect other, even similar arrangements. Accordingly, providers need further action by Congress or the OIG to establish clear rules on which providers can rely in entering into shared savings and other payment reform-driven business relationships, with confidence that they can do so without running afoul of the AKS or CMP statute.

Specifically, the OIG should consider modifications of the AKS safe harbor regulations, as they apply to hospitals, physicians, and post-acute care providers, to address potentially unintended consequences of, and to provide appropriate protection for, bundling, bonus-sharing, and shared savings arrangements among such providers.⁸⁶ The safe harbors should require safeguards to discourage allocation of shared payments based on the volume or value of referrals and withholding of medically necessary services (comparable to the safe harbors for certain managed care arrangements), while protecting the allocation of shared payments based on contributions toward successful achievement of quality and cost containment goals.

Federal Antitrust Laws

The primary federal antitrust statutes consist of the Sherman Act,⁸⁷ the Clayton Act,⁸⁸ and the Federal Trade

Commission Act.⁸⁹ Generally, the Sherman Act prohibits contracts, combinations, and conspiracies in restraint of trade, including price fixing and division of markets, as well as monopolies and attempts or conspiracies to monopolize;⁹⁰ the Clayton Act prohibits mergers and acquisitions that may substantially lessen competition or tend to create a monopoly;⁹¹ and the Federal Trade Commission Act prohibits unfair methods of competition and unfair or deceptive acts or practices.⁹² These laws potentially can affect arrangements among healthcare providers that join forces to participate in ACO, bundling, and shared savings arrangements, particularly if those arrangements involve agreements among competitors on pricing or allocation of healthcare services or combinations of previously competing healthcare providers.

Recognizing that the healthcare industry is rapidly changing and that healthcare providers are looking for new ways to control costs and improve quality and efficiency, the United States Justice Department ("DOJ") and the Federal Trade Commission ("FTC") published Statements of Antitrust Enforcement Policy in Health Care,⁹³ which include statements relating to DOJ's and FTC's enforcement policies relating to networks of multiple providers that jointly market their healthcare services to health plans and other purchasers⁹⁴ (the "Statement on Multiprovider Networks"). Such a network could consist, for example, of an inpatient hospital, a physician group, outpatient facilities, and post-acute care providers that propose to organize an ACO or share in a bundled payment and agree to implement controls aimed at containing costs and assuring quality. While recognizing that affiliations of such providers can offer significant procompetitive benefits to consumers, the DOJ and FTC point out that such affiliations can present antitrust issues, particularly if the multiprovider network includes otherwise competing providers that contract to provide services at jointly determined prices.⁹⁵

Although the Statement on Multiprovider Networks points out that the antitrust laws include *per se* prohibitions of agreements among competitors that fix prices or allocate markets, it also states that, when competitors economically integrate in a joint venture, such agreements, if reasonably necessary to accomplish the procompetitive benefits of the integration, are analyzed under the rule of reason and are not viewed as *per se* illegal. Under a rule of reason analysis, the relevant issues are whether the formation and operation of a venture may have a substantial anticompetitive effect and, if so, whether that potential effect is outweighed by any procompetitive efficiencies resulting from the venture. Procompetitive benefits may consist of lower prices, improved quality, or other significant efficiencies that benefit consumers.⁹⁶

The Statement on Multiprovider Networks explains that, in some multiprovider networks, significant efficiencies may be achieved through an agreement by competing providers to share substantial financial risk for the services provided through the network. In those cases, price-setting would be integral to the network's arrangement and, therefore, would warrant evaluation under the rule of reason.⁹⁷ If a multiprovider network does not involve the sharing of substantial financial risk, a rule of reason analysis may nonetheless be applied if the network involves sufficient integration to demonstrate that the venture is likely to produce significant efficiencies.⁹⁸

Most of the nine statements contained in the Statements of Antitrust Enforcement Policy in Health Care give healthcare providers guidance in the form of antitrust safety zones, which describe conduct that the DOJ and FTC will not challenge under the antitrust laws absent extraordinary circumstances. However, the Statement on Multiprovider Networks states that, because multiprovider networks involve a large variety of structures and relationships among many different types of

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healthcare providers, and because new arrangements are continually developing, the DOJ and FTC are unable to establish a meaningful safety zone for entities participating in a multiprovider network. Essentially, the position of the DOJ and FTC is that they will consider, on a case-by-case basis, whether the circumstances applicable to a particular multiprovider network has the potential for producing efficiencies that warrant rule of reason treatment. Organizers of multiprovider networks who are uncertain whether their proposed arrangements constitute substantial financial risk sharing are encouraged to take advantage of the DOJ's and FTC's expedited business review and advisory opinion procedures.⁹⁹

Potential Liability Issues Raised by the New Delivery Models

By definition, an ACO agrees to become accountable for the overall care of the ACO's patients. An agreement to be "accountable" for the overall care of a patient could expose an ACO to claims based on acts or omissions of contracted participants in the ACO, even if those participants are not employed by or otherwise affiliated with the ACO.

