Physician-Hospital Clinical Integration: Navigating the Complexities
Structuring Integrated Healthcare Models to Meet Incentive Requirements Under Healthcare Reform

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Today’s faculty features:

Ashley McKinney Fischer, Partner, McDermott Will & Emery, Chicago
Joan Polacheck, Partner, McDermott Will & Emery, Chicago
Christopher M. Jedrey, Partner, McDermott Will & Emery, Boston, Mass.
William J. DeMarco, President, Pendulum Healthcare Development Corporation, Rockford, Ill.

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Toward Accountable Care: How Healthcare Reform Will Shape Provider Integration

Bernadette M. Broccolo
McDermott Will & Emery LLP
Chicago, IL
bbroccolo@mwe.com
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I. INTRODUCTION

Horizontally and vertically integrated delivery system models used widely in the 1990s were organized primarily to enhance the managed care contracting position and capabilities of institutional and physician providers. In contrast, models of integration and collaboration developed to respond to the federal health reform legislation, known as the Patient Protection and Affordable Care Act (PPACA or the Act), (Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010). PPACA became law on March 23, 2010) will need to focus primarily on enhanced coordination of patient care across the full care continuum (from primary care through acute care and long-term care to palliative care) in order to both improve the quality of care and patient outcomes, improve patient experience, and control the health care cost curve.

Old and familiar friends such as physician-hospital organizations (PHOs), independent practice associations (IPAs), management service organizations (MSOs), employment arrangements, joint managed care contracting and contractual risk sharing, joint operating agreements (JOAs), formal corporate affiliations and straight mergers and acquisitions will likely appear on the strategic and tactical menu of options for developing an effective response. However, such models will need a new focus and will likely take on new shapes and sizes. And, new and different approaches are likely to emerge. Certainly, models for collaboration focused primarily on the development of shared, robust electronic health systems are likely to emerge, and those collaborations may be the foundation and the catalyst for expansion into expanded relationships for true care delivery integrations.

Following is a discussion of key provisions of the Act and corresponding legal feasibility considerations that institutional providers, individual providers and other key stakeholders should address and analyze closely in the effort to develop an effective strategy for responding to this health reform legislation. While major systemic change may not come quickly, the Act lays the groundwork for achieving it over time. Therefore, all stakeholders will be well served by being ready with a sound and pragmatic plan for effectively managing the strategic and compliance planning steps that will lead to that end.
II. EMPHASIS ON NEW PAYMENT AND CARE DELIVERY MODELS – THE CENTER FOR MEDICARE AND MEDICAID INNOVATION (CMI) (PPACA SECTION 3021)

A. Purpose of CMI

Section 3021 of the Act establishes the CMI for the purpose of “test[ing] innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to individuals.” The CMI will be focused on the promotion of care delivery models that “improve the coordination, quality, and efficiency of health care services.” The CMI is slated to be operational no later than January 1, 2011. Such new Medicare demonstration projects will almost certainly foster the proliferation of ACOs and similar new integrated care delivery models. In fact, various permutations of the ACO concept are already emerging separately from Medicare, and they incorporate a variety of innovative models for provider cost and quality incentives as well as patient care coordination by a wide range of providers.

B. Criteria for Selection of Payment and Delivery Models by CMI

PPACA directs the Secretary to select payment and delivery models that address a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. To this end, CMS will be seeking, among other opportunities, innovative models that accomplish the following actions:

1. Promote broad payment and practice reform in primary care, including patient-centered medical home models for high-need applicable individuals, medical homes that address women’s unique health care needs, and models that transition primary care practices away from fee-for-service-based reimbursement and toward comprehensive payment or salary-based payment.

2. Contract directly with groups of providers of services and suppliers to promote innovative care delivery models, such as through risk-based comprehensive payment or salary-based payment.

3. Utilize geriatric assessments and comprehensive care plans to coordinate the care (including through interdisciplinary teams) of applicable individuals with multiple chronic conditions and either an inability to perform two or more activities of daily living or a cognitive impairment.

4. Promote care coordination between providers of services and suppliers that transition health care providers away from fee-for-service-based reimbursement and toward salary-based payment.

5. Support care coordination for chronically ill applicable individuals at high risk of hospitalization through a health-information-technology-enabled provider network that includes care coordinators, a chronic disease registry and home telehealth technology.

6. Vary payment to physicians who order advanced diagnostic imaging services according to appropriateness criteria for the ordering of such services, as determined in consultation with physician specialty groups and other relevant stakeholders.

7. Utilize medication therapy management services.
8. Establish community-based health teams to support small-practice medical homes by assisting the primary care practitioner in chronic care management, including patient self-management activities.

9. Assist individuals in making informed health care choices by paying providers and suppliers for use of patient decision-support tools that improve individuals’ and caregivers’ understanding of medical treatment options.

10. Allow States to test and evaluate care integration for dual eligible individuals in the State and to test and evaluate systems of all-payer payment reform for the medical care of residents of the State, including dual eligible individuals.

11. Align nationally recognized, evidence-based guidelines of cancer care with payment incentives for treatment planning and follow-up care planning, including identification of gaps in applicable quality measures.

12. Improve post-acute care through continuing care hospitals that offer inpatient rehabilitation, long-term care hospitals, and home health or skilled nursing care following discharge.

13. Fund home health providers who offer chronic care management services to applicable individuals in cooperation with interdisciplinary teams.

14. Promote improved quality and reduced costs by developing a collaborative of high-quality, low-cost health care institutions that are responsible for developing, documenting and disseminating best practices and proven care methods; implementing such best practices and proven care methods within such institutions to demonstrate further improvements in quality and efficiency; and providing assistance to other health care institutions on how best to employ such best practices and proven care methods to improve health care quality and lower costs.

15. Facilitate inpatient care, including intensive care, of hospitalized applicable individuals at their local hospital through the use of electronic monitoring by specialists, including intensivists and critical care specialists, based at integrated health systems.

16. Promote greater efficiencies and timely access to outpatient services through models that do not require a physician or other health professional to refer the service, or be involved in establishing the plan of care for the service, when such service is furnished by a health professional who has the authority to furnish the service under existing State law.

17. Establish comprehensive payments to Healthcare Innovation Zones (HIZ), consisting of groups of providers that include a teaching hospital, physicians and other clinical entities, which, through their structure, operations and joint activity, deliver a full spectrum of integrated and comprehensive health care services to applicable individuals while also incorporating innovative methods for the clinical training of future health care professionals.
C. Other Considerations

CMI is charged with considering the following additional factors in the development of new innovative delivery models:

1. Whether there is a regular process for monitoring and updating patient care plans in a manner that is consistent with the needs and preferences of applicable individuals;

2. Whether care is delivered on a patient-centric basis (i.e., the individual patient and his or her family are at the center of the care team) and involves in-person contact with the individuals;

3. Whether technology, such as EHRs and patient-based remote monitoring systems, is used to coordinate care over time and across settings;

4. Whether there is a close relationship between care coordinators, primary care practitioners, specialist physicians, community-based organizations, and other providers of services and suppliers;

5. Whether there is a team-based approach to interventions, such as comprehensive care assessments, care planning and self-management coaching; and

6. Whether providers of services and suppliers are able to share information with patients, caregivers, and other providers of services and suppliers on a real-time basis.

D. New Payment and Care Delivery Models – Emphasis on Accountable Care Organizations and Medical Homes

1. PPACA Section 3021 specifically states that selection of innovative payment and service delivery models should “give deference to models that also improve the coordination, quality, and efficiency of health care services. Directly reflective of this directive is the recurring emphasis of PPACA on Accountable Care Organizations (ACOs) and Medical Homes.

2. ACOs and Medical Homes can be viewed as closely interrelated or interlocking components under PPACA’s emphasis on innovative payment and care delivery models. Each one also has a slightly different focus – ACOs seek to control costs and improve quality by making incentive payments to multi-provider integrated delivery systems that meet cost and quality targets, while “Medical Homes” seek to promote improvement of patient care outcomes through payments to a patient’s personal physician to manage/coordinate the patient’s care across clinical and non-clinical care delivery settings. The following two sections discuss these concepts in further detail.

III. ACCOUNTABLE CARE ORGANIZATIONS

A. The ACO Concept – Its Origin and Its Future

1. The Accountable Care Organization (ACO) concept arose prior to PPACA from various sources, not the least of which is the Medicare Payment Advisory Commission (MedPac). MEDICARE PAYMENT ADVISORY COMM’N, REPORT TO THE CONGRESS: IMPROVING INCENTIVES IN THE MEDICARE PROGRAM (June 2009), available at www.medpac.gov/chapters/Jun09_Ch02.pdf. In general, ACOs contemplate payment mechanisms that tie incentive provider payments to quality, outcomes and resource utilization
rather than the productivity incentive that has been the underpinning of the fee-for-service model. On the most basic level, ACOs are organizations that connect groups of providers that are willing and able to take responsibility for improving the health status, efficiency and experience of care for a defined patient population.

2. The PPACA has already generated and will continue to generate widespread interest in the creation of ACOs. The Act emphasizes the creation of a legal structure to receive payments, assume responsibility for care, operate through an integrated network, and use health information technology. It also specifically creates a separate ACO demonstration project within the Medicare Program and provides for the implementation of several other coordinated care demonstration programs.

B. Key ACO Elements

Key elements of an effective ACO ideally include the following:

1. Patient-centered “medical homes” that deliver primary care and coordinate with other providers;

2. Aligned networks of specialists, ancillary providers and hospitals focused on enhanced outcomes;

3. Emphasis on effective clinical care integration and coordination mechanisms;

4. Payor-provider contracted relationships and reimbursement models that facilitate and reward cost-effective high-value (not high-volume) health care; and

5. Population health information infrastructure to enable community-wide care coordination, including integrated electronic health records (EHRs).

C. PPACA’s Shared Savings Program for ACOs (Section 3022)

1. PPACA establishes January 1, 2012 as the deadline by which the Secretary of the Department of Health and Human Services (HHS) is required to establish a shared savings program specifically relating to ACOs that will promote accountability for a patient population and coordinate items and services under Medicare Parts A and B, as well as encourage investment in infrastructure and redesigned care processes for high-quality and efficient service delivery.

2. Eligibility to participate in the shared savings program, requires an ACO, among other actions, to establish a mechanism for shared governance and a formal legal structure to receive and distribute payments for shared savings among the following types of providers:

   a. Physicians in group practice arrangements;

   b. Networks of individual practices of physicians;

   c. Partnerships or joint venture arrangements between hospitals and physicians;

   d. Hospitals and their employed physicians; and

   e. Such other groups of providers of services and suppliers as the Secretary determines appropriate.
3. The ACO must agree to become accountable for the quality, cost and overall care of the Medicare fee-for-service beneficiaries assigned to it (not fewer than 5,000 individuals). Medicare beneficiaries will be assigned to an ACO based on the selection of primary care service providers. Each ACO will be required to have a sufficient number of primary care professionals to care for the assigned Medicare beneficiaries. Participation with CMS will be by written agreement for a period of not less than three years.

