Health systems, community hospitals and physician groups should swiftly consider participating in an ACO or similar organization in order to respond effectively to the emerging changes in U.S. health care.

From the moment of its inception, the recently enacted federal Patient Protection and Affordable Care Act generated significant interest in a new form of integrated delivery system known as an accountable care organization (ACO). The Act specifically creates a separate ACO demonstration project within the Medicare Program. The Act also provides for the implementation of several other coordinated care demonstration programs, as well as the creation of the Center for Medicare and Medicaid Innovation, a new entity within the Centers for Medicare and Medicaid Services (CMS) that has the authority to test proposed methods of coordinated care.
delivery.

Such new Medicare demonstration projects will almost certainly further spur the proliferation of ACOs and similar new integrated care models. It should be noted, however, that various permutations of the ACO concept are already emerging separately from Medicare, incorporating a variety of cutting-edge models for provider cost and quality incentives as well as patient care coordination by a wide range of providers.

The earlier incarnations of partially integrated delivery systems—such as formal physician-hospital organizations (PHOs) and hospital-independent physicians association-medical group shared-risk contractual arrangements that do not entail the formation of a separate legal entity—were primarily organized to facilitate joint managed care contracting by institutional and professional providers. In contrast, an ACO is focused on enhanced coordination of patient care as a means of both improving the quality of care and controlling the health care cost curve. The chart below offers a comparison of ACO and PHO models.

**PHO/ACO Comparison**

<table>
<thead>
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<th>PHO</th>
<th>ACO</th>
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<tr>
<td>Insurance risk</td>
<td>Performance risk</td>
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<td>Panel of patients</td>
<td>Population of patients</td>
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<td>Scrum for share of revenue</td>
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<td>Charge based</td>
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<td>Episode of care focused</td>
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<td>Split control and governance</td>
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Do more | Do less
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Intervention | Prevention
Clinical integration to achieve antitrust compliance | Clinical integration to achieve efficiencies and quality improvement

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. Key elements of an effective ACO ideally include the following:

- Patient-centered “medical homes” that deliver primary care and coordinate with other providers
- Aligned networks of specialists, ancillary providers and hospitals focused on enhanced outcomes
- Emphasis on effective clinical care integration and coordination mechanisms
- Payor-provider contracted relationships and reimbursement models that facilitate and reward cost-effective high-value (not high-volume) health care
- Population health information infrastructure to enable community-wide care coordination, including integrated electronic health records (EHRs)

ACOs entail enhanced clinical integration and place a strong emphasis on patient outcomes as well as greater cost-efficiency. While the ACO model theoretically could be an organization consisting solely of physicians, achieving the ideal level of care coordination and quality goals envisioned by the ACO model will require an organization that includes providers across the vertically integrated spectrum of care, from primary care through acute care through long-term and palliative care.

**Medicare Shared Savings Program (Section 3022 of the Act)**

Not later than January 1, 2012, the Secretary is required to establish a shared savings program specifically relating to ACOs. This program is intended to promote accountability for a patient population and to coordinate items and services under parts A and B, as well as to encourage investment in infrastructure and redesigned care processes for high-quality and efficient service delivery.

In order to be eligible to participate in the shared savings program, an ACO, among other actions, must 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:
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.

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

- 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
- 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

Quality, an integral part of the ACO model, will be measured and assessed through the following:

- Clinical processes and outcomes
- Patient and, where practicable, caregiver experience of care
- Utilization (such as rates of hospital admissions for ambulatory care sensitive conditions)

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. 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. In order to achieve this result, the Act requires the Secretary to, over time, 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.

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. 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. 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.

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. 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. The Secretary will have sole and final authority (e.g., not judicial review) over the following:

- The establishment of the quality performance standards and the assessment of the ACO’s performance against such standards
- The assignment of Medicare fee-for-service beneficiaries to the ACO
- 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
- The termination of an ACO in the program

The Act also includes specific provisions pertaining to pediatric accountable care organizations (Section 2706). 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. The demonstration project for pediatric accountable care organizations is to begin on January 1, 2012, and end on December 31, 2016. 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. 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. 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. 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. The incentive payment will be tied to savings in excess of the annual minimal savings level established by the state.

