



American Society for Clinical Pathology

POLICY STATEMENT

ACCOUNTABLE CARE ORGANIZATIONS (ACOs) (POLICY NUMBER 11-01)

Policy Statement

To improve patient and quality of care, as well as to control costs, the American Society for Clinical Pathology (ASCP) believes that pathologists and advanced certified laboratory professionals should be fully incorporated into the administrative and clinical structures of Accountable Care Organizations (ACOs) and Patient-Centered Medical Homes (PCMHs).

I. Background and Rationale

ACOs and PCMHs are two of the many health care reforms contained in the Patient Protection and Affordable Coverage Act (PPACA). Both of these models for the delivery of patient care are relatively new to the realm of health policy. These models appear to present a novel opportunity to improve patient care, control patient health care costs, and improve the patient care experience for Medicare and Medicaid beneficiaries. However, some experts have raised anti-competitive concerns, particularly with ACOs, noting “if ACOs foster more market concentration among providers, they have the potential to shift costs onto private insurers.”^{1, 2}

To assess the ability of ACOs to provide cost savings and improve care, the Secretary of Health and Human Services plans, through the Centers for Medicare and Medicaid Services, to implement the ACO program as a pilot program rather than propose a more wide reaching program.³ PCMHs will be utilized in demonstration projects.

The ASCP believes that to improve cost savings, quality of care, and the patient care experience these patient care delivery models should fully utilize and incorporate into their administrative structure pathologists and advanced certified laboratory professionals to identify inappropriate, unnecessary, and/or duplicative testing. These efforts should be recognized by ACOs and PCMHs when allocating shared savings and/or other financial incentives/benefits. To improve and document quality, these models should utilize nationally-recognized quality measures—but should not penalize physician specialties when adequate specialty-specific metrics are absent—and should allow ACOs and PCMHs to use or develop other quality indicators to reflect the quality of services provided. Moreover, Medicare laws

should be strengthened to prevent physician self referral and other schemes that result in the overutilization of physician-provided medical services.

II. Accountable Care Organizations

A. Overview

Broadly defined, an ACO is “an organization of health care providers that agrees to be accountable for the quality, cost, and overall care of Medicare beneficiaries who are enrolled in the traditional fee-for-service program who are assigned to it.”⁴ The ACO is a relatively new patient care models that has been established within Medicare as part of PPACA’s provisions concerning the Medicare Shared Savings program (See PPACA Section 3022, 2703). Initially, federally recognized ACOs will be used to serve the Medicare population; however, these models are currently being expanded beyond the Medicare populations by private payers.

Policymakers anticipate that ACOs will hold providers accountable not just for the volume and intensity of the service they provide but the quality of care provided as well. As the Medicare Payment Advisory Commission noted in its comment letter to CMS administrator Dr. Donald Berwick, “a shared savings program for ACOs could present an opportunity to correct some of the undesirable incentives inherent in fee-for-service payment and reward providers who are doing their part to control costs and improve quality.”⁵ To accomplish this, ACOs meeting “quality performance standards for shared savings” will be empowered to offer financial incentives to physicians and hospitals to provide quality care while keeping costs down.^{6,7} PPACA requires CMS to implement the ACO option by January 1, 2012.⁸

When compared to other payment reforms, such as PCMHs, bundled payments, etc., ACOs are viewed by policy analysts as preferable in terms of overall strengths and weakness. From the perspective of general strengths and weaknesses, ACOs hold providers accountable for per-capita costs and they don’t require the “lock-in” of patients.⁹ ACOs are also reinforced by other reforms designed to encourage coordinated, lower-cost care.

B. Types of ACOs

PPACA provides for ACOs to utilize a wide assortment of care delivery mechanisms. The statute allows for integrated delivery systems, multispecialty group practices, physician hospital organizations, independent practice associations, physician (and other professionals) group practices, physician (and other professionals) practice networks, partnerships or joint venture arrangements between hospitals and physicians/professionals, hospitals employing physicians and other professionals, and other entities specified by HHS to serve as ACO’s.¹⁰

As currently envisioned, no single organization model is expected to dominate the ACO market nationwide. At the regional or local level, however, such factors as existing practice patterns and population needs are expected to dictate the predominant organizational model. In some locals, the ACO market may be dominated by physician practice-based ACOs while in other areas, hospital-based ACOs may dominate.