Similarly, a hospital that receives payments through a bundling arrangement and shares such payments with physicians and other providers with which the hospital contracts to participate in the bundling arrangement might be exposed to liability arising from acts or omissions of its contracted participants, based on the hospital's alleged negligence in selecting those participants. Also, the effectiveness of a bundled payment system for post-acute care may depend on the hospital's legal and contractual authority to deny payments to post-acute care providers on the basis that a patient does not require post-acute care. The responsibility for making those decisions could place hospitals in an unfamiliar position

as a "gatekeeper" and could expose the hospital to liability if it denies (even in good faith) admission of a patient to, or payment for, post-acute care.

Conclusion

Because Medicare is the largest payor in the U.S. healthcare system, it is critical for healthcare provider organizations to understand and prepare for the Medicare payment reforms that are likely to be implemented in the near future. Medicare is preparing to fundamentally change its role in the healthcare market by moving from a passive payor to an active purchaser in search of demonstrable value – quality care at reasonable costs. The new payment demonstration programs being considered and tested by CMS provide a view into the next generation of delivery systems that will need to emerge in response to these payment reforms.

In contrast with the integration models seen in the 1990s that emerged in response to a rapidly growing managed care market and which were primarily used to gain patient volumes and market share, the new delivery models must have the capacity to both manage and analyze the care for which they will be held accountable. Existing healthcare laws governing financial relationships among providers pose challenges to the implementation of these new delivery models, and modifications of this existing legal paradigm will be necessary in order to accommodate the new models. This transition will not happen overnight, but providers must begin to seriously address these pending payment reforms as an integral part of their strategic planning.



Maria T. Currier is a partner in the Business Law Section of Holland & Knight and chairs the firm's national Health Law and Life Sciences Team. She is also head

of the firm's National Health Care Reform Task Force. Ms. Currier has more than 21 years of experience serving clients in the healthcare industry and is "Board Certified in Health Law" as recognized by The Florida Bar Board of Legal Specialization and Education.

Ms. Currier has counseled clients on Medicare & Medicaid reimbursement and regulatory issues, patient safety and quality initiatives, HIPAA, federal and state fraud and abuse matters, Stark-related matters, corporate compliance plans, False Claims Act compliance and physician incentive arrangements. She has served as counsel to hospitals, nursing homes, long-term care providers, home health companies, large medical groups, ambulatory surgery centers, integrated health systems, provider sponsored organizations, health maintenance organizations, preferred provider organizations, physician-hospital organizations, physician management companies, pharmaceutical companies, employer self-insured plans, prepaid health plans, Medicare Advantage Plans, national diagnostic companies and academic medical centers. She may be reached at maria.currier@hklaw.com.



Morris H. Miller is a partner and member of Holland & Knight's Corporate and Mergers & Acquisitions Practice Group and has more than 30 years of experience in business and healthcare law. He is a Florida Bar Board Certified Health Law attorney and focuses his practice primarily on transactional and regulatory matters within the healthcare and senior living industries. From 1989 until 2001, Mr. Miller served as chair of Holland & Knight's National Health Law practice group. Mr. Miller is also a member of the firm's National Health Care Reform Task Force.

Mr. Miller has substantial experience representing owners, developers, and operators of healthcare and senior living facilities, including nursing homes, assisted living facilities, independent

living facilities, continuing care retirement communities, hospitals, physician groups, medical and diagnostic clinics, and others. He has structured, negotiated, and documented numerous acquisitions, dispositions, financings, and other transactions and business arrangements involving such facilities and businesses. He may be reached at morris.miller@hkklaw.com.

Sheila Madhani, Assistant Director of Health Policy at the American Society for Radiation Oncology in Fairfax, Virginia, also contributed to this article.

