HEALTH MANAGEMENT ASSOCIATES
Accountable Care Institute

Governance of Accountable Care

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This paper contains legal information but is not intended to constitute legal advice or substitute for the particularized advice of competent legal counsel.

Accountable Care Organizations (ACOs) are provider-based entities where providers agree to work together to be responsible for patient care and agree to share in savings (or loss) derived from improvements in quality and efficiency. Most providers participate in multiple insurance plans as well as Medicaid or Medicare. Most if not all payers will move toward, or at least experiment with, new payment and delivery models using the ACO framework. As providers form ACOs, it seems reasonable they will seek to satisfy the requirements of these multiple payers rather than just one in order to participate in these initiatives across their patient mix. Moreover, as states begin to set standards through statute and regulation, it is likely some commonalities will emerge that will allow providers to achieve this goal. As a practical matter, states are likely to look to both the federal government and other states' activity in this area to inform their own approaches to setting qualifications for ACOs. It makes little sense for an ACO to establish itself to participate with only one payer. That could defeat the promise of ACOs if these entities have to expend resources (and jeopardize any savings) on responding to different incentives through differing administrative, organizational and governance structures to satisfy specific payer requirements rather than focusing on providing better and higher-quality care at lower cost.

While there is no standard legal or governance model required for ACOs, there appear to be some patterns emerging in federal and state laws and regulations with regard to functional requirements. This paper discusses legal and governance structures, including practical considerations for safety net providers, as well as legal issues that ACOs should consider as they develop the foundation for this new structure.

Legal Structure

Under the final Medicare Shared Savings Program (MSSP) rule, an ACO must be a legal entity for purposes of all ACO program functions.[1] A corporation (profit or non-profit), partnership, limited liability corporation (LLC), foundation or any other entity recognized under federal, state or tribal law can be an ACO legal entity.[2] This is also the approach taken in some states that have adopted ACO laws. For example, New York's ACO law is silent regarding the type of legal entity that would qualify to be certified as an ACO. While regulations have not yet been adopted and may provide more guidance on this point, the statute simply requires "clinical integration" by health care providers, which appears to leave the door open for any legal entity

[1] Final Rule: Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 FR 67902, 67816, November 2, 2011.

[2] 42 CFR §425.104 (a)

to qualify.[3] Massachusetts follows the MSSP requirement for a separate legal entity for ACO participants but does not prescribe what it must be.[4] Oregon allows either a separate, unspecified corporate structure or integration among providers through contractual arrangements.[5] The Texas version of an ACO, called a Health Care Collaborative, must have a formal legal structure, but, similar to Massachusetts, the law does not specify what it must be.[6] Essentially, in many states, an ACO may take on any legal structure, as long as it can perform the functions necessary to be an ACO under the applicable law. In contrast, New Jersey's Medicaid Accountable Care Demonstration Project permits only non-profit corporations to participate.[7]

Entities will need to make decisions about whether they need to create a new legal entity and, if so, what form it should take. These decisions will necessarily be influenced by the status of the entities that decide to form an ACO as well as financial and tax considerations and applicable laws. For example, an integrated delivery system that already delivers care along a continuum likely has the least distance to travel to become an ACO and may be able to use its existing legal structure. It may have the necessary information technology infrastructure to support quality measurement as well as experience dealing with risk-based payment methodologies so that it will not need to add any new partners. Physician groups may have the provider leadership necessary for an ACO, but they may need partners for care coordination and to provide financial resources to develop the necessary infrastructure to support an ACO. Joint ventures between physician groups, other providers and hospitals are also a possibility.

Tax Issues

Providers who are tax exempt will have to be careful should they decide to participate in an ACO. According to IRS guidance issued in conjunction with the final MSSP regulations, a charitable organization can participate in the MSSP program through an ACO with private parties as long as it continues to meet the requirements of tax exemption.[8] The charitable organization must ensure that its participation does not

- result in net earnings inuring to the benefit of private shareholders or individuals, and

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[3] See A4009-2011 (New York).

[4] Massachusetts Senate Bill 2400: An Act improving the quality of health care and reducing costs through increased transparency, efficiency and innovation, signed by Governor Patrick on August 6. 2012.