C. ACO Cost/Payment Arrangements

The Medicare ACO model is expected to provide a gain-sharing bonus incentive and Fee-for Service (FFS) payments. The gain-sharing bonus is provided when the ACO or responsible provider meets pre-determined clinical performance and per capita FFS cost projections. It is expected—though not likely at the beginning stages of this health care reform—that gain sharing might hold the ACO partly responsible for a portion of cost increases if costs exceed a specific target. The possibility of a “bonus-only” model during the initial stage of the ACO option prompted the Medicare Payment Advisory Commission (MedPAC) to urge CMS to utilize a “two-sided” risk model that would also hold providers accountable if their costs exceed a predetermined amount.¹¹ MedPAC noted that the “bonus-only” model provides an incentive for volume-increasing behavior, whereas a “two-sided” risk model would minimize the incentive for volume increasing behavior that may be brought about by such practices as self referral. A “two-sided” risk approach might make waivers of federal anti-markup or physician self referral laws less problematic. That said, some experts have expressed concern that the two-sided risk” model could undermine interest in establishing ACOs.

Assuming that CMS opts for gain-sharing when it implements the ACO option, it must consider how much of the financial savings it should provide to ACOs that meet their performance targets. As one commentator suggested: “The lessons from early pay-for-performance initiatives show how rewards must be high to provide a strong business case for transformation and overcome the inertia of fee-for-volume. Therefore, in setting the threshold trigger and proportion for shared savings, CMS should ensure a substantial portion of Medicare's savings is given directly to ACOs.”¹² Consequently, the proportion of shared savings provided by CMS to ACOs is likely to have a considerable impact on the ability of the ACO option to match policymakers’ hopes that these new care delivery models can control costs, improve quality and enhance the patient care experience.¹³

As previously mentioned, in addition to gain-sharing CMS is expected to maintain the fee-for-service (FFS) compensation structure to reimburse providers for care provided. As an alternative to FFS, CMS (and other payers) could utilize a partial capitation arrangement. This would be similar to Medicare Part D, where the prescription drug plans receive a flat rate per person, but then also utilize “risk corridors,” which limit a prescription drug plan’s potential losses if the plan happens to encounter higher utilization and costs than anticipated.¹⁴ Policy analysts note that partial capitation, which incorporates both fee-for-service and prospective fixed payments, provides “upfront” payments that can help improve infrastructure and process, but does not provide for full accountability. It provides accountability for services and providers only.

Another possible compensation model is the case-based payment model, which would operate much like the Medicare Prospective Payment System for hospitals, which bundles medical procedures in a case-based payment structure.¹⁵ Bundled payments are believed to enhance efficiency and care coordination within a patient episode; however bundling does not provide accountability for total per-capita cost. Another compensation model that could be used is the capitation model. This may only work for ACOs of sufficient size and for a set group of patients. Capitation would likely involve more risk for the ACO, which would likely decrease interest in the ACO pilot program.

D. ACOs and Quality Measures

One of the hallmarks of ACOs will be the utilization of metrics to demonstrate the quality and cost of care provided. Physicians and hospitals will need to meet certain benchmarks, such as low mortality rates or reduced hospitalizations, to receive shared savings. As CMS has noted, ACOs will need to “report the necessary data [for the agency] to evaluate quality and cost measures.”¹⁶ CMS would probably do this by

incorporating the quality measures and requirements of other programs, such as the Physician Quality Reporting Initiative (PQRI), Electronic Prescribing (eRx), and Electronic Health Records (EHR).

