

**Healthcare Reform:
The Law and its Implications**

**Toward Accountable Care:
How Healthcare Reform Will Shape
Provider Integration**

**May 12, 2010
Arlington, Virginia**

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TABLE OF CONTENTS

	Page
I. INTRODUCTION	1
II. EMPHASIS ON NEW PAYMENT AND CARE DELIVERY MODELS – THE CENTER FOR MEDICARE AND MEDICAID INNOVATION (CMI) (PPACA SECTION 3021)	2
A. Purpose of CMI.....	2
B. Criteria for Selection of Payment and Delivery Models by CMI	2
C. Other Considerations	4
D. New Payment and Care Delivery Models – Emphasis on Accountable Care Organizations and Medical Homes	4
III. ACCOUNTABLE CARE ORGANIZATIONS	5
A. The ACO Concept – Its Origin and Its Future.....	5
B. Key ACO Elements.....	5
C. PPACA’s Shared Savings Program for ACOs (Section 3022).....	6
IV. MEDICAL HOMES	9
A. Evolution of The Medical Home Concept	9
B. PPACA Definition of Medical Home	10
C. PPACA Grants and Contracts to Establish Health Teams to Support Medical Homes (Section 3502)	10
D. Fair Compensation and Grant Support for Primary Care Providers	11
E. Community-Based Collaborative Care Network Program (Section 10333).....	12
F. Qualified Medical Home Plans (Section 10104)	12
V. PPACA’S NATIONAL PILOT PROGRAM ON PAYMENT BUNDLING FOR CARE DURING HOSPITALIZATION (SECTION 3023)	12
A. Duration of the Pilot Program.....	12
B. Bundled Payments	13
C. Quality Improvement and Measurement	13
D. Clinical Focus Areas	13
E. Payment on the Basis of Episodes of Care	14
F. Eligible Entities.....	14
VI. OTHER PPACA PAYMENT REFORMS	15
A. Value-Based Purchasing (Section 3001)	15
B. Hospital Readmissions Reduction Program (Section 3025).....	15
C. Demonstration Projects and Pilots	15

TABLE OF CONTENTS
(continued)

	Page
VII. HEALTH INFORMATION INFRASTRUCTURE – AN ESSENTIAL FOUNDATION AND STRATEGIC TOOL FOR RESPONDING TO HEALTH REFORM	15
A. Evolution of the Emphasis on HIT Infrastructure.....	15
B. Developments Prior to PPACA	16
C. PPACA Provisions.....	19
VIII. LEGAL FEASIBILITY ISSUES	22

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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**),² 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 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 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

¹ The author wishes to thank her partners at McDermott Will & Emery, Gary Scott Davis and Peter Rich, for their contribution to this outline.

² Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010). PPACA became law on March 23, 2010.

time. Therefore, all stakeholders will be well served by being ready with a sound and pragmatic plan for effectively managing the 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**).³ 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**).

³ 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.

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 expenditures 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

1. The Medical Home concept was first introduced in 1967 by the American Academy of Pediatrics. In 1978, the World Health Organization “laid down some of the basic tenets of the medical home and the important role of primary care in its provision.”⁴
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 fro 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.⁵

⁴ World Health Organization, International Conference on Primary health Care Declaration of Alma-Ata, WHO CHRON 1978; 32(11): 428-30.

⁵ 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; AMERICAN COLLEGE OF PHYSICIANS, Position Paper: The Advanced Medical Home: A Patient-Centered, Physician-Guided Model of Health Care, 4 (2005); Thomas C. Rosenthal, M.D., The Medical Home: Growing Evidence to Support a New Approach to Primary Care, 21 JOURNAL OF THE AMERICAN BOARD OF FAMILY MEDICINE 427, 427 (Sept.-Oct. 2008); THE ROBERT GRAHAM CENTER, THE PATIENT CENTERED MEDICAL HOME: HISTORY, SEVEN CORE FEATURES, EVIDENCE AND TRANSFORMATIONAL CHANGE, 10 (Nov. 2007), available at: <http://www.adfammed.org/documents/grahamcentermedicalhome.pdf>; and THE ROBERT GRAHAM CENTER at 11; American Association of Pediatrics, Care Coordination in the Medical Home: Integrating Health and Related

(continued...)

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.

Systems of Care for Children with Special Health Care Needs, 116 PEDIATRICS 1238, 1239 (Nov. 2005); THE AMERICAN COLLEGE OF PHYSICIANS, JOINT PRINCIPLES OF PATIENT CENTERED MEDICAL HOME (2007), available at: <http://www.acponline.org/pressroom/pcmh.htm>; W. Carl Cooley et al., Improved Outcomes Associated with Medical Home Implementation in Pediatric Primary Care, 124 PEDIATRICS 358, 359 (2009).