[5] Oregon Revised Statute 414.625

[6] S.B. 8-2011 (Texas)

[7] P.L.2011, Chapter 114 (New Jersey)

[8] See IRS Fact Sheet: Tax-Exempt Organizations Participating in the Medicare Shared Savings Program through Accountable Care Organizations, FS-2011-11, October 20, 2011.

- result in the charitable organization being operated for the benefit of private parties participating in the ACO.

The IRS guidance also indicates it is possible for an ACO not participating in the MSSP to qualify for tax exemption under §501(c)(3) as long as its activities further a charitable purpose. Serving Medicaid or indigent populations are examples of activities that might serve the charitable purpose of relieving the poor and distressed.

Another concern for tax-exempt ACO participants is whether non-MSSP activities will generate unrelated business income. The IRS response to that question is that if the ACO's activities are related to the tax-exempt charitable purpose, unrelated business income will not be generated.[9] An ACO involved in non-MSSP activities that do not further a charitable purpose will not automatically jeopardize the tax-exempt status of charitable organization participants as long as the non-charitable activities are not a substantial part of the participant's total activities. Determining whether an activity is substantial or not requires a case-by-case analysis, thus the answer will depend on all of the relevant facts and circumstances.[10]

Governance

ACOs contemplating participation in multiple payer ACO initiatives will want to establish a single governance structure that meets the requirements for all payers. Medicare often leads the way for Medicaid and commercial insurance, so it is worthwhile to consider what the MSSP regulations require. Fortunately, the final rule removed some of the more onerous requirements for governance that were in the proposed rule in favor of a more relaxed and flexible approach.

Under MSSP rules, the governing body and its members are responsible for the oversight and strategic direction of the ACO, for holding ACO management accountable for the ACO's activities, and for maintaining a transparent governing process. Further, the members must have a fiduciary responsibility to the ACO and act in accordance with that duty. The ACO must also have a conflict-of-interest policy that applies to all members of the governing body.[11]

The ACO must have a mechanism for shared governance among the providers who are members of the ACO.[12] The governing body must be separate and unique to the ACO when the ACO is made up of otherwise independent participants.[13] While CMS had initially proposed

[9] FS-2011-11
[10] FS-2011-11
[11] 42 CFR §425.106
[12] 42 CFR §425.105
[13] 42 CFR §405.106(b)(4)

that all ACO participants be included as members of the governing body, in the final rule, this requirement was relaxed to require that the ACO "provide meaningful participation in the composition and control of the ACO's governing body for ACO participants or their designated representatives."[14] Because of this decision, the final rules do not set any specific standards or requirements for representation by particular provider or stakeholder categories. This approach allows each ACO to determine how the governing board will be established.

The rule does establish an overall requirement for the composition of the governing body, but even that is flexible. The general rule requires that at least 75 percent control of the governing body be held by ACO participants. In addition, there must be Medicare beneficiary representation. However, if the governing body does not meet these requirements, it may still be permissible for purposes of participation in the MSSP if the ACO can adequately describe why it seeks to deviate from the requirements and can demonstrate how it will involve ACO participants in "innovative ways" in governance or provide for "meaningful participation" in ACO governance by Medicare beneficiaries.[15] This flexibility could be important if, for example, the ACO is a professional medical corporation since, in some states, only licensed practitioners can serve on a board of directors. Such an ACO would have a good reason not to include a Medicare beneficiary on its board since doing so would violate state law, but it would need to provide a mechanism for meaningful participation by Medicare beneficiaries —perhaps through an advisory group to the board. Even if the legal entity could have a beneficiary on its board, it may prefer to establish a new legal entity and separate board to keep its current operations from being subject to the MSSP requirements. If the ACO intends to participate in public programs, however, beneficiary or consumer participation in governance is likely to be a requirement. Oregon, Massachusetts, and New Jersey provide examples of this requirement.

Oregon's version of accountable care will be provided through what it calls Coordinated Care Organizations (CCOs). [16] CCOs will enter into risk contracts with the state to provide Medicaid services within a defined geographic area. CCOs must be local, community-based organizations or statewide organizations with community-based participation in governance, or a combination of the two. The CCO may be a single corporate structure, or it can be a network of providers organized through contractual relationships. The governance requirements for either approach are the same and include the following make-up for the governing body:

- Entities or organizations that share in the financial risk must constitute a majority of the governing body.