4. With respect to leadership and management structure, the ACO must have clinical and administrative systems capable of the following:

   a. Promoting evidence-based medicine and patient engagement, reporting on quality and cost measures, and coordinating care, such as through the use of telehealth, remote patient monitoring and other such enabling technologies;

   b. Demonstrating compliance with the patient-centeredness criteria specified by the Secretary, such as through the use of patient and caregiver assessments or the use of individualized care plans; and

   c. Measuring and assessing quality, an integral part of the ACO model, through the following:

      (i) Clinical processes and outcomes;

      (ii) Patient and, where practicable, caregiver experience of care; and

      (iii) Utilization (such as rates of hospital admissions for ambulatory care sensitive conditions).

5. Each ACO will be required to submit data in a form and manner specified by the Secretary as deemed necessary to allow the proper evaluation of the quality of care furnished by the ACO.

   a. Such data may include care transitions across health care settings, including hospital discharge planning and post-hospital discharge follow-up care. ACOs are expected to improve the quality of care provided to Medicare beneficiaries over time.

   b. To achieve this result, the Act requires the Secretary, over time, to specify higher standards, new measures or both, for the purposes of assessing such quality of care. Other quality metrics may include electronic prescribing and EHRs.

6. Providers participating through an ACO will continue to be paid in accordance with the original Medicare fee-for-service program, but will also be eligible to receive payment for shared savings if the ACO meets quality performance standards established by the Secretary, and the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries for Parts A and B services, adjusted for beneficiary characteristics, are at least the percentage specified by the Secretary below the applicable benchmark.

   a. In setting the “savings percentage,” the Secretary is to account for normal variation in expenditures under this title, based upon the number of Medicare fee-for-service beneficiaries assigned to an ACO.
b. The benchmark will be based on the most recent available three years of per-beneficiary expenses for parts A and B services for Medicare fee-for-service beneficiaries assigned to the ACO, adjusted for beneficiary characteristics and such other factors as the Secretary determines appropriate, and updated by the projected absolute amount of growth in national per capita expenditures for parts A and B services under the original Medicare fee-for-service program, as estimated by the Secretary. The benchmark will be reset at the start of each agreement period.

7. If the ACO meets the applicable quality performance standards, then a percentage (as determined appropriate by the Secretary and subject to an aggregate limit) of the difference between the estimated average per capita Medicare expenditures in a year, adjusted for beneficiary characteristics, under the ACO and such benchmark for the ACO, is payable to the ACO as shared savings (with the government retaining the remainder of the savings). The remainder of such difference will be retained by the program. The Secretary will have sole and final authority (e.g., not judicial review) over the following:

a. The establishment of the quality performance standards and the assessment of the ACO’s performance against such standards;

b. The assignment of Medicare fee-for-service beneficiaries to the ACO;

c. The determination of whether an ACO is eligible for shared savings or the amount of such shared savings, including the determination of the estimated average per capita Medicare expenditures under the ACO for Medicare fee-for-service beneficiaries assigned to the ACO and the average benchmark for the ACO, the percent of shared savings and any limit on the total amount of shared savings; and

d. The termination of an ACO in the program.

8. ACOs will be prohibited from taking steps to avoid patients at risk in order to reduce the likelihood of increasing costs to the ACO. The Secretary may impose appropriate sanctions on ACOs that try to avoid such patients, including the ultimate sanction of termination from the Medicare Program.

9. Pediatric ACOs

The Act also includes specific provisions pertaining to pediatric accountable care organizations (Section 2706).

a. The purpose of these provisions is to allow pediatric medical providers that meet specified requirements to be recognized as accountable care organizations for purposes of receiving incentive payments.

b. The demonstration project for pediatric accountable care organizations is to begin on January 1, 2012, and end on December 31, 2016.

(i) It is the responsibility of individual states desiring to participate in this demonstration project to submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.
(ii) The Secretary, in consultation with the states and pediatric providers, is to establish guidelines to ensure that the quality of care delivered to individuals by a provider recognized as a pediatric accountable care organization is not less than the quality of care that would have otherwise been provided to such individuals.

(iii) The incentive payment will be tied to savings in excess of the annual minimal savings level established by the state.

(iv) Each participating state, in consultation with the Secretary, will establish an annual minimal level of savings in expenditures for items and services covered under the Medicaid Program and the Children’s Health Insurance Program that must be reached by an accountable care organization in order for such organization to receive an incentive payment.

(v) A provider desiring to be recognized as a pediatric accountable care organization will be required to enter into a participation agreement with a minimum term of three years.

IV. MEDICAL HOMES

A. Evolution of The Medical Home Concept


2. The concept has been refined over time to include various key components including: (a) a personal physician who is directly accountable for, and serves as and care advocate for and partner with the patient (rather than acting as a gatekeeper who restricts access to services); (b) a physician directed medical practice, which includes a team of individual practitioners that is led by the personal physician, takes responsibility for the ongoing care of patients, integrate and individualize care; (c) whole person orientation provided by the personal physician, which addresses all health care needs of a patient along the continuum of care and across various life stages; (d) care coordination and integration, which provides identification of the need for, and strategic management of access to, the full array of specialty and subspecialty services so as to minimize overtreatment and under-treatment, efficiently allocate resources and improve the quality of care; (e) continuous quality and safety improvement through voluntary engagement in proper and safe performance measurement by the physician-directed medical practices guided by evidence-based medicine and involving active physician participation; (f) enhanced access available through systems such as open scheduling, expanded ours and new options fr communication between patients, the personal physician and the practice staff; and (g) payment reform that involves a reformulation of reimbursement policy underlying the current fee-for-service payment model to appropriately recognize the added value a medical home provide through reward of continuity, patient-centered care and accountability and fair compensation of primary care physicians for care coordination and patient education. See, NATIONAL COMMITTEE FOR QUALITY ASSURANCE, GUIDELINES: PHYSICIAN PRACTICE CONNECTIONS, PATIENT CENTERED MEDICAL HOME, available at: http://www.ncqa.org/Portals/0/Programs/Recognition/RPtraining/PPCPCMH_Training.pdf.
B. PPACA Definition of Medical Home

Section 3502 of the PPACA defines a “patient-centered medical home” in simple terms as “a mode of care that includes: personal physicians; a whole person orientation; coordinated and integrated care; safe and high-quality care through evidence-informed medicine, appropriate use of health information technology, and continuous quality improvements; expanded access to care; and payment that recognizes added value from additional components of patient-centered care.” This definition encompasses the key components of the medical home concept as articulated by various sources prior to the enactment of PPACA, with the addition of emphasis on the necessary health information technology.

C. PPACA Grants and Contracts to Establish Health Teams to Support Medical Homes (Section 3502)

1. Section 3502 directs the Secretary to establish a program to provide grants to, or enter into contracts with, “eligible entities” (State, State-designated entity, Indian tribe or tribal organization) to establish “community-based interdisciplinary, inter-professional teams (referred to as “health teams”) to support primary care practices, including obstetrics and gynecology practices, within the hospital service areas served by the eligible entities.

   a. Health Teams established pursuant to such a grant or contract must support patient-centered medical homes.

   b. Section 3502 defines “primary care” as the “provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community.”

2. Section 3502’s requirements for Health Teams are extensive and detailed and might be viewed as a more detailed articulation of the spirit and concept of a medical home than the simple definition provided in that same section of the Act. As with many if not most other PPACA health reform components, these requirements include the ability of Health Teams (a) to support local primary care providers in the collection and reporting of data that permits evaluation of the success of the collaborative effort on patient outcomes, including collection of data on patient experience of care, and identification of areas for improvement; and (b) to demonstrate a capacity to implement and maintain EHR technology that meets the HITECH
Act certification requirements and facilitates coordination among members of the applicable care team and affiliated primary care practices.

D. Fair Compensation and Grant Support for Primary Care Providers

This component of the medical home concept is expressly encompassed within PPACA.

1. Incentive Payments for Primary Care Services (Section 5501)

   a. The PPACA establishes an additional payment for services provided by a “primary care practitioner” between January 1, 2011 and January 1, 2016 in an amount equal to 10% of the amount otherwise paid under Medicare.

   b. “Primary Care Practitioner” is defined to include any physician whose primary specialty designation is family, internal, geriatric or pediatric medicine, and any nurse practitioner, clinical nurse specialist, or physician assistant, for whom “primary care services” accounted for at least 60% of the allowed charges in such prior period as determined by the Secretary.

   c. “Primary Care Services” include services identified by HCPS codes 99201 through 99215, 99304 through 99340, and 99341 through 99350, as the same may be subsequently modified by the Secretary.

2. Grants for Primary Care Training (Section 5301)

   PPACA authorizes the Secretary to make grants to, or enter into contracts with accredited public or nonprofit hospitals, schools of medicine and others for training in various dimensions of primary care, which may include a demonstration program to train primary care physicians in the provision so care through medical homes.

3. PPACA Primary Care Extension Program (Section 5405)

   a. This program, which will be administered by the Agency for Healthcare Research and Quality (AHRQ) and implemented through the use of community-based health connectors referred to as “Health Extension Agents,” will provide support and assistance to “primary care providers” to provide education to other providers about preventive medicine, health promotion, chronic disease management, mental and behavioral health services (including substance abuse prevention and treatment) and evidence-based and evidence-informed therapies and techniques. The support will be in the form of competitive grant awards to State Hubs and Local Primary Care Extension Agencies. Among other things, Primary Care Extension Agencies must demonstrate that they assist primary care providers to implement medical homes.

   b. “Primary Care Provider” for purposes of this program is defined in general as “a clinician who provides integrated, accessible health care services and who is accountable for addressing a large majority of personal health care needs, including providing preventive and health promotion services for men, women, and children of all ages, developing a sustained partnership with patients, and practicing in the context of family and community.
E. Community-Based Collaborative Care Network Program (Section 10333)

PPACA authorizes the Secretary to award grants to support “Community-Based Collaborative Care Networks” that focus on delivery of care to low-income populations.

1. Such Networks are defined as “a consortium of health care providers with a joint governance structure (including providers within a single entity) that provides comprehensive coordinated and integrated care services (as defined by the Secretary) for low-income populations.

2. The network must include hospitals and FQHCs.

3. Grant funds may be used, among other things, to enable low-income individuals to obtain a primary care provider or medical home.