Endnotes

- 1 The Board of Trustees Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds was established under the Social Security Act to oversee the financial operations of the Medicare Hospital Insurance and Supplementary Medical Insurance trust funds. The Board consists of six members, including the Secretary of the Treasury, the Secretary of Labor, the Secretary of Health and Human Services, the Commissioner of Social Security, and two members appointed by the President and confirmed by the Senate. The Board of Trustees reports annually to Congress on the financial operations and actuarial status of the Medicare program. See Centers for Medicare and Medicaid Services website at http://www.cms.hhs.gov/reportstrustfunds/03_abouttheboard.asp, and <http://www.cms.hhs.gov/ReportsTrustFunds/>.
- 2 The Medicare Payment Advisory Commission (MedPAC) is an independent Congressional agency established by the Balanced Budget Act of 1997 (P.L. 105-33) to advise Congress on issues affecting the Medicare program, including access to care and quality of care. The Commission consists of 17 members who are appointed to three-year terms (subject to renewal) by the Comptroller General. See MedPAC's website at <http://www.medpac.gov/about.cfm>.
- 3 The U.S. Government Accountability Office ("GAO") is an independent agency that supports Congress by auditing federal agency operations to determine whether federal funds are being spent efficiently and effectively; investigating allegations of illegal and improper activities; reporting on how well government programs and policies are meeting their objectives; performing policy analyses and outlining options for congressional consideration; and issuing legal decisions and opinions, such as bid protest rulings and reports on agency rules. The head of the GAO is the Comptroller General of the United States, who is appointed to a 15-year term by the President from a slate of candidates proposed by Congress. See the GAO's website at <http://www.gao.gov/about/>.
- 4 Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds, 2009 Annual Report of The Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds (2009), available at <http://www.cms.hhs.gov/reportstrustfunds/downloads/tr2009.pdf>.
- 5 See Medicare Payment Advisory Commission, <http://www.medpac.gov/about.cfm>.
- 6 Medical Payment Advisory Commission, Report to the Congress: Improving Incentives in the Medicare Program (2009), at xi, available at http://medpac.gov/documents/Jun09_EntireReport.pdf.
- 7 *Id.* ("A reformed system would pay for care that spans across provider types and time (encompassing multiple patient visits and procedures) and would hold providers accountable for the quality of that care and the resources they use to provide it.")
- 8 See Centers for Medicare and Medicaid Services, Dept. of Health and Human Services, Medicare Demonstrations, <http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/list.asp?listpage=1>.
- 9 Although this article focuses specifically on proposed Medicare payment reforms, healthcare providers should take into account that private payers may test and implement similar payment reforms, either on their own initiative or by adopting new payment methods similar to those implemented by the Medicare program. The kinds of organizational changes driven by reforms in Medicare payment methods may also develop in response to changes in payment methods adopted by private payers.
- 10 Medical Payment Advisory Commission, Report to the Congress: Reforming the Delivery System 97 (2008), available at http://www.medpac.gov/documents/jun08_entirereport.pdf.
- 11 Congressional Budget Office, Budget Options Volume I: Health Care 62-63 (2008), available at <http://www.cbo.gov/ftpdocs/99xx/doc9925/12-18-HealthOptions.pdf>.
- 12 President Barack Obama, Address as the annual Conference of the American Medical Association (June 15, 2009).
- 13 Congressional Budget Office, Budget Options Volume I: Health Care 62 (2008).
- 14 *Id.*
- 15 Congressional Budget Office, Budget Options Volume I: Health Care 63 (2008); Medical Payment Advisory Commission, Report to the Congress: Reforming the Delivery System 97-100 (2008).
- 16 Section 1886(d) of the Social Security Act sets forth a system of payment for the operating costs of acute care hospital inpatient stays under Medicare Part A (Hospital Insurance) based on prospectively set rates. Under this inpatient prospective payment system, each case is categorized into a diagnosis-related group, or DRG, and each DRG has a payment weight assigned to it based on the average resources used to treat Medicare patients in that DRG. See the Centers for Medicare and Medicaid Services website at <http://www.cms.hhs.gov/AcuteinpatientPPS/>.
- 17 See Centers for Medicare and Medicaid Services, Dept. of Health and Human Services, <http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=3&sortOrder=descending&itemID=CMS1204388&intNumPerPage=10>.
- 18 See Medical Payment Advisory Commission, Report to the Congress: Reforming the Delivery System 97 (2008), at 99; Medical Payment Advisory Commission, Report to the Congress: Improving Incentives in the Medicare Program at 54 (2009).
- 19 Medical Payment Advisory Commission, Report to the Congress: Reforming the Delivery System 97 (2008), at 97, 99.
- 20 Patient Protection and Affordable Care Act, Senate Amendment of H.R. 3962, 111th Cong. §3023 (2009).
- 21 Patient Protection and Affordable Care Act §3023.
- 22 *Id.* The bill authorizes the Secretary, as appropriate, to establish a different period for an episode of care under the pilot program.
- 23 *Id.*
- 24 Affordable Health Care for America Act, H.R. 3962, 111th Cong. (2009).
- 25 Affordable Health Care for America Act §1152.
- 26 *Id.*
- 27 Medical Payment Advisory Commission, Report to the Congress: Improving Incentives in the Medicare Program 39-57 (2009).
- 28 *Id.* at 39, 43.
- 29 *Id.* at 39.
- 30 *Id.* at 43.
- 31 MedPAC April 9, 2009 meeting transcript, available at http://www.medpac.gov/transcripts/0408_0409_MedPAC_transcript.pdf Page 341, line 14-21.
- 32 Medical Payment Advisory Commission, Report to the Congress: Improving Incentives in the Medicare Program 39-41, 49-50 (2009).
- 33 Medical Payment Advisory Commission, Report to the Congress: Improving Incentives in the Medicare Program, at 40-41, 56 (2009).
- 34 *Id.* At 53, 56.
- 35 See *id.*, at 41.
- 36 See *id.*, at 57 (note 1).
- 37 See *id.*, at 56.
- 38 See *id.*, at 40.
- 39 *Id.*, at 42, 45 – 48.
- 40 Patient Protection and Affordable Care Act §3022.
- 41 *Id.*
- 42 *Id.* Section 2706 of the Senate Bill also requires the Secretary to establish the Pediatric Accountable Care Organization Demonstration Project to authorize participating States to allow pediatric medical providers that meet specified requirements to be recognized as an ACO for purposes of receiving incentive payments in the same manner as an ACO is recognized and provided with incentive payments under the shared saving ACO program established under Section 3022 of the Senate Bill.