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 HCPCS 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 RESPONDING TO HEALTH REFORM

A. Evolution of the Emphasis on HIT Infrastructure

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. This emphasis on HIT infrastructure to support healthcare reform has roots in the Patient Safety and Quality Improvement Act of 2005 and, of course, the various provisions of 2009 federal stimulus legislation.

B. Developments Prior to PPACA

1. Patient Safety and Quality Improvement Act

The Patient Safety and Quality Improvement Act was enacted on July 29, 2005 in response to growing concern about patient safety in the United States and the Institute of Medicine's (IOM) 1999 report, *To Err is Human: Building a Safer Health System* to improve patient safety by encouraging voluntary and confidential reporting of events that adversely affect patients. It creates Patient Safety Organizations (PSOs) to collect, aggregate, and analyze confidential information reported by health care providers. By analyzing patient safety event information, PSOs identify patterns of failures and propose measures to eliminate patient safety risks and hazards. The Act calls for the establishment of a Network of Patient Safety Databases (NPSD), which provides an interactive, evidence-based management resource for providers, PSOs, and other entities and will be used to analyze national and regional statistics, including trends and patterns of patient safety events. The NPSD employs common formats (definitions, data elements, and so on) and will promote interoperability among reporting systems.⁶

2. Quality Improvements Through Evidence-Based Medicine

Evidence-based medicine seeks to apply evidence gained from the scientific method (mainly randomized controlled trials) to certain parts of medical practice to predict outcomes. It seeks to assess the quality of evidence relevant to the risks and benefits of treatments (including lack of treatment). According to the Centre for Evidence-Based Medicine, "Evidence-based medicine is the conscientious, explicit and judicious use of current best evidence in making decisions about the care of individual patients."⁷

CMS has been engaged for several years in the use of data registries to collect outcomes information as evidence of whether the effectiveness of certain treatments and products where clinical information is limited but promising as a basis for registries is sufficient to support Medicare reimbursement coverage for such treatments and products. The concept is known as "Coverage with Evidence Development."⁸

3. Federal Government's Vision and Mandate for Electronic Health Record Infrastructure

- a. In January 2006, President George W. Bush announced a plan designed to ensure that most Americans have electronic health records within ten years. The Plan

⁶ <http://www.ahrq.gov/qual/psoact.htm>

⁷ http://en.wikipedia.org/wiki/Evidence-Based_Medicine

⁸ "Coverage with Evidence Development," is described in a final guidance document CMS issued on July 12, 2006. "National Coverage Determinations with Data Collection as a Condition of Coverage: Coverage with Evidence Development, http://www.cms.hhs.gov/mcd/ncpc_view_document.asp?id=8

called for the adoption of health information standards, increased funding for health information technology (HIT) demonstration projects, and use of the federal government's clout as one of the largest purchasers of health care in the world to create incentives for health care providers to adopt health information technology. The HIT contemplated by the vision includes electronic medical records, computerized prescribing and ordering of diagnostic tests, clinical decision support tools, and the technology that will enable the interoperability needed to achieve the secure exchange of electronic health information among providers, payors and others.

- b. President Obama's 2009 economic recovery legislation⁹ converted President Bush's HIT vision into the equivalent of a "funded mandate." The Health Information Technology for Economic and Clinical Health Act (**HITECH Act**)¹⁰ commits approximately \$20 Billion of federal support for the establishment of a nationwide health information network and corresponding standards to assist in that endeavor, including meaningful Medicare and Medicaid reimbursement incentives for physicians and hospitals who move quickly to acquire and implement electronic health record (**EHR**) technology.
- c. The Office of the National Coordinator for Health Information Technology (**ONC**) of the Department of Health and Human Services (**HHS**), which is responsible for providing the leadership and coordination for implementation of this HIT vision, previously articulated four important and interrelated goals: (1) to inform clinical practice with the use of EHRs; (2) to interconnect clinicians so that they can exchange health information using advanced and secure electronic communications; (3) to personalize care with consumer-based health records and better information for consumers; and (4) to improve public health through advanced biosurveillance methods and streamlined collection of data for quality measurement and research.¹¹ Together, these goals capture the various dimensions of the current and rapidly growing demand for an electronic health information exchange that will support uses extending well beyond traditional clinical care delivery, operations and research - - such as more robust quality and patient safety measurements, pay-for-performance incentive programs, and leading edge genomic and translational research that explores individualized

⁹ American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (2009).