F. Qualified Medical Home Plans (Section 10104)

PPACA authorizes the Secretary to permit a qualified health plan to provide coverage through a qualified direct primary care medical home plan so long as it meets certain requirements.

V. PPACA’S NATIONAL PILOT PROGRAM ON PAYMENT BUNDLING FOR CARE DURING HOSPITALIZATION (SECTION 3023)

Separate from the ACO program, the Act also empowers the Secretary to establish a pilot program for integrated care during an episode of care provided to an applicable beneficiary around a hospitalization in order to improve the coordination, quality and efficiency of health care services.

A. Duration of the Pilot Program

1. PPACA sets January 1, 2013 as the deadline by which the Secretary is to establish the pilot program, and, in consultation with the Agency for Healthcare Research and Quality, the quality measures for use in the pilot program.

2. The pilot program is to be conducted for a period of five years, and is subject to extension if the Secretary determines that an extension will result in improving the quality of patient care and reducing spending under the Medicare Program.

3. Following the pilot program’s completion, but not later than January 1, 2016, the Secretary is responsible for submitting a plan for the implementation of an expansion of the pilot program if the Secretary determines that such expansion will result in improving or not reducing the quality of patient care, and reducing spending under the Medicare Program.

B. Bundled Payments

Payment under the pilot program is envisioned to include bundled payments and bids from entities for episodes of care. The payment methodology must be established in a manner that does not result in spending more than if the pilot program were not implemented. The payment methodology will include payments for the furnishing 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.
C. Quality Improvement and Measurement

As required of ACOs, entities that participate in the pilot program will be expected to improve the quality of care provided. Quality measures (including quality measures of process, outcome and structure) to be established include the following:

1. Functional status improvement
2. Reduction in rates of avoidable hospital readmissions;
3. Rates of discharge to the community;
4. Rates of admission to an emergency room after a hospitalization;
5. Incidence of health care acquired infections;
6. Efficiency measures;
7. Measures of patient-centeredness of care;
8. Measures of patient perception of care; and
9. Other measures, including measures of patient outcomes, determined appropriate by the Secretary.

To the extent practicable, the data relating to these measures is to be submitted through the use of qualified EHRs.

D. Clinical Focus Areas

The program will be focused on up to eight medical conditions, selected by the Secretary, after taking into consideration the following factors:

1. Whether the conditions selected include a mix of chronic and acute conditions;
2. Whether the conditions selected include a mix of surgical and medical conditions;
3. Whether a condition is one for which there is evidence of an opportunity for providers of services and suppliers to improve the quality of care furnished while reducing total expenditures under the Medicare Program;
4. Whether a condition has significant variation in the number of readmissions, and in the amount of expenditures for post-acute care spending under the Medicare Program;
5. Whether a condition is high-volume and has high post-acute care expenditures under the Medicare Program; and
6. The conditions that the Secretary determines are most amenable to bundling across the spectrum of care, given practice patterns under the Medicare Program.
E. Payment on the Basis of Episodes of Care

1. The bundled payment will cover an “episode of care” defined, with respect to the applicable condition and beneficiary, by the period including the following:

   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 such hospital; and

   c. The 30 days following the discharge of the applicable beneficiary from such hospital.

2. Services to be included within the bundled payment are as follows:

   a. Acute care inpatient services;

   b. Physicians’ services delivered in and outside of an acute care hospital setting;

   c. Outpatient hospital services, including emergency department services;

   d. 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

   e. Other services the Secretary determines appropriate.

F. Eligible Entities

Entities eligible to participate in the pilot program are those composed of providers of services and suppliers, including a hospital, a physician group, a skilled nursing facility and a home health agency. The Secretary will be developing the participation requirements, which are intended to ensure that beneficiaries have an adequate choice of providers of services and suppliers under the pilot program.

VI. OTHER PPACA PAYMENT REFORMS

A. Value-Based Purchasing (Section 3001)

Beginning October 1, 2012, Medicare will implement a value-based purchasing program (VBP). The program will award incentive payments for meeting certain quality performance standards, and beginning in 2014 certain efficiency measures. Performance results will be publicly reported. Implementation of the program will involve the development of measures to be used to assess achievement of the standards. Section 10301 of the PPACA directs the Secretary to submit a report on the development of a similar program for skilled nursing facilities and home health agencies.

B. Hospital Readmissions Reduction Program (Section 3025)

Hospitals determined to have an “excess readmissions ratio” (to be defined by the Secretary) will experience Medicare reimbursement reductions beginning after October 1, 2012.
C. Demonstration Projects and Pilots

1. The PPACA extends the ongoing Gainsharing Demonstration project until 2014.

2. Section 2705 of the PPACA establishes a Medicaid Global Payment System Demonstration Project which will operate from 2010 through 2012 in up to 5 states and will be coordinated with CMI. It will allow the states to adjust payments to safety net hospital systems or networks from fee for service to global capitation.

3. Section 2704 authorizes states to establish a demonstration project to evaluate integrated care around hospitalization, including bundled payments around an episode of care for inpatient care of Medicaid Patients.

VII. HEALTH INFORMATION INFRASTRUCTURE – AN ESSENTIAL FOUNDATION AND STRATEGIC TOOL FOR ACO IMPLEMENTATION

The need for an EHR and other health information technology (HIT) infrastructure to support both the measurement and the reporting of achievements in quality and clinical and cost effectiveness of health reform initiatives and strategies, such as ACOs, Medical Homes and innovative payment systems, is a recurring theme throughout PPACA.

A. Pre-PPACA Developments

This emphasis on HIT infrastructure to support healthcare reform has evolved rapidly since 2004 through initiatives such as the Patient Safety and Quality Improvement Act of 2005, the federal government’s vision and regulatory support for the widespread implementation of electronic health records, the growing emphasis on evidence-based medicine and comparative effectiveness research and the trend toward translational research and personalized medicine. For a detailed discussion of the history and evolution of the emphasis on HIT infrastructure, see Bernadette M. Broccolo and Sandra M. DiVarco, “Health Information Technology: An Essential Ingredient in the New Health Reform Recipe,” 2 HITR 27 Bureau of National Affairs (7/5/10).

B. PPACA Provisions

Following is a representative sample of PPACA provisions that reflect the legislation’s emphasis on, and recognition of the importance of, EHR and other health information technology (HIT) infrastructure to support both the measurement and the reporting of achievements in quality and clinical and cost effectiveness of health reform initiatives and strategies.

1. Measurement and Reporting Requirements Relating to Payment and Care Delivery Provisions Generally

a. CMI and Development of New Models of Care and Payment (Section 3051)

The criteria and considerations PPACA provides for CMI’s use in testing and assessing new care delivery and payment models include use of a health information technology-enabled provider network to support care coordination for chronically-ill individuals at high risk of hospitalization and the use of technology such as EHR and patient-based remote monitoring systems to coordinate care over time and across settings.
b. ACO Reporting Requirements (Section 3022)

An ACO will be required to submit data on measures to be prescribed by the Secretary (e.g., care transition (discharge planning and follow-up) across health settings, and in a form and manner specified by the Secretary. In light of the PPACA’s recurring emphasis on having an EHR and other HIT infrastructure, it is likely submission in electronic form will be required.

c. Physician Quality Reporting Initiative (Section 3002)

PPACA authorizes the Secretary to incorporate into the current PQR Initiative reporting and incentive payments related to electronic prescribing and meaningful use of electronic health records.

d. Community Health Teams to Support Medical Homes (Section 3502)

Community Health Teams created under this Section must (1) collect and report data that permits the evaluation of the success of the collaborative effort on patient outcomes (including collection of data on patient experience and areas for improvement) and quality measures; and (2) demonstrate the capacity to implement and maintain certified EHR technology to facilitate coordination among members of the care team and affiliated primary care practices.

e. Quality Reporting by Health Plans and Insurers (Section 2717)

Within two years of PPACA’s enactment, the Secretary will develop reporting requirements for use by a group health plan and a health insurance issuer offering group or individual health insurance coverage, with respect to plan or coverage benefits and health care provider reimbursement structure that, among other things, implement activities to improve patient safety and reduce medical errors through appropriate use of health information technology.

2. PPACA – Focus on Measurement of Outcomes and Evidence-Based and Evidence-Informed Care

a. Patient-Centered Outcome Research Institute and Comparative Clinical Effectiveness Research (Section 6301)

PPACA establishes a nonprofit “Patient-Centered Outcomes Research Institute” in order to “assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of [certain] medical treatments, services, and items.”

(i) The Institute is neither an agency nor an establishment of the federal government.

(ii) It will be focused on identifying opportunities for, and carrying out, “comparative clinical effectiveness research” defined as research to “evaluate and compare health
outcomes and the clinical effectiveness, risks, and benefits of 2 or more of [certain] medical treatments, services and items.”

(iii) The “medical treatments, services and items” are “health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.”

(iv) The Institute’s efforts will be funded through a trust fund.

(v) The data used to support the comparative clinical effectiveness research will be either provided by the Secretary from data collected by CMS, derived from data networks developed by the Public Health Service Act, and data the Institute may request and obtain from Federal, State or private entities, including data from clinical databases and registries. Section 6301 appears to contemplate the conduct of both primary and secondary research under the Institute’s auspices.

(vi) The AHRQ Office of Communication and Knowledge Transfer, in consultation with NIH, is charged with broad dissemination of the results of the research findings published by the Institute as well as other comparative effectiveness research funded by the government, to physicians, health care providers, patients, vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans.

(vii) Section 6301 imposes various limitations on the Secretary’s ability to use the findings from Comparative Clinical Effectiveness Research to make coverage decisions. Among other things, any such use must be through an iterative and transparent process that includes public comment and considers the effect on subpopulations.

b. CMI and Development of New Models of Care and Payment (Section 3051)

The criteria and considerations PPACA provides for CMI’s use in testing and assessing new care delivery and payment models include alignment of nationally recognized, evidence-based guidelines of cancer care with payment incentives for treatment planning and follow-up and identification of gaps in quality measures.

c. National Strategy for the Improvement of Care (Section 3011)

The National Strategy PPACA directs the Secretary to establish on or before January 1, 2011 must address various priorities enumerated in Section 3011, including the enhancement of the use of data to improve quality, efficiency, transparency and outcomes and the improvement of research and dissemination of best practices to improve patient safety and reduce medical errors, preventable readmissions and health care-associated infections.

d. PPACA Primary Care Extension Program (Section 5405)

The areas in which this program will provide education and other assistance to primary care providers includes evidence-based and evidence-informed therapies and techniques.
The support will be in the form of competitive grant awards to State Hubs and Local Primary Care Extension Agencies. Among other things, Primary Care Extension Agencies must demonstrate that they assist primary care providers to implement medical homes.

e. Community Transformation Grants (Section 4201)

These competitive grants will fund efforts by State and local governmental agencies and community-based organizations to implement, evaluate and disseminate evidence-based community preventive health activities to reduce chronic disease rates, prevent the development of secondary conditions, address health disparities, and develop a stronger evidence-base of effective prevention programming.

