Accountable Care, Clinical Integration and Provider Alignment

McDermott Will & Emery is uniquely positioned to help our clients develop and implement health care delivery and payment reform strategies, such as the formation of accountable care organizations (ACOs) and the development of other forms of clinical integration and provider alignment. We provide highly competent and creative advice and solutions in all respects and contexts by drawing on both our in-depth understanding of today’s rapidly changing business, legal and regulatory terrain, and our extensive knowledge and experience from representing hundreds of health industry clients in connection with widespread restructuring, integration and alignment initiatives in the 1980s and 1990s. We approach each engagement with the same priority: giving our client a clear sense of “what is” and “what needs to be,” and what must be different this time around to be successful in the marketplace through the provision of practical and strategic advice and counsel.

COMMERCIAL MARKET INITIATIVES

Our focus has been on many leading-edge projects involving the development of clinical integration programs, pay-for-performance programs and other value-based payment arrangements in the commercial marketplace including:

- The design, development and implementation of the full range of structures and transactions needed to respond to the current health care delivery and payment reform movement across a broad spectrum of approaches, players and markets

- Modifying provider payments and compensation to achieve the optimal balance between efficiency and quality outcomes while remaining compliant with complex health care laws and regulations

- Anticipating health insurance benefit designs that will foster consumer utilization of networks of providers organized and operating on a clinically integrated basis

- Establishing governance and tax structures that balance and address the needs of multiple constituencies and address conflicts of interest under state corporate law and emerging governance standards and best practices

- Developing effective and compliant strategies for data sharing between payors and providers

Our multidisciplinary team of health lawyers is equipped to address the complex legal issues involved in the myriad dimensions of alignment projects, including antitrust, Fraud and Abuse/Stark/Civil Monetary Penalty (CMP) laws, tax exemption, state health maintenance organization (HMO) and insurance licensure laws, corporate practice of medicine, peer review, and federal and state privacy and confidentiality laws. Our experience in these areas is critical in determining the feasibility of, designing and implementing sustainable new delivery and payment models. We have long been at the forefront of creatively addressing compliance consideration in the development of legal strategies to facilitate
hospital and physician integration arrangements and payment innovation, such as gain-sharing programs, physician practice acquisitions, employed physician compensation innovations, joint ventures and service line co-management agreements.

MEDICARE SHARED SAVINGS PROGRAM, PIONEER MODEL ACOS AND RELATED INITIATIVES

We have worked on several projects focused on responding to the Medicare Shared Savings Programs and pilot Medicare ACO programs that grew out of the Patient Protection and Affordable Care Act (PPACA), including satisfying the governance requirements of the proposed Medicare Shared Savings Program regulations. We have a team experienced in advising clients on the complex and competing compliance considerations in the current Medicare context. For example, we have written an 85-page white paper on the applicability of these laws and regulations to ACOs, and have assisted clients in the development of comments on the Medicare Shared Savings Program proposed regulations and the corresponding Centers for Medicare & Medicaid Services (CMS)/Office of Inspector General (OIG) proposed waivers of the Fraud and Abuse/Stark/CMP laws, the proposed Federal Trade Commission (FTC)/Department of Justice (DOJ) Policy Statement and Internal Revenue Service (IRS) Notice 2011-20, as well as on medical home and other federal health reform demonstration programs. Our tax-exemption specialists are playing a leadership role in active discussions with the IRS and the Treasury Department as they strive to develop the appropriate policy and enforcement position on how current tax-exemption requirements and standards will apply to the relationships contemplated by health reform.

DEMONSTRATED LEADERSHIP

- With more than 85 health lawyers counseling leading organizations in every major sector of the health care industry for over 30 years, McDermott has one of the United States’ largest and most prestigious health industry groups and it is the only health industry practice to receive a Tier 1 ranking in the 2010 and 2011 Chambers USA Guide: America’s Leading Lawyers for Business. Our Health Industry Advisory Practice Group also received a Tier 1 ranking in Legal 500 USA 2011 and our German health care practice was ranked Tier 1 by Chambers Europe 2011.

- McDermott was chosen to represent the Premier ACO Collaborative in a three-year project assisting approximately 85 health systems to develop ACOs and other accountable care capabilities.

- Our lawyers often speak on accountable care and clinical integration at established industry conferences, including programs hosted by Healthcare Financial Management Association, American Health Lawyers Association, the University Health System Consortium and Strafford Publications.
We have created the ACO Resource Center, available through the Firm’s website at www.mwe.com, which serves as a valuable resource for ACO updates, including various agency resources and CMS Fact Sheets.