National Pilot Program on Payment Bundling (Section 3023 of the Act)

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

- Whether the conditions selected include a mix of chronic and acute conditions
- Whether the conditions selected include a mix of surgical and medical conditions
- 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
- 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
- Whether a condition is high-volume and has high post-acute care expenditures under the Medicare Program
- The conditions that the Secretary determines are most amenable to bundling across the spectrum of care, given practice patterns under the Medicare Program

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

- Acute care inpatient services
- Physicians’ services delivered in and outside of an acute care hospital setting
- Outpatient hospital services, including emergency department services
- 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
- Other services the Secretary determines appropriate

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

- The three days prior to the admission of the applicable beneficiary to a hospital for the applicable condition
- The length of stay of the applicable beneficiary in such hospital
- The 30 days following the discharge of the applicable beneficiary from such hospital

The Secretary is to establish the pilot program not later than January 1, 2013, and, in consultation with the Agency for Healthcare Research and Quality, is to develop quality measures for use in the pilot program. The pilot program is to be conducted for a period of five years, subject to extension if the Secretary determines that such extension will result in improving or not reducing the quality of patient care, and
reducing spending under the Medicare Program. 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. 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.

Similar to 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:

- Functional status improvement
- Reduction in rates of avoidable hospital readmissions
- Rates of discharge to the community
- Rates of admission to an emergency room after a hospitalization
- Incidence of health care acquired infections
- Efficiency measures
- Measures of patient-centeredness of care
- Measures of patient perception of care
- 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.

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.

The Patient Protection and Affordable Care Act and the Encouragement of New Patient Care Models

Finally, in another development that bodes well for ACOs, Section 3021 of the Act establishes the Center for Medicare and Medicaid Innovation (CMI) within CMS. As stated in the Act, the purpose of the CMI “is to test 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 be operational no later than January 1, 2011.
These new innovative care delivery models are expected to 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:

- 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
- 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
- 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
- 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
- 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 tele-health technology
- 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
- 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
- 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
- Establish comprehensive payments to Healthcare Innovation Zones, 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

When considering the development of new innovative delivery models, the following are factors that, pursuant to the Act, the CMI is charged with considering:

- 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

- Whether care is delivered on a patient-centric basis
- Whether technology, such as EHRs and patient-based remote monitoring systems, is used to coordinate care over time and across settings
- Whether there is a close relationship between care coordinators, primary care practitioners, specialist physicians, community-based organizations, and other providers of services and suppliers
- Whether there is a team-based approach to interventions, such as comprehensive care assessments, care planning and self-management coaching
- 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

Legal Issues

When assessing the development and implementation of an ACO or other innovative care delivery model, numerous legal issues will need to be analyzed and addressed, including the following:

- The most appropriate legal organization and operational model, as well as related governance structure
- 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)
- State HMO/insurance/managed care organization laws, including plan licensing, “any willing provider” laws and the like
- Federal antitrust law and related clinical integration requirements
- HIPAA, HITECH and state laws governing the sharing of patient data among providers
- The various federal statutes applicable to physician payments, including the federal Anti-Kickback Law, Stark Law and the Civil Monetary Penalty (CMP) Law, as well as Internal Revenue Code Section 501(c)(3) requirements applicable to arrangements involving tax-exempt hospitals or other tax-exempt affiliates

The applicable legal issues may include the following:

- 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? Does the integrated delivery system present any other antitrust issues?
- 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?
- 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? Must there be an independent valuation for any quality incentive or shared savings payments? Does the CMP Law prevent making any physician employment compensation contingent on a reduction in LOS and readmission rates? 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?

- 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?

Conclusion

All health systems, community hospitals and physician groups should swiftly consider and carefully analyze forming or otherwise participating in an ACO or similar organization in order to respond effectively to the emerging changes in U.S. health care flowing from the new federal health care reform law and related initiatives sponsored by commercial payors.

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