VIII. LEGAL FEASIBILITY ISSUES

A. Overview

When assessing the development and implementation of an ACO, Medical Home or other innovative care delivery or payment model, numerous legal and regulatory feasibility considerations will need to be analyzed and addressed, including the following:

1. The alternative form of organization, related governance and operating structure.

2. Tax status of any ACO entity or entities created.

3. Effect of participation in any entity and financial relationships it develops on the exempt status of any exempt hospital or other exempt participant.

4. Federal and state privacy and security laws governing the sharing of patient data among providers.

5. Applicable state laws governing the corporate practice of medicine, fee-splitting and medical foundations.

6. The various federal statutes applicable to relationships between institutional and providers and physicians, including the federal Anti-Kickback Law, Stark Law and the Civil Monetary Penalty (CMP) Law, and Internal Revenue Code Sections 501(c)(3) and 4958:

a. For example, are any “gainsharing arrangements” or similar “pay for performance” compensation arrangements (including risk-sharing arrangements) structured to meet the federal CMP Law as interpreted by applicable Office of Inspector General advisory opinions, in addition to applicable tax-exemption requirements?

b. Must there be an independent valuation for any quality incentive or shared savings payments?

c. Does the CMP Law prevent making any physician employment compensation contingent on a reduction in LOS and readmission rates?
d. Can physician employees be paid a percentage of a hospital’s Medicare-related cost savings (or step-up in payment for quality) under the Stark employment exception without a volume/value problem and under federal tax-exemption standards?

e. If the Stark Law employment exception is limited to compensation “for identifiable services,” are changes in clinical and administrative conduct “identifiable services?” If so, what is the fair market value of the changes?

7. State HMO/insurance/managed care organization laws, including plan licensing, “any willing provider” laws and the like.

For example, do applicable state HMO/insurance/managed care organization statutes and regulations, or applicable corporate practice of medicine and fee-splitting laws, require the ACO or similar integrated entity to obtain a health plan or other managed care organization license or certificate in order to receive global capitation for inpatient, outpatient and physician services, or similar risk payments from health plans?

8. Federal antitrust law and related clinical integration requirements.

For example, are the physicians participating in the ACO or similar integrated delivery system clinically integrated to a sufficient extent to avoid violating the price-fixing prohibition under the Sherman Act?

Following is a discussion of issues 1 through 5 above. The remaining issues are discussed in detail in the outline of co-presenter for this session, Peter Pavarini.

B. Tax-Exemption Considerations

1. Overview

The legal structure of an ACO organization and the nature of the relationships between and among its participating providers will vary widely as will the corresponding tax-exemption issues. The primary focus of the following discussion is on the tax-exemption issues applicable to the hospital-physician relationships dimensions in the formation and operation of an ACO (other than those involved in the acquisition of physician practices). Among the key tax-exemption issues that are likely to arise are the following:

a. Whether an entity that is formed or restructured to implement the hospital-physician relationship aspects of an ACO will qualify for tax-exemption under Section 501(c)(3).

b. Whether an exempt hospital or health system’s participation in an ACO-related hospital-physician joint venture will jeopardize its tax-exempt status or generate unrelated business taxable income (UBTI).

c. What rules and requirements will affect the structuring of incentive compensation, pay-for-performance, and shared savings distributions arrangements with physicians in an ACO in which a Section 501(c)(3) organization participates.

All three issues implicate regulations, cases, rulings and IRS guidance that were applied successfully in prior generations of hospital-physician integration (particularly from the mid-
1990s to the early 2000s). However, the ACO context will present new challenges, new twists and variations on familiar themes.

2. Stand-Alone Tax-Exemption for ACO Entity as an Organization that Promotes Health for the Benefit of the Community

a. Since the issuance of Revenue Ruling 69-545, the basis for Section 501(c)(3) tax exemption for hospitals and other healthcare organizations has been that they qualify as charitable because they promote the health of the community. In Rev. Rul. 69-545, the IRS recognized the promotion of health as a charitable purpose within the meaning of IRC § 501(c)(3) and the corresponding Treasury Regulations, even if “the class of beneficiaries eligible to receive a direct benefit from activities does not include all members of the community, such as indigent members of the community, provided that the class is not so small that its relief is not of benefit to the community.” 1969-2 C.B. 117.

b. IRS has consistently issued tax-exemption under this “community benefit” standard to hospitals that operate an emergency room open to all persons and provide hospital care for all persons in the community able to pay the cost thereof either directly or through third party reimbursement. Compare Rev. Rul. 56-185, 1956-1 C.B. 202; Rev. Rul. 83-157, 1983-2 C.B. 94. Additional criteria articulated in Rev. Rul. 69-545 include an open medical staff and a community board (discussed further below).

c. Beginning in 1993, the IRS issued Section 501(c)(3) status to many “integrated delivery system (IDS) organizations created during the 1990s to operate medical practices acquired by physicians and for-profit professional corporations. These organizations were also involved in the direct provision of medical services to a broad segment of the community in which they operated.


d. Direct Provision of Medical Care

The direct provision of medical, hospital or nursing care to individuals is not the exclusive means by which an organization can establish that it promotes health for the benefit of the community within the meaning of Section 501(c)(3).

(i) Even prior to the IDS movement of the 1990s, the IRS was willing to extend the concept of “promoting health” beyond the traditional acute care hospital context to include organizations that do not directly provide medical care, but otherwise promote the health of the community.


(c) An organization that constructed a hospital and it leased to a public entity to operate the hospital Rev. Rul. 80-309, 1980-2 C.B. 183.

(d) Organization operating a free computerized donor authorized retrieval system to facilitate the transplantation of body organs. “[B]y facilitating the donation of organs which will be used to save lives, the organization is serving the health needs of the community and, therefore, is promoting health within the meaning of the general law of charity. Rev. Rul. 75-197, 1975-1 C.B. 156.

(e) A regional health data system formed to conduct studies and propose improvements regarding quality, utilization and effectiveness of health care and health care agencies and to educate those involved in furnishing, administering and financing health care. Rev. Rul. 76-455, 1976-2 C.B. 150.

(ii) HMO Exemption

On the other hand, in Geisinger Health Plan v. Commissioner, 62 T.C.M. 1656 (1991), rev’d 985 F.2d 1210 (3rd Cir. 1993); remanded 100 T.C. No. 26, filed May 3, 1993, the Third Circuit ruled that a health maintenance organization that provided or arranged for health services only to its subscribers did not qualify as a §501(c)(3) organization. The Tenth Circuit reached the same result in IHC Health Plans, Inc. v. Commissioner, 325 F.3d 1188 (10th Cir. 2003). In a subsequent decision after remand, Geisinger Health Plan v. Commissioner, 30 F.3d 494 (3d Cir. 1994), the Third Circuit determined that the HMO was not entitled to exemption on the theory that it formed an integral part of the related hospital and clinic. See also, GCM 39828 (August 30, 1990).
(iii) PHO Exemption

(a) In a 1995, the IRS characterized a PHO as an “independent practice association” with a hospital participant formed for the purpose of arranging with managed care payers (e.g., insurance companies or employers), on behalf of the participants in the PHO, to provide physician or hospital care. Charles F. Kaiser, Phyllis D. Haney and T. J. Sullivan, “Integrated Delivery and Joint Venture Dissolution Update,” IRS Exempt Organization Continuing Professional Education Technical Instruction Program for Fiscal Year 1995, p. 153 (1994) (“1995 CPE Text”). The IRS focused on the fact that a PHO itself provides no health care services; rather, its primary functions are to plan and implement a coordinated, cost-effective health-care delivery system that assures all needed medical treatments and resources are available and avoids duplication of services. The IRS characterized this as a “joint marketing arrangement.” As a result, the IRS stated that a PHO will not qualify for stand alone § 501(c)(3) status because:

(1) it does not engage in the practice of medicine or operate a hospital; and

(2) despite the hospital’s participation, the PHO's primary beneficiaries are its member-physicians rather than the community as a whole (citing Rev. Rul. 86-98, 1986-2 C.B. 74) and its activities are substantially devoted to serving those physicians’ interests (and thus cannot satisfy the private inurement or private benefit prohibitions of § 501(c)(3)).

This position is restated by the IRS in its 1996 CPE Text (p. 401).

The 1995 CPE Text also states that a PHO will not qualify for integral part exempt status because negotiating managed care contracts for the member-physicians is a substantial activity of the PHO and such activity is not an essential service to the hospital participant in the PHO.


e. Charity Care as an Indicia of Community Benefit

(i) The IRS included the level of charity care as a factor supporting the favorable determination letters issued to many of the IDS entities in the 1990s, thus expanding the Rev. Rul. 69-545 community benefit criteria in the context of a provider other than a hospital. This arguably provided the IRS with a tangible basis for distinguishing the IDS entities from the for-profit medical practices from which they were derived.
(ii) New Code Section 501(r), which was enacted as part of the federal health reform legislation, imposes several additional requirements on exempt “hospitals” described in section 501(c)(3) of the Code Patient Protection and Affordable Care Act, Pub. L. 111-148, § 9007(a), 124 Stat. 1035. A tax-exempt hospital now must: (1) conduct a community health needs assessment at least once every three years, adopt an implementation strategy for meeting the needs the assessment identifies, and make the assessment widely available to the public; (2) adopt, publicize and make widely available its financial assistance policy; (3) restrict charges for emergency or medically necessary care provided to patients eligible under the financial assistance policy to no more than the lowest amounts generally charged to insured patients and refrain from using gross charges; and (4) take “reasonable efforts” to determine if a patient qualifies for financial assistance before initiating “extraordinary” collection actions (e.g., referral to collection agencies). These new requirements apply for tax years beginning after the Act’s enactment date. Failure to satisfy them will result in loss of exemption under section 501(c)(3) at either the entity level or at the hospital-specific level and monetary penalties for failure to comply with certain of the new requirements.

(a) An ACO entity that does not provide hospital or other healthcare services but instead is a vehicle for achieving coordination and accountability for the provision of quality and affordable care should not be required to comply with the Section 501(r) financial assistance policy requirement (including the charity care component implicit in it).