[14] 76 FR 67818
[15] 76 FR 67822
[16] Oregon Revised Statute 414.625

- The governing body must reflect the major components of the health care delivery system.
- At least two health care providers in active practice must be members of the governing body (a physician or nurse practitioner in primary care and a mental health or chemical dependency treatment provider).
- One member of the Community Advisory Council[17] must be included.
- Two members from the community at large must be included.

In applying to the state for certification as a CCO, the entity must explain how its governing body make-up reflects community needs and supports the goals of health care transformation. Similar to the MSSP, CCOs must provide for transparency in their governance.[18] The overarching theme of Oregon's CCOs is that they must be local, provider-driven, transparent in their governance and involve consumers.

In August 2012, the next phase of Massachusetts health reform became law when a comprehensive bill intended to address health care cost and quality was passed.[19] Among the many provisions of the new law is the creation of a new Health Policy Commission that will implement standards for certification of ACOs. The legislation requires a certified ACO to establish a governance structure that includes an administrative officer, a medical officer, and patient or consumer representation. It must also obtain a risk certificate from the Division of Insurance. The Health Policy Commission is also responsible for establishing standards for ACOs related to financial conflicts of interest and transparency. The Commission also has authority to adopt regulations consistent with federal law, regulations, demonstrations and rules governing ACOs and shared savings programs.

New Jersey's demonstration requires voting representation from at least two consumer organizations on the non-profit corporation's ACO governing board. [20]

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[17] CCOs are required to convene a Community Advisory Council that includes representatives from the community and county government, but with consumers making up the majority of the CAC. See Oregon Revised Statute 414.625(1)(i).

[18] Oregon Health Authority, Section 1115 Medicaid Demonstration Special Terms and Conditions, Numbers 21-W-00013/10 and 11-W-00160/10, pages 50-51

[19] See Massachusetts Senate Bill 2400: An Act improving the quality of health care and reducing costs through increased transparency, efficiency and innovation.

[20] P.L.2011, Chapter 114 (New Jersey)

Practical Considerations for Safety-Net Providers

Safety net providers may be subject to unique governance and legal structure constraints that must be taken into account as they consider participation in ACOs. They must consider how participation could impact their current structures, how governance and leadership should be allocated, and how to address liability for losses.

While the Health Resources and Services Administration (HRSA) Bureau of Primary Health Care (BPHC)—the federal agency charged with oversight of Federally Qualified Health Centers (FQHCs) and Look-Alikes—encourages affiliation and collaboration between these health centers and other entities, the agency has expressed concerns that some affiliations could compromise centers' ability to comply with requirements of Section 330 of the Public Health Service (PHS) Act, the legislation that authorizes the establishment and operation of health centers. [21]The formation of ACOs involving health centers is likely to raise similar concerns on the part of BPHC, so the guidance it has already issued regarding affiliations may be helpful to centers as they consider whether to become part of an ACO. [22] BPHC is particularly concerned that health centers maintain their integrity and autonomy with regard to corporate structure, governance, management and finance, and health services delivery. Affiliations or collaborations cannot compromise the health center's ability to comply with federal grant requirements or involve terms that would:

- Impede the health center's compliance with requirements related to the size, composition, and authority of its board of directors.[23]
- Interfere with the autonomy of the health center's administrative, financial, or clinical operations.
- Allow another entity to control the health center's relationships with other providers unless the control is so limited that it does not prevent the health center from collaborating with other providers.[24]

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[21] 42 U.S.C. 254(b)

[22] Policy Information Notice (PIN) #97-27, Affiliation Agreements of Community and Migrant Health Centers, issued July 27, 2007. PINs are issued by the BPHC to define and clarify policies and procedures that grantees funded under Section 330 must follow.

[23] Health Centers have a unique consumer-directed governance model requiring a board composed of at least nine but not more than twenty-five individuals, a majority of whom are being served by the center and who, as a group, represent the individuals being served by the center in terms of demographic factors such as race, ethnicity and gender. See 42 U.S.C. 254(b)(k)(H).