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- ⁴³ Affordable Health Care for America Act, H.R. 3962, 111th Cong. §1301.
- ⁴⁴ *Id.*
- ⁴⁵ *Id.*
- ⁴⁶ *NCQA Standards and Guidelines for Physician Practice Connections – The Patient Centered Medical Home*, published by the National Committee for Quality Assurance, 2008.
- ⁴⁷ See Affordable Health Care for America Act §1302. Section 1302 of the House Bill would also repeal the Medicare Medical Home Demonstration project established by Section 204 of the Tax Relief and Health Care Act of 2006. CMS was to begin the Medical Home Demonstration project in January of 2010. But on October 21, 2009, CMS issued a statement that it would not be pursuing the demonstration in light of proposed health reform legislation in H.R. 3200. The three-year Medicare Medical Home Demonstration project was going to be run in as many as eight states. CMS had planned on selecting 50 practices at each of eight sites for a total of 400 practices. The demonstration project would have included risk-adjusted monthly care management fee payments to the practices of between \$40.40 and \$51.70 per patient per month. Instead, CMS intends to replace the Medicare Medical Home pilot with a Multi-Payer Advanced Primary Care Practice Demonstration that would be implemented in 2010 <http://www.hhs.gov/news/press/2009pres/09/20090916a.html>
- ⁴⁸ “Reforming America’s Health Care Delivery System”, Medicare Payment Advisory Commission Statement before the Senate Finance Committee Roundtable, MedPAC, April 21, 2009. Also see America’s Affordable Health Choices Act of 2009, H.R. 3200, 111th Cong. § 1302 (2009) (Proposing the establishment of a medical home pilot program for the purpose of valuating the feasibility and advisability of reimbursing qualified patient-centered medical homes for furnishing “medical home services” to “high need beneficiaries” and to targeted “high need beneficiaries.”).
- ⁴⁹ See Centers for Medicare and Medicaid Services, Dept. of Health and Human Services, <http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=3&sortOrder=descending&itemID=CMS1198992&intNumPerPage=10>.
- ⁵⁰ The ten physician groups represent 5,000 physicians and 220,000 Medicare fee-for-service beneficiaries. The demonstration started April 1, 2005 and is scheduled to end March 31, 2010. See Centers for Medicare and Medicaid Services, Dept. of Health and Human Services, Medicare Demonstrations Show Paying for Quality Health Care Pays Off (2009), available at http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/PGP_Press_Release.pdf.
- ⁵¹ The five groups that shared in the Medicare savings included: Dartmouth-Hitchcock Clinic, Geisinger Clinic, Marshfield Clinic, St. John’s System and the University of Michigan Faculty Group Practice. See Centers for Medicare and Medicaid Services, Dept. of Health and Human Services, Medicare Demonstrations Show Paying for Quality Health Care Pays Off (2009), available at http://www.cms.hhs.gov/DemoProjectsEvalRpts/downloads/PGP_Press_Release.pdf.
- ⁵² See The Medicare Physician Group Practice Demonstration: Lessons Learned on Improving Quality and Efficiency in Health Care, RTI International, published by The Commonwealth Fund, February 2008; See also, results from the PGP Demonstration project at the CMS Web site at <http://www.cms.hhs.gov/DemoProjectsEvalRpts/>.
- ⁵³ See article on Accountable Care Organizations – Physician Hospital Integration, *The Health Lawyer*, ABA Health Law Section, Volume 21, Number 6, August 2009, at 1.
- ⁵⁴ See *supra* note 7.
- ⁵⁵ See information about the Acute Care Episode Demonstration on CMS website at <http://www.cms.hhs.gov/DemoProjectsEvalRpts/MD/itemdetail.asp?filterType=none&filterByDID=-99&sortByDID=3&sortOrder=descending&itemID=CMS1204388&intNumPerPage=10>
- ⁵⁶ *Id.*