(b) Nonetheless, consideration should be give to incorporating charity care and financial assistance components into the ACO’s care coordination, cost and quality programs in a way that will contribute favorably to the case for exemption, as should a provision for treatment on a non-discriminatory basis (i.e., regardless of payor).

f. Independent Community Board Requirement As an Indicia of Community Benefit

The various criteria the IRS considers in applying the community benefit standard include whether the hospital is governed “by a board of directors composed of independent civic leaders.” In 2007, the IRS renewed its consideration of the community board factor as part of a new and broader focus on “good governance” overall. The IRS currently links good governance and compliance – that is, good governance is more likely to lead to compliance with the requirements for Section 501(c)(3) exempt status (both exempt purposes and absence of private inurement and more than incidental private benefit). See “Governance and Related Topics – 501(c)(3) Organizations,” p.1, released February 4, 2008, available at http://www.irs.gov/pub/irs-tege/governance_practices.pdf.

The role of physicians in the governance of an ACO will clearly be a key consideration in the IRS’ review of an ACO’s qualifications for 501(c)(3) status.

(i) In the early to mid-1990s, the IRS took the position that no more than 20% of the governing board of a tax-exempt entity formed to operate a physician practice could be comprised of a combination of disinterested persons, including both officers and physicians. This conservative position was motivated in large part by the concern that it is difficult to distinguish tax-exempt medical groups from taxable medical groups that operate primarily for the benefit of the group’s physicians.
In 1996, however, the IRS moved away from this conservative position and announced the following three criteria for demonstrating appropriate community representation:

(a) a majority of the voting members of the organization’s board are independent community members;

(b) the organization has a conflict-of-interest policy applicable to transactions or arrangements with interested persons; and

(c) the board and all committees with board-delegated powers, as part of their systems of controls, conduct periodic reviews of the organization’s activities to ensure that it is operating for community benefit, rather than private interests, in areas such as compensation arrangements, practice acquisitions, and joint ventures. Lawrence M. Brauer and Charles F. Kaiser, “Tax-Exempt Healthcare Organizations Community Board and Conflicts of Interest Policy,” IRS Exempt Organizations Continuing Professional Education Technical Instruction Program for Fiscal Year 1997, at 18 (1996) (“1997 CPE Textbook”). For the model conflicts policy the IRS has recommended for use by exempt organizations, see the Instructions to Form 1023 (Rev. June 2006) at http://www.irs.gov/pub/irs-pdf/i1023.pdf.

The IRS has specifically stated that “[p]racticing physicians affiliated with the hospital, officers, department heads, and other employees of the hospital are not independent due to their close and continuing connection with the hospital.” Id.

Derived Community Board

(a) In liberalizing its position on the community board requirement in the context of IDS formations in the 1990s, the IRS also took the following position regarding physician-controlled boards of entities created as subsidiaries of exempt parent organizations:

“In a multi-entity hospital system, the board of a subsidiary non-profit health care organization is considered to be comprised of independent community members if it is controlled by an exempt organization whose board is comprised of a majority of voting members who are independent community members.” 1997 CPE Textbook, p. 21.

(b) In 2000, the IRS addressed the derived community board concept in the context of professional corporations (“PCs”) seeking tax-exemption in those states with strict corporate practice of medicine prohibitions. More specifically, tax-exempt hospitals located in states with strict corporate practice of medicine prohibitions had difficulty forming tax-exempt hospital affiliated group practices because the states in which such hospitals were located required such group practices to be established as PCs, but the IRS would not grant exemption to PCs because of the organizational structure of such entities.

(1) To rectify this problem, the IRS took the position that it would agree to recognize tax-exempt hospital affiliated PCs as described in Section 501(c)(3) of the Code if certain conditions were satisfied. With respect to
board composition, the IRS stated that while the board members of the PCs may be physicians (as required under state law), the community board of the tax-exempt parent must retain and exercise reserved powers that are sufficient to ensure that the PC’s activities always accomplish charitable purposes and avoid inurement and private benefit, including the right to: (1) elect, appoint, remove and change the number of the directors; (2) amend, alter or repeal the articles of incorporation and bylaws; and (3) approve significant actions including (a) the annual operating and capital budgets and material deviations from such budgets, (b) the sale, lease, mortgage or other transfer or encumbrance of real or certain valuable personal property; (c) the merger, acquisition, consolidation, liquidation, or dissolution; (d) the settlements of claims and litigation; and (e) the selection of auditors. Charles F. Kaiser III and Marvin Friedlander, “Corporate Practice of Medicine,” IRS Exempt Organization Continuing Professional Education Technical Instruction Program for Fiscal Year 2000, at 58 (1999) (“2000 CPE Textbook”).

(2) The 2000 CPE Text provides an exhaustive coverage of the IRS’ rational and criteria for granting § 501(c)(3) status to Captive PCs and attaches as exhibits the relevant portions of those favorable determination letters.

(3) Additional guidance may be drawn from the precedent dealing with tax-exempt status of medical faculty groups associated with university hospitals, an area of scrutiny announced by the IRS in mid-1991. Notably, the focus of such scrutiny is whether there are qualitative differences between medical faculty groups and groups that are in reality little more than the physicians’ private charity. See, e.g., University of Maryland Physicians, P.A., 41 T.C.M. (CCH) 732 (1981); University of Massachusetts Medical School Group Practice v. Comm’r, 74 T.C. 1299 (1980); B.H.W. Anesthesia Found., Inc., 72 T.C. 681 (1971).

3. Stand-Alone Tax-Exemption for ACO Entity as an Organization that Lessens the Burdens of Government

Lessening the burdens of government is a basis for exemption advanced recently in support of the exemption of Regional Health Information Organizations (RHIOs). While relying on this theory alone may be insufficient to support exemption for an ACO, it is worth considering as a means of lending further support to the case for exemption.

a. An ACO entity seeking Section 501(c)(3) exemption under a lessening of the burdens of government rationale must demonstrate that:

(i) the applicable governmental unit considers the ACO activities to be its burden, and

(ii) the ACO’s activities actually lessen such burden.

b. An activity is considered a burden of the government if there is an objective manifestation by such governmental unit that it considers the activities to be its burden.
c. Whether the organization is actually lessening the burdens of government is
determined by considering all of the relevant facts and circumstances. (See, e.g.,
Rev. Rul. 85-1, 1985-1 C.B. 17.) In Rev. Rul. 81-276, for example, the IRS
determined that the operation of a peer review organization qualified for
exemption under a lessening the burdens of government rationale.

d. A significant positive factor for finding a qualifying governmental burden is the
level of involvement of the applicable government in the governance and
activities of the organization or the existence of significant governmental financial
support, especially in the form of general grants.

e. See Louthian and Henchey, “Lessening the Burdens of Government,” IRS
Exempt Organizations Continuing Professional Education Text (1993), which
may be found at http://www.irs.gov/pub/irs-tege/eotopicb93.pdf.

4. Exemption Under the Integral Part Theory

a. In general, the integral part doctrine provides that an organization will be entitled
to exemption under Section 501(c)(3) if it provides necessary services solely to
exempt organizations to which it is related.

b. Satisfaction of the integral part doctrine by an ACO entity will require a
demonstration that its activities are conducted for the purpose of enabling the
related organization(s) to accomplish its own charitable purposes more
effectively, less costly, or more competitively.

c. A close working relationship with an existing Section 501(c)(3) organization and
a demonstration that the operation of the ACO entity is an essential service of
such exempt organization are key.

5. Section 509(a) Public Charity Status

Section 501(c)(3) organizations are classified either as “public charities” or “private
foundations.” By default, all Section 501(c)(3) organizations are private foundations unless
they qualify as a public charity under Section 509(a)(1), (2) or (3) as: (1) being a specified
type of organization (including churches, universities, hospitals, and medical research
organizations) (509(a)(1)); (2) receiving a substantial part of their support from the
governmental or the public (509(a)(1) or (2)); or (3) providing support to another Section
501(c)(3) entity that falls under one of the first two categories (509(a)(3)). Structuring the
governance of the ACO to satisfy the requirements of Section 509(a)(3) as well as Section
501(c)(3) will be a key feasibility consideration for an exempt ACO entity.

6. Participation in Joint Venture ACO Entity

a. Prior to 1980, the IRS generally took the view that participation as a general
partner in a joint venture with a for-profit entity was per se inconsistent with
continued tax-exempt status for a § 501(c)(3) organization. Compare GCM
36293 (May 30, 1975) (stating the per se position) with GCM 37852 (Feb. 15,
1979) (retreating somewhat from the per se rule). The IRS’s per se rule was based on the view that (1) the joint venture is a vehicle for sharing profits with other investors, (2) as a general partner the exempt organization has a fiduciary duty under state partnership law to further the private financial interests of its partners, and (3) as a general partner the exempt organization is exposed to unlimited liability for the debts of the partnership, which benefits its partners.

b. The IRS’s per se prohibition was rejected by the Tax Court in Plumstead Theatre Society v. Commissioner, 74 T.C. 1324 (1980) in which a § 501(c)(3) organization acted as the sole general partner in a limited partnership with a for-profit corporation and individuals. The purpose of the partnership was to raise funds to produce a play. The Tax Court approved Plumstead’s role as general partner and found that (a) the formation of the partnership was the result of arm’s length negotiations; (b) the exempt organization was not obligated to use its own funds to return any capital contributed by the limited partners; (c) the partnership had no interest in the exempt organization; (d) the limited partners had no control over the way the exempt organization managed its affairs; and (e) none of the limited partners was an officer or director of the exempt organization.

c. Since the Tax Court’s decision in Plumstead, the IRS’ administrative position has been that, under appropriate circumstances, an exempt organization may participate in a joint venture with a taxable entity without jeopardizing its tax-exempt status. The IRS’s post-Plumstead position is generally regarded as imposing two basic requirements on an exempt organization serving as the general partner of a joint venture with for-profit participants: (a) the partnership must further the exempt organization’s charitable purposes, and (b) the partnership agreement must permit the exempt organization as general partner to operate exclusively in furtherance of its exempt purposes, without regard to any state-law duty to maximize profits for other partners. GCM 39005 (June 28, 1983). See also GCM 39862 (November 22, 1991); GCM 39732 (November 4, 1987); GCM 39546 (August 14, 1986).

d. This two-part test has been interpreted and applied in many GCMs and PLRs that have added various refinements: (a) the exempt general partner should receive distributions of partnership income at least in proportion to its capital contribution and its losses should not exceed its share of partnership capital (GCM 39732 (November 4, 1987)); (b) transactions between the partnership and its for-profit partners must be at arm’s length and reflect fair market value, including reasonable compensation for services provided to the partnership (Id.); (c) in determining whether the charitable purpose requirement is met, there should be evidence of community benefit such as creation of a new healthcare provider, expansion of community healthcare resources, improvement of treatment modalities, reduction of healthcare costs, or improvement of patient convenience and access to physicians (GCM 39862 (November 22, 1991)); and (d) there should be protections against conflicts of interest if insiders of the exempt organization general partner invest in the joint venture (GCM 39444 (July 18, 1985)).
e. Revenue Ruling 2004-51 (May 6, 2004) addresses an exempt organization’s participation in a joint venture with a for-profit entity in which the joint venture’s activities represent an insubstantial portion of the total activities of the exempt participant. Revenue Ruling 2004-51 involves the formation of a limited liability company by a tax-exempt university and a for-profit company for the purpose of offering off-campus, summer training programs for secondary school teachers using interactive video technology.