[24] Rosenbaum, S., Zakheim, M.H., Leifer, J.C., Golde, M.D., Schulte, J.M., Margulies, R. "Assessing and Addressing Legal Barriers to the Clinical Integration of Community Health Centers and Other Community Providers;" The Commonwealth Fund, July 2011.

The consequences for noncompliance can be serious for the health center, potentially affecting eligibility for Section 330 grants, FQHC status, malpractice protection through the Federal Tort Claims Act, reduced prices for drugs under 340B of the PHS Act, and special reimbursement under Medicare, Medicaid and CHIP.

Like health centers, public hospitals may have structural and governing board requirements established in state law or local ordinance that must be observed. For example, some members may be elected or appointed by elected officials. Compliance with these provisions may complicate the development of governing board structures for ACOs where public hospitals are participants.

Whether an affiliation occurs through a contractual arrangement, joint venture, or some other form of corporate integration, the question of how the affiliation will be governed and managed arises. The parties could allocate control based on contributions of the participants. These contributions could be financial, but such an approach may advantage hospitals at the expense of other participants (e.g., physicians, health centers) who likely have less access to capital. Moreover, such an approach might undermine the goal of provider accountability for care. Physician leadership and participation is key to ACO success given the emphasis that will be placed on provider accountability for clinical care, coordination, and quality. Without physician buy-in and leadership, development of processes to promote evidence-based medicine and establish meaningful performance and quality measures would be difficult if not impossible. Health centers also will play a role as an important source of primary care in medically underserved communities. Whatever allocation method is chosen for control, it should recognize the critical role that all participants must play in the success of an ACO.

While the goal of accountable care is higher quality at less cost, it may take time to achieve savings. Methodologies for sharing savings and dividing losses should be considered up front and addressed in ACO agreements. Participants will want to ensure they understand how any losses will be calculated and shared. This may also be a point of negotiation with payers. To provide an incentive to participate, CMS has established limits on shared losses in the MSSP, and initially providers will share only in savings, not in losses. This may be an approach that other payers will take and certainly one that potential ACO participants may want to suggest to them. In addition, ACO participants might consider other mechanisms to limit their liability, such as purchasing reinsurance or establishing a reserve. If the ACO is regulated under state law, there may be regulatory requirements that will have to be followed to address these issues.

Other Legal Issues

In addition to concerns about legal structure and governance, there are other legal issues for potential ACO participants to consider before embarking on this path. To implement the MSSP program, the federal government has established certain protections and safe harbors with respect to federal anti-trust, fraud, and abuse laws. However, if the ACO does not participate in the MSSP, these protections do not technically apply. In addition, ACOs (even if they participate in the MSSP) must also consider the application of similar laws at the state level (which have not been pre-empted) as well as state laws concerning health plan regulation and the corporate practice of Medicine. ACOs should also be mindful of HIPAA compliance.

Anti-Trust

The final policy statement issued by the Department of Justice (DOJ) and Federal Trade Commission (FTC) in conjunction with the MSSP rules indicates that the agencies will apply a "rule of reason" analysis to ACOs that meet CMS' eligibility criteria and use the same governance and leadership structures and clinical and administrative processes to serve patients in Medicare and commercial markets. This approach recognizes that ACOs are intended to be integrated and produce efficiencies that will benefit consumers. A "rule of reason" analysis means that the agencies will evaluate whether the collaboration is likely to have a substantial noncompetitive effect and if so, whether the efficiencies realized outweigh those anticompetitive effects. [25]

With regard to state approaches, anti-trust issues can be addressed under the state-action doctrine which allows immunity when anti-competitive acts are the product of state regulation. To qualify for this exemption, the activity must be clearly articulated and affirmatively expressed as state policy, and the conduct must be actively supervised by the state itself.[26] New York passed legislation in 2011 establishing authority to create an accountable care organization demonstration program. While regulations have yet to be adopted, the law sets forth the intent to provide state action immunity under state and federal antitrust laws to payers and health care providers in order to accomplish the purposes of the law. Oregon has taken a similar approach with its CCOs.[27] New Jersey has also adopted legislation intended to take advantage of the state action doctrine in the formation of ACOs for its Medicaid demonstration. Texas has

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[25] FTC/DOJ Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 FR 67026, October 28, 2011.