- ⁵⁷ The Stark law (Section 1877 of the Social Security Act and the regulations promulgated thereunder at 42 CFR §§411.350, et. seq.) prohibits certain “referrals” by a physician to an entity with which the physician has a “financial relationship.” In general, the Stark law provides that, with certain exceptions, if a physician (or an immediate family member of the physician) has a financial relationship with an entity, then the physician may not make a referral to the entity for the furnishing of “designated health services” for which payment otherwise may be made under Medicare, and the entity may not bill Medicare or any third party for “designated health services” furnished pursuant to a prohibited referral.
- ⁵⁸ Section 1128B(b) of the Social Security Act, which generally prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration to induce, or in return for, the referral of a person for the furnishing of any item or service for which payment may be made in whole or in part under Medicare.
- ⁵⁹ Section 1128A(b) of the Social Security Act imposes civil monetary penalties on a hospital that knowingly makes a payment to a physician as an inducement to reduce or limit services provided with respect to individuals who are entitled to Medicare benefits or Medicaid assistance or who are otherwise under the direct care of the physician, and on a physician who knowingly accepts such payments.
- ⁶⁰ This article focuses on federal laws only. However, the arrangements discussed in this article also could be affected by similar state laws.
- ⁶¹ See Financial Relationships Between Physicians and Entities Furnishing Designated Health Services, 73 Fed. Reg. 38,548 – 38,551, 38,604 – 38,606 (Jul. 7, 2008) (to be codified at 42 C.F.R. 411.357(x)), which discusses and sets forth a proposed exception for incentive payment and shared savings programs.
- ⁶² Under the MedPAC ACO model, an ACO would be required to have a formal legal structure that would allow the organization to receive and distribute bonuses to participating providers. Aside from requiring an organizational structure that would facilitate the administration of the receipt and distribution of bonuses, this implies that the structure must be one that permits the lawful distribution of bonuses under the Stark law.
- ⁶³ The criteria for participation in the shared savings feature of the ACE demonstration require that incentives to physicians be tied to specific actions by the physicians.
- ⁶⁴ 42 CFR §411.357(c).
- ⁶⁵ *Id.*
- ⁶⁶ Although the achievement of some quality or cost containment goals could be traced to a particular physician’s identifiable, personal services (for example, the physician’s personal compliance with specific patient-care protocols developed by the organization), the achievement of other goals would more likely be attributable to actions of the organization and its administration, as a whole, and would not be traceable to the performance of specifically identifiable services by a physician. The exception for bona fide employment relationships under the Stark law would not apply to the payment of a bonus to a physician who makes referrals to the organization for designated health services unless the bonus were consistent with the fair market value of identifiable services performed personally by the physician.
- ⁶⁷ 42 CFR §411.357(d).
- ⁶⁸ 42 CFR §411.357(l).
- ⁶⁹ As in the case of an employment arrangement, the achievement of some quality or cost containment goals may be traceable to a particular physician’s identifiable services, but the achievement of other goals would more likely be attributable to actions of the organization as a whole. The exception for personal service contracts or fair market value compensation would not apply to a bonus paid to a referring physician unless the bonus were paid for services of the physician that were specified or identified in a written contract with the physician.
- ⁷⁰ 42 CFR §411.357(d)(1)(v); 42 CFR §411.354(d)(1).
- ⁷¹ See 42 CFR §411.357(g).
- ⁷² See 42 CFR §411.357(p).
- ⁷³ See 42 CFR §411.357(n).
- ⁷⁴ Financial Relationships Between Physicians and Entities Furnishing Designated Health Services, 73 Fed. Reg. 38,604 – 38,606 (Jul. 7, 2008) (to be codified at 42 C.F.R. 411.357(x)).