In June 2011 McDermott released a White Paper entitled The Controversial Draft Medicare ACO Regulations: Analysis, Comments and Recommended Action. The publication will be updated when CMS issues a final rule.

McDermott lawyers continue to publish articles and book chapters on this important topic, including a chapter entitled “Accountable Care Organization Anatomy” in the book Accountable Care Organizations: Your Guide to Strategy, Design and Implementation. The chapter reviews and evaluates the options for (and makes recommendations regarding) structuring and organizing an ACO.

Our lawyers have been called upon for their substantial knowledge in this area and have been quoted in various publications regarding ACOs, including BNA’s Health Law Reporter, Modern Healthcare, the New York Times and the Wall Street Journal.

PAYOR/PROVIDER RELATIONSHIPS

McDermott has advised the full range of health care industry participants in their efforts to create and restructure managed care arrangements throughout the United States, as well as internationally. This includes HMOs, health insurers and self-funded payors, as well as key providers. We have developed payment arrangements from basic discounted fee-for-service arrangements to creative risk withhold and clinically integrated models to complex global capitation, percent of premium or other innovative risk sharing arrangements. McDermott has substantial experience in creating single specialty or disease “carve out” networks consisting of single specialty physicians and related ancillary providers and in the development of case rates, specialty capitation rates and other payment arrangements for defined populations.

Our lawyers have also worked with organizations composed of national health care systems in the development of an ACO contract templates between payors and health care providers. These templates address such critical issues as the significance of data sharing between payors and providers and the manner in which compensation will be modified to achieve the balance between efficiency and quality outcomes. Unlike current Medicare demonstration projects, these templates anticipate health insurance benefit designs that will facilitate the utilization of the ACO health care system and providers by consumers. Our experience with the regulatory issues related to required insurance benefit designs and insurance payment requirements afford our Firm unique insights when structuring the evolving payor-provider relationships.
PHYSICIAN-HOSPITAL ALIGNMENT

McDermott has considerable experience in the development and implementation of alignment strategies between hospitals and physicians. Physicians and hospitals continue to look for ways to align their clinical and economic interests in response to growing regulatory and financial challenges, including the weakened economy and the associated financial pressure it brings to bear on health care delivery and finance; pricing transparency demanded by employers, regulators and others; continuing payor consolidation; increasing quality reporting requirements; governmental and commercial payment reform; and shortages of physicians in key specialties. In addition, the PPACA and commercial payor initiatives have caused many health systems to seek closer financial and clinical alignment with their physicians in order to address proposed payment reform initiatives, including Medicare and commercial pay-for-performance and other value-based purchasing programs; pilot programs for bundled payments for courses of treatment; payment adjustments for re-admissions; financial penalties for hospital-acquired conditions; and extension of gain-sharing demonstration projects. In response, we have been working with many of our clients to assist them with the development and implementation of alignment strategies to reduce costs (by eliminating duplication of services and creating economies of scale), improve quality through care management and measured outcomes and to improve access to care (i.e., to provide accountable care).

ANTITRUST

McDermott routinely counsels health care providers on all antitrust issues associated with the formation and operation of provider networks. These issues include the steps that provider networks must take to avoid liability for the unlawful exercise of monopoly power, as well as price-fixing and boycotts in connection with negotiations with third-party payors.

Our lawyers have been advising clients on the antitrust implications of provider networks since the early 1980s. Our health antitrust practice includes lawyers who previously practiced at the DOJ and FTC. Our practice has also sought and obtained favorable business review letters from the DOJ, including one pertaining to a physician contracting network.

Our experience helps us avoid rookie mistakes and reduces the need for basic research, and also helps us steer hospitals and physician groups away from issues or structures that are likely to produce more conflict than cooperation. Significantly, we know what is required, and we work with clients to tailor their clinical integration programs to meet their individual needs. Because of our long-standing involvement in this area of law, we are able to work with clients to create customized clinical integration programs based upon the client’s provider network, patient demographics and other factors. As the three favorable advisory opinions concerning clinically integrated networks demonstrate, the manner in which a network develops and implements its program for clinical integration varies based on a number of factors. We are not wed to any one particular model, and have the skills to assess alternatives and options that are best suited for the success of each client’s program based on the client’s business needs and competitive situation.
McDermott lawyers have discussed the application of the DOJ and FTC’s guidance pertaining to clinically integrated networks with those agencies, and have commented on their Proposed Statement of Antitrust Enforcement Policy Regarding ACOs Participating in the Medicare Shared Savings Program.