[26] See *Parker v. Brown*, 317 U.S. 341 (1943); *Patrick v. Burget*, 486 U.S. 94 (1988)

[27] HB 3650-2011 (Oregon)

done the same and provides for review by its Attorney General to determine whether the Health Care Collaborative's application will reduce competition. [28]

Fraud and Abuse Laws

CMS and the Office of Inspector General for HHS published a joint rule establishing waivers of certain fraud and abuse laws to encourage ACO formation in connection with the MSSP.[29] The fraud and abuse laws whose application is subject to waiver are:

- Physician Self-Referral Law (Stark) – Prohibits a physician from referring Medicare beneficiaries to an entity for certain services if the physician has a direct or indirect financial relationship with the entity.[30]
- Federal Anti-Kickback Law[31] – Prohibits any person from knowingly and willfully offering to pay another for referrals for services that would be paid for by a federal healthcare program.
- Gainsharing Civil Monetary Penalty (CMP) Law[32] – Prohibits hospitals from paying a physician to reduce or limit services to Medicare or Medicaid beneficiaries.
- Beneficiary Inducement Law[33] – Prohibits remuneration to Medicare or Medicaid beneficiaries intended to influence the beneficiary to receive services that may be paid for by Medicare or Medicaid.

The five waivers are:

- ACO Pre-participation waiver of the physician self-referral law, Federal anti-kickback statute, and gainsharing CMP with respect to start-up arrangements that pre-date an ACO's MSSP participation agreement if the governing body determines (and documents) that the overall arrangement is related to a purpose of the MSSP.
- ACO participation waiver of the same three laws during the course of the ACO's participation in the program. As with the pre-participation waiver, the board must determine and document that the arrangement is related to a purpose of the MSSP.

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[28] S.B. 8-2011 (Texas).

[29] Interim final rule with comment period: Medicare Program; Final Waivers in Connection with the Shared Savings Program, 76 FR 67992, November 2, 2011.

[30] 42 USC §1395nn

[31] 42 USC §1320a-7b

[32] 42 USC §1320a-7a(b)(1)

[33] 42 USC §1320a-7a(a)(5)

- Shared savings distribution waiver of the same three laws – Protects shared savings payments received by the ACO from the MSSP.

- Compliance with the physician self-referral law that waives the gainsharing CMP and federal anti-kickback statute. Payment to a physician from the ACO must qualify for a Stark exception and be made within the MSSP framework. Payments to physicians from hospitals must not be made to limit medically necessary care.

- Patient incentive waiver of the beneficiary inducements CMP and federal anti-kickback statute for medically related incentives offered to beneficiaries to encourage preventive care and compliance with treatment regimens.

Many states have enacted anti-trust and fraud and abuse statutes. The federal pronouncements do not pre-empt any of these state laws, so ACOs must ensure they do not violate them. Some states have attempted to address these issues in their ACO legislation. For example, the New York law provides authority for the adoption of regulations to provide safe harbors that would exempt ACOs from state laws concerning restraint of trade, fee-splitting, and self-referral.[34] New Jersey's law establishing a Medicaid Accountable Care Demonstration Project also provides authority for the state's Commissioner of Human Services to secure waivers, exemptions or advisory opinions to ensure the ACOs are in compliance with state and federal laws concerning fraud and abuse.[35] However, an ACO should seek the advice of experienced legal counsel regarding these matters before concluding that it has done enough to be protected and not run afoul of these laws, which can have significant fines and penalties if they are violated.

Health Plan Regulation

Many states have statutes or regulations requiring risk-bearing entities that provide or arrange for the provision of health care to be licensed and comply with insurance or HMO requirements. While both Oregon and Massachusetts clearly require licensure in their state ACO schemes, even with no change in law, an ACO could find itself subject to the existing requirements applicable to insurers or HMOs if it accepts risk. ACOs should clarify with state regulators whether they are subject to these provisions in the state where they operate and ensure that they obtain the appropriate license, if necessary.