(i) The exempt university did not have majority control over the venture. Nonetheless, the Ruling concludes that the university’s participation in the joint venture will not adversely affect the university’s continued tax-exempt status because the activities the university is conducting through the joint venture are not a substantial part of the university’s activities.

(ii) The Ruling does not indicate how the IRS determined that the university’s participation in the joint venture was an insubstantial part of its activities, and in fact there is no bright-line test for substantiality. However, the Ruling clearly indicates that majority control by the exempt organization is not essential for a favorable ruling on that issue in the context of an ancillary joint venture.

(iii) The Ruling also concludes that the activities the university is conducting through the joint venture are not an unrelated trade or business and do not create UBI for the university. The key factor supporting this conclusion is the exclusive control the exempt university exercises over the important, educational aspects of the joint venture’s activities that affect whether the joint venture operates in a manner consistent with the exempt organization’s exempt purposes.

(iv) Other facts and circumstances the IRS cites in support of the favorable ruling focus primarily on: the provisions of the LLC governing documents dealing with the purposes and activities of the LLC and their compliance with the exempt status of the university; the equal voice of the members in making non-curriculum or business decisions with respect to the LLC; the allocation of profits and losses of the venture in proportion to each party’s capital contribution; and the arm’s-length nature and market comparability of the contractual relationships between the LLC and either of the venturers or third parties.

f. PHO Joint Ventures

(i) With respect to whether an exempt hospital or one of its affiliates can participate in a PHO joint venture without jeopardizing its exemption, the IRS 1995 CPE Text provides that the participation should be analyzed using the well-established three-part test the IRS has traditionally used to analyze the effect on exempt status of participation in a partnership with non-exempt
entities or individuals. It also reiterates the factors set forth in GCM 39372 for analyzing an exempt organization’s participation in a joint venture:

(a) Is there a disproportionate allocation of profit or loss in favor of the for-profit partner?

(b) Is there nominal or insufficient capital contribution by the for-profit partner?

(c) Are new equipment or services brought into the partnership or is the service or equipment already available in the area?

(d) Is existing hospital equipment or facilities sold or leased to the partnership?

(e) Is any service being provided by the hospital at less than fair market value?

(f) Does a for-profit limited partner have significant influence and control over operations?

(g) Does the exempt organization bear all risk or liability for the partnership losses?

Are commercially reasonable loans made to the partnership (low interest or inadequate security)?

(ii) The 1995 CPE Text focuses on the following special considerations in the PHO context:

(a) whether the hospital’s control or profit share in the PHO is smaller than its share of the capital contribution (In such case, the IRS believes that the PHO member physicians would derive benefits disproportionately greater than their risk. In other words, “to be consistent with § 501(c)(3) status, the expenses of the arrangement should be paid by the hospital and the aggregate physician members in proportion to the benefit derived by each to assure that only incidental private benefit is conferred on the physician members, who otherwise would have no financial risk.”); and

(b) whether the PHO is a vehicle for sharing capitated payments with the physicians and the physicians are being paid more than reasonable compensation for their services or the hospital otherwise receives less than a fair portion of income.

g. In the 1996 CPE Text, the IRS discussed the tax issues posed when there is disproportionality between the benefits of participation and capital contributions of the tax-exempt hospital and physician investors in a PHO joint venture.
The discussion attempts to provide some flexibility with respect to the application of the general rule that a hospital’s control and financial share of the PHO must be proportionate with its capital contribution. It suggests that while PHO capitalization should be commensurate with expected benefits therefrom, all of the benefits of participation should be considered in making this analysis. The opportunity to control the PHO is a benefit of participation therein and may evince a hospital’s intention to protect its investment. Significantly, though, the IRS notes that absolute parity between investment and control in the PHO may not be required if other benefits to the hospital, such as properly structured loans and preferred stock arrangements, where reasonable, are in place. 1996 CPE Text, p. 403.

The CPE Text fails to discuss the extent to which community benefits associated with the venture (i.e., absent the venture the hospital would need to expend additional funds to directly provide the activity) offset any disproportionality.

7. Compensation Arrangements Involving ACOs with Exempt Organization Participants

a. Private Inurement

An organization does not qualify for exemption under Section 501(c)(3) if any part of its net earnings inures to the benefit of any private shareholder or individual. Treas. Reg. § 1.501(a)-1(c). This “insider” group (in whose favor private inurement is prohibited) has evolved considerably over the past 15 years.

b. Private Benefit

An organization does not qualify for exemption under Section 501(c)(3) unless it serves a public rather than private interest. Treas. Reg. § 1.501(c)(3)-1(d)(1)(ii). Private benefit is not completely prohibited (as is private inurement), but instead must be “incidental,” both qualitatively and quantitatively relative to the public benefit served. See GCM 37789 (December 18, 1978) for a discussion of the meaning of incidental. See also, Sonora Community Hosp. v. Comm’r, 46 T.C. 519 (1966), aff’d, 397 F.2d 814 (9th Cir. 1968).

c. Intermediate Sanctions

Code Section 4958 allows the IRS to impose excise taxes on “excess benefit transactions” involving an organization exempt from tax under Code Section 501(c)(3) or (c)(4) and a disqualified person. 26 C.F.R. § 53.4958-1 – 53.4958-8.

(i) Excess Benefit Transactions Include:

(a) A non-fair market value (“FMV”) transaction, in which a disqualified person pays less than FMV to the exempt organization or charges the exempt organization more than FMV (the preamble to the Temporary regulations made clear that embezzlement is included);
(b) An **unreasonable compensation transaction**, in which a disqualified person receives unreasonable compensation from the exempt organization; and

(c) A **prohibited revenue sharing transaction**, in which a disqualified person receives payment based on the revenue of the exempt organization in an arrangement **specified in final regulations** under Section 4958 that violates the inurement prohibition under current law. Those regulations have not been issued. Until they are the same reasonableness standards apply to all compensation arrangements, regardless of whether those arrangements are structured as revenue-sharing arrangements. This includes the rebuttable presumption of reasonableness discussed below.

(ii) Physicians as DQPs

The legislative history of Section 4958 rejects the position that all physicians are insiders. H.R. Rep. No. 506, 104th Cong., 2d Sess. (1996) at 58.n.12. The regulations include two examples involving physicians.

(iii) Initial Contract Exception

(a) A person can become a disqualified person as the result of entering into a contract. However, the regulations establish an “initial contract exception” to protect from intermediate sanctions liability certain “fixed” payments for the provision of services or property made under a binding written contract to persons who were not disqualified immediately before entering into the contract. Treas. Reg. § 53.4958-4(a)(3).

(b) “Fixed payments” are defined to include an amount of cash or other property that is either specified in the contract or determined using a “fixed formula” specified in the contract. Treas. Reg. § 53.4958-4(a)(3)(ii).

(c) Payments that include a variable component (such as achieving certain levels of revenue or business activity) may qualify as a fixed payment so long as the components are calculated pursuant to a pre-established, objective formula.

(iv) Intent to Treat Payments as Compensation

(a) An economic benefit is not treated as consideration for the performance of services unless the exempt organization clearly indicated its intent to so treat the benefit. Code Section 4958(c)(1)(A); Treas. Reg. § 53.4958-4(c).

(b) Payments or benefits that are not clearly indicated to be intended as compensation may be treated as excess benefits under Section 4958 (or might be treated as resulting in private inurement), even if they would have been reasonable if treated as compensation. For this reason, it is very
important to establish clearly all the payments to an employee that are intended to be treated as compensation.

(c) To indicate clearly that payments or benefits are intended as compensation, the exempt organization must create written substantiation contemporaneous with the transfer. If the organization or a disqualified person reports the benefit (e.g., Forms W-2/1099, 990 and 1040), or if the failure to report is due to reasonable cause, there is contemporaneous written substantiation of intent. Treas. Reg. § 53.4958-4(c)(3).

(v) Rebuttable Presumption of Reasonableness – Essential Criteria

The regulations under Section 4958 provide an important protection in assuring that compensation is reasonable and that no private inurement occurs. See Treas. Reg. § 53.4958-6. A “rebuttable presumption of reasonableness” (referred to as “the presumption”) applies to a compensation arrangement between an exempt organization and a DQP if all three of the following requirements are met:

(a) The arrangement must be considered and approved by an authorized body composed entirely of individuals who do not have a conflict of interest with respect to the transaction. Treas. Reg. § 53.4958-6(c)(1).

A board or committee will not qualify as independent for purposes of the rebuttable presumption if any of its members has a substantial financial interest affected by the transaction, regardless of whether the board of the applicable tax-exempt organization determines that the financial interest results in a “conflict of interest” under the organization’s conflicts of interest policy.

(b) The approval body must obtain and rely upon appropriate data as to comparability (e.g., compensation levels paid by similarly situated organizations, both taxable and tax-exempt, for functionally comparable positions; the location of the organization, including the availability of similar specialties in the geographic area, independent compensation surveys compiled by independent firms; or actual written offers from similar institutions competing for the services of the disqualified person). Treas. Reg. § 53.4958-6(c)(2).

(c) The board or committee must adequately document the basis for its determination (e.g., the meeting minutes or other records must include an evaluation of the DQP whose compensation was being established and the basis for determining that the DQP’s compensation is reasonable in light of that evaluation and data). Treas. Reg. § 53.4958-6(c)(3).

The three conditions for the presumption must be met before making any payments under the arrangement being considered. Treas. Reg. § 53.4958-6(f).

d. Reasonableness of Compensation Generally

An exempt organization is permitted to pay reasonable compensation to individuals who provide services to it. Whether compensation is reasonable is determined in light of all the
facts and circumstances. As a general rule, “reasonable” compensation is the amount that a
like organization in like circumstances would pay for like services.