**FEDERAL REGULATORY COMPLIANCE**

McDermott’s extensive health law transactional work and the national scope of our practice allows our lawyers to evaluate a wide variety of transactions under federal health care program fraud and abuse, physician self-referral (Stark) and analogous state laws. We have extensive experience and background counseling clients regarding Stark, Fraud and Abuse, and Civil Monetary Penalty Law (CMP) issues raised by various hospital-physician clinical integration and coordinated care models, including providing written guidance to hospital members of a large group purchasing organization on the regulatory issues raised by ACO development and operations. Most recently, we have assisted clients in evaluating and submitting comments on the proposed ACO waivers, and will be working with these clients on understanding the implications of these waivers for their ACOs. This ongoing activity enables our lawyers to help clients plan, structure and implement hospital-physician clinical integration arrangements to address and manage their regulatory compliance risks.

**TAX EXEMPTION**

McDermott is uniquely positioned to advise tax-exempt organizations with respect to all aspects of forming or participating in ACOs, including reviewing and recommending possible accountable care models (pros and cons), clinical integration issues and provider alignment issues all from a tax and tax-exemption perspective. McDermott structured and obtained exemption for one of the first regional health information organizations (RHIOs) to apply for and receive tax-exemption under Section 501(c)(3) of the Internal Revenue Code, and we played a key leadership role in discussions with the IRS that led to its adoption of a favorable policy and enforcement position with regard to the donation of electronic health record technology by hospitals to independent physicians. Like RHIOs a few years ago, ACOs present a case of first impression for the IRS, which situations require careful navigation through unchartered waters. To that end, McDermott has long been at the forefront of resolving novel nonprofit issues raised in complex health care arrangements including, for example, gain-sharing arrangements, multi-corporate tax-exempt and taxable physician practice structures, cutting-edge provider arrangements, all of which raise significant nonprofit issues in areas in which there is little or no formal guidance from the IRS. In these cases, like ACOs, the key is creating flexible structures that can evolve with emerging IRS guidance down the road, thereby limiting the likelihood of full-scale restructurings in the future.

Given the inadequacy of current applicable guidance from the IRS, knowing how best to structure new types of tax-exempt organizations (or new types of arrangements in which tax-exempt entities will participate) during what will likely be an extensive period of IRS review and deliberation will be critical for an ACO to achieve success. In addition, McDermott is and will continue to be actively involved in discussion with the IRS regarding the development of the IRS’ ultimate legal position on ACOs and ACO arrangements with tax-exempt participants. By continuing to communicate with the IRS on such
issues, McDermott will be able to react quickly as details emerge and continue to be at the forefront of the industry.

INFORMATION TECHNOLOGY

McDermott’s health information technology (HIT) practice is at the forefront of the convergence of health care reform and HIT. We are one of a few law firms to maintain an entire group focused on HIT, which has the depth and breadth of experience to bring to bear in the structural, compliance and contracting dimensions of designing and implementing the data exchange strategies and corresponding HIT capabilities that are critical to support any ACO or clinical integration strategy. We have more than 30 years of experience in negotiating for the licensing, development, implementation and support of the full spectrum of both traditional and emerging HIT infrastructure and service relationships, including cloud computing and other emerging outsourcing relationships. We are frequently engaged to provide strategic, regulatory compliance and contracting advice in connection with the formation of networks for the electronic exchange of clinical and claims information for providing care and undertaking quality and other performance measurement; the creation of joint data warehouses to support clinical decision-making as well as quality assurance research and other healthcare operations analyses; and the creation of national and international disease registries and tissue repositories.

QUALITY

An understanding of the integration of quality concepts and measurement metrics into accountable care is of key importance. Our lawyers have assisted hospital and health system clients with the development and enhancement of quality assessment and performance improvement programs (commonly referred to as QAPI). We have also assisted clients with policy and procedure revisions focused on tracking internal quality processes and on development of reporting mechanisms to fully incorporate quality efforts into those processes.

External reporting of quality data is at the forefront in accountable care. We have assisted hospital and health system clients with coordinating reporting processes and streamlining data from these reports for use both internally and externally. We have significant experience guiding multidisciplinary care groups (i.e., physicians and practitioners from a variety of specialty areas, operations staff and administration) to consensus on complex quality assurance matters and in using a team approach to analyzing and addressing quality of care concerns. Likewise, we have also worked with health care systems on developing quality measures applicable to inpatient and outpatient providers.