Corporate Practice of Medicine

Some states have laws prohibiting the corporate practice of medicine, which essentially means a corporation cannot practice medicine or employ physicians to provide professional medical

[34] See A4009-2011 (New York).
[35] P.L.2011, Chapter 114 (New Jersey)

services. ACOs may run afoul of these laws and should consider this issue in their structure to ensure compliance, if they operate in a state that has such a law. New York has specifically exempted ACOs from the application of its corporate practice of medicine law.[36]

HIPAA

The HIPAA Privacy Rule allows providers to share patient-identifiable data between themselves for treatment purposes. [37] While this aspect of data-sharing is a key part of coordinating and integrating care, analyzing the data to perform quality assessment and improvement activities will also be necessary. Again, the HIPAA Privacy Rule should not be a barrier to this kind of legitimate data sharing, as these uses are squarely within the definition of health care operations under HIPAA.[38] As part of their affiliation agreements, ACO participants should include business associate language to address data use and data sharing parameters, including who will be responsible for data analysis, ensuring that data exchanges are limited to the minimum necessary to accomplish the purpose of the permitted use.

Conclusion

No standard legal or governance model is required for ACOs, but some patterns are emerging in federal and state laws and regulations with regard to functional requirements. Meaningful board representation of the ACO participants as well as consumer input or representation (at least for public programs) is a common requirement in states that have adopted ACO legislation as well as in the MSSP. Safety net providers have additional issues to consider because of the constraints they may already be subject to under state and federal law with respect to governance.

A significant consideration for all providers in deciding to participate in ACOs is whether the potential benefits will outweigh the costs and burdens of participation. The lack of federal pre-emption of state fraud and abuse laws as well as the existence of an established regulatory framework may add another level of complexity and create challenging compliance issues that must be taken into account.

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[36] See A4009-2011 (New York).

[37] 45 CFR §164.502

[38] 45 CFR §164.501

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From 2008-2009, Catherine served as a Senior Policy Advisor with the National Association of State Units on Aging (NASUA) in Washington, DC, where her primary duties included providing technical assistance to states under a federal planning grant. In addition to responding to requests for assistance from member states, she wrote and analyzed surveys, as well as participated in collaborations with other aging network organizations to represent member states' interests in Washington.

Prior to that, Catherine served in various capacities over a fifteen year career with the Indiana Family and Social Services Administration, the umbrella health care and social services funding agency that includes Indiana's State Unit on Aging, as well as Medicaid, TANF, Food Stamps and programs for the mentally ill and developmentally disabled. For ten years, she was Deputy General Counsel where she was the primary legal advisor for the Medicaid program. She was a member of the team that received Governor Mitch Daniels' 2008 Public Service Achievement Award for her work on the Healthy Indiana Plan (HIP) that provides health insurance to low income citizens under an 1115 waiver.

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Health Management Associates (HMA) has amassed a wealth of on-the-ground experience that is important to share more widely as the nation undergoes the dramatic changes anticipated over the next several years. To that end, it is forming the Accountable Care Institute (ACI). The ACI will:

- provide a venue in which to share experiences and best practices from across the country related to the development of community-specific integrated delivery systems, new financial strategies to incentivize value, and innovative partnerships between providers and payers to assure effective care for the unique populations they are both trying to serve;
- develop and offer resources to others to help spread lessons learned in the development of these new approaches to the delivery of accountable care;
- facilitate the training of new leaders in health system change; and
- translate delivery system lessons learned on the ground into policy and policy into change at the delivery system level, whether financial, legal, clinical or organizational.

Over the past decade, HMA has been assembling a growing practice of senior health care clinicians and administrators, finance experts, behavioral health professionals, managed care leaders, long term care innovators and others committed to developing new approaches to delivering health care services, particularly to populations and communities that have traditionally been under-served. HMA has worked for large health systems, consortia of providers, individual hospitals and ambulatory providers, states and counties, foundations and managed care plans to assess current delivery of care, plan new approaches and assist in implementation. This work has been growing in volume as the country has started to seriously grapple with how to assure access and quality—and the improvement of health status—while rolling back the cost trajectory which is universally agreed to be unsustainable. Expertise in integrated and accountable care as it applies to the delivery of care to those funded by public dollars is in demand; it is anticipated that the ACI will provide a vehicle for meeting that demand.