(i) Compensation includes: salary, fees, bonuses, and severance payments;
deferred compensation that is earned and vested, whether or not funded (but if
deferred compensation for services performed in multiple prior years vests in
a later year, the compensation is attributed to the years in which the services
were performed); premiums for liability or other insurance and payment or
reimbursement for charges, expenses, fees, or taxes not ultimately covered by
the insurance coverage; all other benefits, whether or not included in income
for tax purposes, including payments to welfare benefit plans (e.g., medical,
dental, life insurance, severance, disability), and taxable and nontaxable fringe
benefits (other than working condition fringe benefits described in Section
132(d) and de minimis fringe benefits described in Section 132(c)), including
expense allowances or reimbursements or foregone interest on loans. See

(ii) The Internal Revenue Manual lists the following factors to be considered by
an examining agent in a reasonable compensation examination: nature of
employee’s duties; employee’s background and experience; employee’s
knowledge of the business; size of the business; employee’s contribution to
the profit of the business; time devoted by employee to the business;
economic conditions in general and locally; haracter and amount of
responsibility of employee; time of year when compensation is determined;
relationship of shareholder-officer’s compensation to stock holdings; whether
alleged compensation is in reality, in whole or in part, payment for a business
or assets acquired; and the amount paid by similar size businesses in the same
area to equally qualified employees for similar services. Internal Revenue
Manual 4233, Sec. 232.2. Although it is evident from this list of factors that
they were derived from the Code Section 162 standards that were developed
for taxable organizations, the final intermediate sanctions regulations state that
Code Section 162 apply in determining reasonableness of compensation.

(iii) The IRS’s Hospital Audit Guidelines contain a somewhat different list of
factors to be examined in determining the reasonableness of compensation:
duties performed and amount of responsibility; time devoted to duties; special
knowledge and experience; individual ability; previous training; compensation
paid in prior years; working conditions; prevailing general economic
conditions (including wage levels for work of similar scope and nature, price
levels and inflation); living conditions in the particular locality; and
comparability to similar positions in similar entities. Internal Revenue Service
Audit Guidelines for Hospital, Manual Transmittal 7(10) 69-38, Exempt
Organizations Guidelines Handbook Section 331(1) (March 27, 1992).
e. Structuring Incentive Compensation and Performance Based Income Distributions

(i) Tax-exempt organizations are not per se prohibited from providing incentive compensation to their employees. All compensation, including incentive compensation that is contingent on the occurrence of certain events, must be reasonable and must not exceed fair market value for the services provided.

(ii) The IRS has expressed particular concern that incentive compensation arrangements can create a significant conflict between serving the personal interests of the individual involved and serving the tax-exempt purposes of the organization. Accordingly, the IRS has approved incentive compensation arrangements, but only with the presence of certain safeguards. The following factors are indicative of a permissible incentive compensation arrangement:

(a) Arm’s-length relationship;
(b) Contingent payments serve a real and discernible business purpose;
(c) Amount of compensation is not dependent principally on incoming revenues but on accomplishment of objectives of compensation arrangement;
(d) Compensation is not merely a device to distribute profits to principals or transfer organization’s principal activity into a joint venture;
(e) Actual results do not indicate abuse or unwarranted benefits; and
(f) A ceiling or cap assures a reasonable maximum amount of compensation. GCM 38322 (March 24, 1980). GCMs 39670 (October 14, 1987) and 39674 (October 23, 1987).

(iii) The 1996 CPE Textbook lists a series of questions that should be asked when reviewing compensation arrangements for employed physician. Notably, the questions include the following:

Before total compensation of all physicians (base and benefits minus bonus and risk pool withholds) is determined, how much surplus remains for the exempt organizations? After total compensation is determined how much surplus remains? What percentage of surplus do the physicians receive? What percentage does your organization receive?

(iv) In its 2000 CPE Text, the IRS discussed the safeguards set forth in GCM 38322 in the context of physician incentive compensation and identified the following additional factors to be considered:

(a) Was the arrangement established by an independent board of directors or independent compensation committee?
(b) Does the arrangement have the potential for reducing the charitable services or benefits the organization would otherwise provide?

(c) Does the arrangement take into account data that measures quality of care and patient satisfaction?


(v) IRS Information Letter 2002-0021 (January 9, 2002) provides a useful summary of the factors, outlined above, that IRS will consider in analyzing any physician incentive compensation arrangement.

(vi) Additional Guidance Relating Specifically to “Gainsharing”

(a) Reportedly, the IRS issued at least one favorable, but unpublished, private letter ruling approving a gainsharing arrangement in early 1999, raising hopes that the government might approve of gainsharing. See 1999 TNT 128-39 (July 1, 1999).


(1) Any program that incentivizes physicians to reduce costs by sharing a portion of the savings with them should be considered gainsharing.

(2) The OIG’s key concern in [prohibiting gainsharing is the impact on quality of care, because of the perceived incentive to reduce medical services. However, there need not be any actual decrease in care for a gainsharing arrangement to be violation of the law.

(3) Any incentive compensation program for physicians that is based in whole or in part on the clinical cost side should be structured as a traditional incentive compensation program – with fixed compensation (or percentage of salary) paid for achieving certain objectives.

(c) In the preamble to the temporary regulations under Section 4958 published in January 19, 2001, the IRS stated that it would not issue private letter rulings on gainsharing transactions because the OIG believes the methodology involved in calculating payments under gainsharing arrangements violates sections 1128A(b)(1) and (2) of the Social Security Act in situations where patient care may be affected by the cost savings.
66 Fed. Reg. 2143, 2155-6 (January 10, 2001). The preamble also noted that there is a question whether gainsharing arrangements, which involve payments contingent on cost savings to the organization, should be treated in the same manner as revenue-sharing arrangements.

(d) In its 2002 CPE Text, the IRS noted indicated that in light of the question whether gainsharing arrangements should be treated like revenue-sharing arrangements, it is unlikely the IRS will issue private letter rulings even on gainsharing arrangements that the OIG considers legal until final regulations on revenue-sharing arrangements are published. Lawrence M. Brauer, Mary Jo Salins, and Marvin Friedlander, “Update on Health Care,” IRS Exempt Organization Continuing Professional Education Technical Instruction Program for Fiscal Year 2002 (2001) at 155.

C. Privacy and Security Laws

As outlined above, both the HITECH Act and PPACA incentivize investment in EHRs and other health information technology infrastructure that will support widespread electronic exchange, aggregation and analysis of healthcare information. Various domestic and international laws governing the privacy and security of personal health information will apply to these new data sharing and analysis strategies such as the exchange of information between and among participants through interoperable EHRs and in an HIE or electronic data repository. Any strategy for addressing these laws should address, in particular, both the initial inclusion of data in an HIE or repository and each subsequent exchange or use of the data.

1. HIPAA Privacy and Security

   a. HIPAA Provisions in the HITECH Act

      (i) Recognizing that the proliferation of electronic data exchange as a means of promoting health reform also elevates the privacy and security risks regulated by the Health Insurance Portability and Accountability Act of 1996 and accompanying regulations (45 C.F.R. §§ 160, 162 and 164) (“HIPAA”), the HITECH Act also strengthened existing HIPAA privacy and security requirements in several significant respects. In particular, the Act:

         (a) extended the applicability of the HIPAA security standards and penalties for security and privacy violations directly to business associates;

         (b) established rigorous data security breach notification requirements;

         (c) extended the accounting for disclosures requirement to treatment, payment and healthcare operations;

         (d) imposed an express prohibition on the “sale of data” other than in limited circumstances; and

         (e) significantly modified the categories of HIPAA violations, the range of civil money penalty amounts and the available defenses to a HIPAA action. See, Economic Stimulus Package: Policy Implications of the Financial Incentives to

(ii) The new federal data security breach notification requirements apply in addition to those recently adopted in various states for the breach of either personal health information or personal information of any kind. See, e.g., M.G.L.A. 93H § 1 et seq.; Cal. Health & Safety Code § 1280.15.

(iii) Increased and more aggressive HIPAA privacy and security compliance enforcement is expected. See, HHS Issues Interim Final Rule Conforming HIPAA Civil Money Penalties to HITECH Act, McDermott Will & Emery White Paper (November 12, 2009), available at http://www.mwe.com/index.cfm/fuseaction/publications.nl dedicate/object_id/ae68626d-301b-4aa7-9a20-911cbe1b1f4a.cfm (last visited June 20, 2010);

b. HIPAA Implications for Interoperable EHRs and Other Health Reform HIT Strategies

(i) Whether and to what extent HIPAA will permit providers to share protected health information (“PHI”) (as defined by HIPAA in 45 C.F.R. § 160.103) from their EHR systems with each other and with non-providers will be driven by various considerations, including:

(a) whether the providers sharing the network are participants in the same organized health care arrangement (“OHCA”); Id.

(b) the nature and extent of the information in the EHR to which they are permitted access (e.g., their own patient information only, information of patients of the hospital or other physicians);

(c) who will have access and the purpose of the access and use (e.g., treatment, payment, health care operations 45 C.F.R. § 164.501 (including those of an
OHCA that engages in joint quality assurance and utilization review or joint managed care contracting involving financial risk), and research);

(d) whether the information is in individually identifiable or in de-identified form, 45 C.F.R. §§ 164.514(b)(1) and (2)(i), or part of a limited data set; and

(e) whether the network includes HIPAA’s administrative, physical, technical and organizational security safeguards.

(ii) Worth noting here is that studies undertaken using an electronic network or repository for purposes of cost, quality and safety studies may be considered “health care operations” rather than “research” under HIPAA and that use for such health care operations purposes are not subject to the HIPAA authorization requirement. Careful consideration must nonetheless be given to whether the study is research under the Common Rule. 45 C.F.R. §§ 164.514(2)(i) and (e)(2). Drawing the lines is not always easy. In December 2008, an official of OHRP publicly addressed the need to carefully draw lines between these two activities. “OHRP Official Recommends Drawing Lines To Determine Which Activities are Research,” BNA Medical Research Law and Policy Report, 7 MRLR 761 (December 3, 2008).

(iii) Any electronic sharing of PHI, other than sharing by providers in connection with treatment or payment matters for common patients, should be carefully analyzed to verify compliance with HIPAA privacy requirements such as:

(a) the need for patient authorizations and eligibility for exceptions to or waivers of the authorization requirement;

(b) establishing access controls to meet minimum necessary standards and comply with the provisions of authorizations, authorization exceptions and authorization waivers;

(c) patient record access and amendment rights provisions;

(d) patient rights to accounting of disclosures;

(e) the criteria and contracting requirements for engaging business associates;

(f) the criteria and contracting requirements relating to creation and use of de-identified data and limited data sets; and

(g) the new prohibition against the sale of data.

Typically, the strategy for meeting these requirements will involve a combination of the HIT infrastructure design elements, policies and procedures, and associated training.