- 75 For example, the exception is available only if the arrangement does not violate the AKS. The absence of specific safe harbor protection under the AKS for incentive payment and shared savings arrangements could discourage physicians and providers from participating in such arrangements in reliance on the proposed Stark exception.
- 76 73 Fed. Reg. at 38,548.
- 77 *Id.*
- 78 Affordable Health Care for America Act §1302(g)(2).
- 79 Affordable Health Care for America Act §1302(f)(2).
- 80 See, e.g., *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3rd Cir. 1985).
- 81 See *supra* note vii.
- 82 See Social Security Act §1128A(b). Such arrangements also could be problematic under the Stark exception for personal service arrangements. See 42 CFR §411.357(d)(2)(i).
- 83 This distinction could be particularly significant for providers located in states that prohibit the corporate practice of medicine. Although an analysis of corporate practice issues is beyond the scope of this article, state laws that prohibit physicians from becoming employed by hospitals or other corporate entities could present additional compliance challenges for physicians and organizations seeking increased integration in preparation for potential payment reforms.
- 84 See 42 CFR §1001.952(d).
- 85 See, e.g., OIG Advisory Opinion No. 09-06, issued June 23, 2009 (available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/2009/AdvOpn09-06.pdf>); OIG Advisory Opinion No. 08-21, issued November 25, 2008 (available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-21.2.pdf>); OIG Advisory Opinion No. 08-16, issued October 7, 2008 (available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-16A.pdf>); OIG Advisory Opinion No. 08-15, issued October 6, 2008 (available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-15.pdf>); OIG Advisory Opinion No. 08-09, issued August 7, 2008 (available at <http://oig.hhs.gov/fraud/docs/advisoryopinions/2008/AdvOpn08-09B.pdf>).
- 86 The mission of the OIG is to protect the integrity of HHS programs, as well as the health and welfare of the beneficiaries of those programs. See OIG's website at <http://oig.hhs.gov/organization.asp>. Among OIG's duties are the development and promulgation of "safe harbor" regulations under the AKS, which specify various payment and business practices that are not treated as criminal offenses under the AKS, even though they may potentially be capable of inducing referrals of Medicare-reimbursable business. See Social Security Act §1128B(b)(3)(E).
- 87 15 USC §§1 - 7.
- 88 15 USC §§12 - 27.
- 89 15 USC §§41 - 58.
- 90 15 USC §§1, 2.
- 91 15 USC §18.
- 92 15 USC §45.
- 93 See Department of Justice and Federal Trade Commission Statements of Antitrust Enforcement Policy in Health Care (available at <http://www.ftc.gov/bc/healthcare/industryguide/policy/index.htm>) (last updated: July 8, 2009).
- 94 See Statement of Department of Justice and Federal Trade Commission Enforcement Policy on Multiprovider Networks (available at <http://www.ftc.gov/bc/healthcare/industryguide/policy/statement9.htm>).
- 95 *Id.*
- 96 *Id.*
- 97 The Statement on Multiprovider Networks lists several examples of types of arrangements through which substantial financial risk can be shared among competitors in a multiprovider network, including: (1) an agreement by the network to provide services to a health plan at a capitated rate; (2) an agreement by the network to provide designated services or classes of services to a health plan for a predetermined percentage of premium or revenue from the plan; (3) use by the network of significant financial incentives for its provider participants, as a group, to achieve specified cost-containment goals, including withholds of compensation pending achievement of the network's cost containment goals and financial rewards or penalties based on achievement or failure to achieve the network's targeted performance; and (4) agreement by the network to provide a complex or extended course of treatment that requires substantial coordination of care by different types of providers offering a complementary mix of services, for a fixed, predetermined payment, where the costs of the course of treatment for any individual patient can vary greatly due to the individual patient's condition, the choice, complexity, or length of treatment, or other factors. *Id.*
- 98 See Statement of Department of Justice and Federal Trade Commission Enforcement Policy on Multiprovider Networks (available at <http://www.ftc.gov/bc/healthcare/industryguide/policy/statement9.htm>).
- 99 *Id.*

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