¹⁰ H.R. 1, S.1, American Recovery and Reinvestment Act of 2009, Health Information Technology for Economic and Clinical Health Act (the HITECH Act), § 13001, et seq. (Feb. 17, 2009).

¹¹ "The Decade of Health Information Technology: Delivering Consumer-centric and Information-rich Health Care Framework for Strategic Action," U.S. Department of Health and Human Services (July 2004). <http://www.hhs.gov/news/press/2004pres/20040721.html>.

The HITECH Act restates ONC's goals as: (a) ensuring that each patient's health information is secure and protected; (b) improving health care quality, reducing medical errors, reducing health disparities and advancing the delivery of patient-centered medical care; (c) reducing health care costs resulting from inefficiency, medical errors, inappropriate care, duplicative care and incomplete information; and (d) facilitating health and clinical research and health care quality. HITECH Act, § 13101 (to be codified at 42 U.S.C. § 3001(b)).

disease states and treatments and ultimately supports the delivery of personalized medicine.¹²

4. Comparative Effectiveness Research

The 2009 federal stimulus legislation¹³ provides \$1.1 billion in funding to support comparative effectiveness research (CER), created a Federal Coordinating Council to oversee use of the funds, and commissioned reports on CER by the Federal Coordinating Council and The Institutes of Medicine (IOM); both reports were issued in June 2009.¹⁴ The Council's report in particular identified four categories of investment and activity as part of its strategic framework, including the development of a data infrastructure consisting of distributed practice-based data networks and longitudinally-linked administrative or EHR databases or patient registries.

CER involves the "rigorous evaluation of the impact of different options that are available for treating a given medical condition for a particular set of patients."¹⁵ Traditional healthcare research which focuses on whether an item or service is effective and safe in ideal rather than "real world" settings are difficult to apply to a given patient or population. In contrast, CER takes a retrospective look at health information from particular patient populations or subpopulations to compare similar products (*e.g.*, competing drugs) or diagnosis or treatment approaches (*e.g.*, surgery versus drug therapy). Both the public and private sectors have been involved in advancing CER for the last couple of years, and CER will likely be an essential tool for achieving healthcare reform, particularly payment reform, regardless of the shape healthcare reform legislation ultimately takes.¹⁶

¹² Personalized Medicine or Personalized Health Care is an explicit health reform goal that HHS has addressed in detail in two recent reports: "Personalized Health Care: Opportunities, Pathways, Resources," <http://www.hhh.gov/myhealthcare/news/personalized-healthcare-9-2007.html>, last visited January 10, 2009; and "Personalized Health Care: Pioneers, Partnerships, Progress," <http://www.hhh.gov/myhealthcare/news/personalized-healthcare-2008.html>. See also, "HHS Secretary Releases Second Report From Initiative on Personalized Healthcare," *Life Sciences Law & Industry Report*, 2 LSLR 1004, BNA (November 2008); Michael O. Leavitt and Raju Kucherlapati, "The Great Promise of Personalized Medicine," *boston.com* at http://www.boston.com/bostonglobe/editorial_opinion/oped/articles/2008/12/26/the_great_prom... (December 26, 2008).

¹³ American Recovery and Reinvestment Act of 2009, Pub. L. No. 111-5, 123 Stat. 115 (2009).

¹⁴ "Federal Coordinating Council for Comparative Effectiveness Research Report to the President and the Congress," U.S. Department of Health and Human Services (June 2009). <http://www.hhs.gov/recovery/programs/cer/cerannualrpt.pdf>. and "Initial National Priorities for Comparative Effectiveness Research," Institute of Medicine (June 2009). <http://www.iom.edu/Reports/2009/ComparativeEffectivenessResearchPriorities.aspx>.

¹⁵ Congressional Budget Office Report, "Research on the Comparative Effectiveness of Medical Treatments," (December 2007). <http://www.cbo.gov/ftpdocs/88xx/doc8891/12-18-ComparativeEffectiveness.pdf>.

¹⁶ See, *e.g.*, "Comparative Effectiveness: Better Value for the Money," Alliance for Health Reform (August 2008). http://www.allhealth.org/Publications/Quality_of_care/Comparative_Effectiveness_Better_Value_for_the_Money_84.pdf.

C. 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

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 legal organization, related governance and operating structure and tax status.
2. Applicable state laws governing the corporate practice of medicine, fee-splitting and medical foundations (in some states, even certificate of need laws may apply to the formation of a medical foundation or similar new entity).
3. 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?
4. 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?

5. 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?

6. HIPAA, HITECH and state laws governing the sharing of patient data among providers.

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