2. Other Federal Privacy Laws and State Laws Protecting the Confidentiality of Sensitive Health Information.

a. Certain other federal laws protect particular categories of information that may be included in the electronic information exchange. Principal among them is the federal law protecting the confidentiality of alcohol and drug abuse patient records. 42 U.S. C. §
b. Similarly, the laws of most if not all states prohibit or restrict uses and disclosures of information relating to mental health, developmental disabilities, AIDS and other sexually transmitted diseases, and genetic testing and counseling information, and some states have laws protecting the confidentiality of health information generally. A comprehensive review of state sensitive information confidentiality laws is outside the scope of this article. Examples of such state laws include the following: IND. CODE. ANN. § 16-18-2-226 (mental health information); MASS. GEN. LAWS. ch. 111, § 70F; ARIZ. REV. STAT. 12-2802; 74 ILCS 110/ (mental health information); 410 ILCS 305/ (HIV/AIDS information); 410 ILCS 513/ (genetic information); 410 ILCS 50/ (medical information generally).

c. Further, use of information from an HIE for clinical research may also trigger applicability of (a) the protections afforded human subjects in research by the federal regulations that protect human subjects who participate in federally funded research (i.e., the Common Rule), 45 C.F.R.§ 46(A)-(D), (b) the FDA regulations applicable to research conducted in support of an application for FDA approval of the marketing of a new product, 21 C.F.R.§ 50.1, and (c) the Genetic Information Nondiscrimination Act of 2008 (“GINA”) which addresses the use of genetic information by group health plans, health insurers in group and individual markets, and issuers of Medigap policies in connection with certain insurance business functions. The Genetic Information Nondiscrimination Act of 2008, Pub.L. 110-233, § 1(a) (May 21, 2008). See also, 45 C.F.R. § 144.103.

d. In certain respects, these other federal and state privacy and confidentiality laws are more restrictive than, and thus preemptive of, HIPAA. In particular, they may require a written patient consent for both uses and disclosures for which HIPAA would not require an authorization, even at times when the information is being used internally by a covered entity or being exchanged only between or among treatment providers or with a business associate who has been hired to convert the information to a limited data set or fully de-identified form.

(i) Obtaining consent to use of data collected over several years and from a large number of patients prior to the creation of the electronic network or repository can be particularly challenging. Whether the state law permits an opt-out approach to the consent requirement, rather than an opt-in, is an essential consideration.

(ii) Other challenges arising from a consent requirement include (a) developing ways to track and firewall all information from a patient who refuses to give consent or who withdraws consent, and (b) attempting to segregate sensitive from non-sensitive information contained in a single patient record of a non-consenting individual (particularly in the context of mental health information where the lines between the two can be extremely gray).
3. EU and Other Foreign Data Protection Laws

Electronic information exchanges and repositories that contain identifiable health information of a foreign national may be subject to privacy requirements under myriad privacy laws of foreign countries, including those of the twenty-seven countries comprising the European Union ("EU"). The cornerstone of privacy protection in the EU is the EU Data Privacy Directive. Directive 95/46/EC of the European Parliament and of the council of 24 October 1995 on the protection of individuals with regard to the processing personal data and on the free movement of such data. Official Journal of the European Communities, November 23, 1995, No. L. 281/31. The EU adopted the Data Privacy Directive to establish a minimum level of protection among the member states and to prevent diverse national laws from becoming an obstacle to the integration of a single European market. While it provides some level of harmonization, it does not establish uniformity among the various national laws of the member states. Countries outside the EU also have privacy laws needing to be addressed.

D. Federal Laws Regulating the Donation of EHR Technology by Hospitals to Physicians

The health reform related HIT strategy of many hospitals and health systems is likely to include the donation of EHR technology to physicians to expedite their adoption of EHR. Such donations raise implications under federal healthcare fraud and abuse laws as well as tax-exemption laws.

1. Fraud and Abuse Laws

Prior to the adoption of the HITECH Act’s financial incentives for meaningful use of Certified EHR Technology, the federal government implemented some relief from the fraud and abuse concerns that were impeding EHR initiatives.

a. Specifically, in August 2006, the Centers for Medicare & Medicaid Services ("CMS") published final regulations setting forth an exception to the Stark Law for the provision of EHR items and services by hospitals to physicians ("EHR Exception") 42 C.F.R. § 411.357(w) and the Office of the Inspector General ("OIG") published final regulations setting forth a corresponding safe harbor under the Anti-Kickback Statute 42 C.F.R. § 1001.952(y) ("EHR Safe Harbor" and collectively, with the EHR Exception, the "Federal EHR Regulations").

b. The EHR Regulations provide a roadmap for structuring permissible donations of EHR technology by hospitals to physicians. The structural considerations and conditions relate to (i) which individuals and entities are permitted to be donors; (ii) which individuals and entities are permitted to be recipients; (iii) what items and services may be donated; (iv) what agreements must be in place to document the donation; (v) what requirements exist for cost sharing; and (vi) certain other conditions that must be satisfied in order to assure that the arrangement avoids improper inducements to make referrals for Medicare and Medicaid-covered items and services and that the hospital makes prudent use of the resources it has available to invest in a donation program. For a more detailed discussion of the criteria and conditions, see the Federal EHR Regulations themselves supra at Notes 66 and 67 and McDermott Will & Emery White Paper “Donating Health Information Technology: Final Regulations Compete with HR 4157 for Public Policy Control,” available at http://www.mwe.com/info/news/wp1006a.pdf (last visited June 24, 2010).
2. Federal Tax-Exemption Laws

The Internal Revenue Service (“IRS”) subsequently issued a directive concerning the tax-exemption implications of the EHR donations contemplated by the Federal EHR Regulations under the private inurement and more than incidental private benefit prohibitions of Section 501(c)(3) of the Internal Revenue Code (“Code”) (the “IRS EHR Directive”). IRS Memorandum, “Hospitals Providing Financial Assistance to Staff Physicians Involving Electronic Health Records” (May 11, 2007). The IRS EHR Directive states that the IRS will not treat the corresponding benefits a hospital provides to its medical staff physicians as an impermissible private benefit or inurement if the hospital meets several requirements:

a. the hospital and the participating physicians comply with the requirements of the Federal EHR Regulations on a continuing basis;

b. to the extent permitted by law, the hospital may access all of the electronic medical records created by a physician using the donated items or services;

c. the hospital ensures that the donated items and services are available to all of its medical staff physicians; and

d. the hospital provides the same level of subsidy to all of its medical staff physicians or varies the level of subsidy by applying criteria related to meeting the healthcare needs of the community.

The IRS subsequently clarified that for any entity that is not able to meet all of these requirements, it would utilize a facts and circumstances analysis to determine whether the arrangement poses any tax concerns. The directive thus amount essentially to a “safe harbor” that can be varied from as necessary so long as alternative facts and circumstances exist to provide a defensible position.

E. Corporate Practice of Medicine and Fee-Splitting Prohibitions

State corporate practice of medicine and fee-splitting laws may restrict the ways physicians and non-physicians can affiliate through ownership and employment relationships.

1. Corporate Practice of Medicine

a. The laws of more than half the states prohibit the practice of medicine by other than licensed physicians or entities that are wholly owned and controlled by licensed physicians. The source and nature of the prohibition and corresponding exceptions, if any, varies from state to state. The principal ACO formation consideration is the ability to employ physicians or retain them as independent contractors to provide medical services.

b. The source of the prohibition may be statutes, case law, regulations, or advisory opinions.

c. Exceptions

(i) Some states provide exceptions for employment by a licensed hospital, hospital affiliates and/or other licensed health care facilities. A key consideration in certain exceptions is the distinction between control over business operations and control
over the exercise of medical judgment in the delivery of medical care. Following are several examples.

(a) Illinois allows employment by a licensed hospital or by another entity directly or indirectly “controlled” by, or under common “control” with, a licensed hospital. The controlled entity must be devoted primarily to the provision, management or support of health care services. Control exists if the entity is 100% controlled by some combination of hospitals, their parent corporations, or physicians licensed to practice medicine in Illinois. Further, the employed physician must be a member of the medical staff of the hospital or affiliated entity and the quality of the medical services provided must be periodically reviewed by non-employed physicians. See, e.g., 210 Ill. Comp. Stat. § 85/10.8.

(b) 35 Pa. Stat. Ann. § 448.817a; 35 Pa. Stat. Ann. § 448.103 permits hospitals and a broad range of other health care facilities (e.g., psychiatric, rehabilitation and other specialty hospitals, long-term nursing facilities, certain cancer treatment centers, and inpatient drug and alcohol treatment facilities) to contract with physicians to provide medical services as employees or independent contractors.

d. California and Texas have established the “medical foundation model” as an alternative to employment of physicians. Under this model, which was used prevalently in the physician integration movement of the 1990s, licensed professional corporations sell their practices, not simply the tangible assets, to the a nonprofit hospital or nonprofit hospital affiliate referred to as a “foundation.” The foundation owns and controls the “practice” and the reimbursement for professional services. The physicians, remain employees of the professional corporation that sold its assets to the foundation. The foundation in turn enters into an independent contract for the professional services of the professional corporation.

e. The “Captive” or “Friendly” PC discussed above has been used as an alternative in various states.

2. Fee Splitting

a. The laws of various states prohibit physicians from sharing fees with non-physicians. These laws are directed, in part, to prevention of payments for referrals. As is the case with corporate practice of medicine laws, laws banning fee-splitting vary from state to state, but typically these laws bar physicians from sharing professionally earned fees with non-physicians on an unearned basis. Fee-splitting laws are often targeted at curtailing specific arrangements that the state deems undesirable, especially payments for referrals, but the statutory language also often serves to prohibit physicians from paying more than fair market value management fees to lay entities.

b. For example, Virginia has a fee-splitting statute that is specifically targeted at fee-splitting between surgeons and non-surgeons. However, while non-surgeons may not generally share in surgeons fees, the statute permits flexibility in the division of fees by an organized partnership of surgeons and non-surgeons:

“No surgeon or physician shall directly or indirectly share any fee charged for a surgical operation or medical services with a physician who brings, sends or recommends a patient to such surgeon for operation, or such physician for such
medical services; and no physician who brings, sends, or recommends any patient to a surgeon for a surgical operation or medical services shall accept from such surgeon or physician any portion of a fee charged for such operation or medical services. This chapter shall not be construed as prohibiting the members of any regularly organized partnership of such surgeons or physicians from making any division of their total fees among themselves as they may determine or a group of duly licensed practitioners of any branch or branches of the healing arts from using their joint fees to defray their joint operating costs. Any person violating the provisions of this section shall be guilty of a Class 1 misdemeanor.” Va. Code Ann. § 54.1-2962

IX. ACO IMPLEMENTATION RECOMMENDATIONS

For further recommendations concerning the development and implementation of an ACO strategy, see McDermott Will & Emery’s Health System Reform: An Implementation Checklist, which can be obtained at http://www.mwe.com/info/healthreformchecklist/.