Our lawyers are currently working on a joint venture between a health insurer and an academic health care system for the development of a patient centered medical home. Viewed by many as a critical entry point to the ACO, the patient centered medical home is designed to change the manner in which primary care services are delivered as well as the need for and management of specialty and hospital services that would be addressed through the ACO. In both models, the emphasis is on quality measurements that improve the overall health care of the patient while reducing the need for additional health care services. Our experience is in helping design and implement strategies where cost
accountability is redefined by new payment models with quality indicators as a condition precedent to the payment of any shared savings.

STATE REGULATION

At their core, ACOs are a highly evolved form of provider network. McDermott has been involved in the development of, contracting for and ongoing representation of hundreds of provider networks since the early 1980s, and we have seen these arrangements evolve over the years. We have worked with numerous providers in creating both risk-bearing and non-risk bearing networks, including physician-hospital organizations (PHOs), independent practice associations (IPAs) and single-specialty and multi-specialty provider networks. In those contexts, we have analyzed the various state laws that may be implicated by the creation of risk-bearing and non-risk bearing networks, such as insurance law regulation of insurance risk arrangements, state preferred provider organization (PPO) and HMO requirements for provider contracts, third party administrator (TPA) licensure and certification requirements, and utilization review licensure and certification requirements. Some of the networks evolved into HMOs or other entities similarly positioned to take global risk as a traditional state-licensed HMO (or other licensed risk-bearing entity).

GOVERNANCE

Our lawyers have extensive experience providing advice to ACOs and similar “shared governance” health care organizations in connection with the selection and implementation of governance structures. This experience reflects McDermott's nationally recognized practice representing multiple different forms of health care entities in connection with corporate law and governance matters. McDermott corporate governance lawyers are nationally recognized thought leaders in the field.

We provide advice in connection with governance structures appropriate for the choice of legal entity selected for ACO operations; identification of the specific fiduciary duties relevant to the selected form of legal entity; satisfaction of the governance requirements of the draft ACO regulations; governance-related provisions included in the corporate organizational documents; and particular corporate governance requirements under state law. Additional areas of related ACO experience include identification of the specific fiduciary duties relevant to the selected form of legal entity; unique oversight obligations of ACO board members; special issues related to managing conflicts of interest and other challenges associated with constituent governance; board composition, size, organization and authority; appropriate committee structures; applicable fiduciary duties and governance best practices, and related policies and procedures; and strategies intended to resolve business issues arising from the divergent interests of ACO board member constituencies.

McDermott’s experience in ACO governance reflects its historical practice representing other forms of organizations with constituent governance, e.g., limited partnerships, limited liability companies, unincorporated associations and closely held corporations.
GOVERNMENT STRATEGIES

McDermott’s health government strategies practice assists clients in positioning themselves to be leading candidates in federal government sponsored care delivery and financing demonstration projects. We are able to leverage our knowledge of federal administrative and legislative funding processes and the operations of the Department of Health and Human Services, CMS, the Health Resources and Services Administration and Congress to assist with the development and advancement of political and legislative solutions when necessary to facilitate our client’s health reform objectives and strategies. We also assist clients with comments to federal agencies on shared savings models, medical home demonstrations and other federal reform initiatives. When political or legislative solutions may be necessary to facilitate a reform objective, our team is well-positioned with the experience and relationships to assist with those endeavors.

ACO WEBCAST SERIES

Following the passage of the PPACA, McDermott offered a five-part complimentary webcast series focused on providing practical, can-do commentary and stimulating dialogue regarding the provision of accountable care and the formation of ACOs, including electronic health information, governance, management and provider alignment. The webcast series was viewed more than 1,500 times by Firm clients and friends. The webcast sessions included:

- So You Want to Partner with CMS … Practical Considerations for Medicare ACOs
- Payment, At-Risk Arrangements and Funds Flow Models
- Payor Perspectives on Provider Realignment and ACOs
- Regulatory Hurdles, Best Practices, Evidence-Based Medicine and the Evolution of Clinical Care
- Use of Information, Governance, Management and Provider Alignment Issues

All of the webcasts and presentations are archived and can be viewed at www.mwe.com/info/aco.

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For more information about McDermott’s ACO practice, please contact your regular McDermott lawyer or Gary Scott Davis at +1 305 347 6520 or gsdavis@mwe.com.

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