As for the type of measures that will be required, CMS “will include measures in such categories as clinical processes and outcomes of care, patient experience, and utilization (amounts and rates) of services.”¹⁷ In terms of assessing ACO quality of care, CMS will “seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both.”¹⁸

One potential issue is that the metrics embraced by CMS to create ACOs may reflect *only* those quality indicators found in the programs identified in the statute, such as the Electronic Health Records (EHR) Incentive Grant Program (meaningful use) final rule. Should an approach may prove troubling for some medical specialties, however. Participating in the EHR Incentive Program appears difficult, if not impossible, for a number of medical specialties, such as pathology and radiology.^{19, 20}

MedPAC suggested additional metrics would be needed when it wrote to CMS arguing that it did not think that “all important aspects of ACO performance can be assessed with available metrics.”²¹ Failure to allow for additional measures that can capture the value added by pathology and laboratory medicine, for example, to control costs, improve care, and enhance the patient experience by curtailing unnecessary, duplicative or inappropriate laboratory tests and procedures would undermine the agency’s ability to fully realize the potential of the ACO option as well as hurt the ability of pathology and laboratory medicine to participate in ACO gain sharing.

E. Minimum Requirements for ACO Medicare Participation

Though the final regulations for the ACO program won’t be known till late 2011, there are a few minimum requirements that are known: ACOs will have to have a patient base of at least 5,000 Medicare Fee-for-Service patients; providers participating in the program must commit to accepting responsibility for overall patient care and quality for at least three years; and the ACO must have sufficient numbers of primary care physicians to serve the patient population.

Additionally, ACOs must also satisfy the following requirements:

- “have a formal legal structure that would allow the organization to receive and distribute payments for shared savings.
- include primary care ACO professionals that are sufficient for the number of Medicare fee-for-service beneficiaries assigned to the ACO.
- have in place a leadership and management structure that includes clinical and administrative systems.
- define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care, such as through the use of telehealth, remote patient monitoring, and other such enabling technologies.
- demonstrate that it meets patient-centeredness criteria specified by the Secretary, such as the use of patient and caregiver assessments or the use of individualized care plans.”²²

It remains to be seen in the final rule what other requirements will be imposed on ACOs.

F. ACO Performance: What Does the Evidence Tell Us?

While ACOs are fairly new, there have been several demonstration projects of this model, and the results of these projects have been largely positive from a cost savings and overall patient experience perspective. For example, Boeing recently concluded a pilot of the ACO model in Seattle involving 740 individuals considered “medically complex” because they had on average four different medical conditions. The pilot resulted in a “20 percent net savings in medical costs among patients in the medical home. The project also led to increased employee and physician satisfaction rates, and it reduced the number of days employees missed because of illnesses.”²³ In addition, the California Public Employees' Retirement System (CalPERS) launched a pilot program in early 2010, which reported some results several months into the program. CalPERS reported that its program, which involves 41,000 individuals, had faced some challenges with interoperability between three different health IT systems, but had improved quality while reducing costs, enhanced communication and cooperation, and is expected to produce \$10 million in savings by the end of 2010.²⁴

Additionally, the Brookings-Dartmouth ACO collaborative is currently operating 5 private sector ACOs in Arizona, California, Kentucky and Virginia; however, it has not announced any results at this point. The Congressional Budget Office has estimated that the Medicare ACO initiative will save \$5 billion during its first eight years.”²⁵

II. The Patient Centered Medical Home

PCMHs—a recent reinvention of the decades-old medical home—have received increased attention over the last few years (See PPACA Sections 3021, 3502, 5301, 5405, 10333). The PCMH “is a health care setting that facilitates partnerships between individual patients, and their personal physicians, and when appropriate, the patient’s family.”²⁶ The model “utilizes a multi-disciplinary “home” for each patient; evidence-based medicine; clinical decision support tools; advanced management techniques such as electronic medical records, quantitative indicators of quality, easy patient access, and prevention; and care coordination.”²⁷

Advocates of the medical home model, like advocates of the ACO option, contend that the model should reduce preventable hospitalizations, hospital readmissions, and emergency room visits while, at the same time, improving health outcomes and reducing the cost of health care services.^{28, 29}

PCMHs and ACOs share a number of similarities. Both, though employing different tactics to do so, consolidate multiple levels of care for patients and are not intended to operate purely within the FFS payment system. One notable area where they differ is that in the PCMH the patient maintains an ongoing relationship with a primary care physician who leads the patient’s healthcare team. This primary care physician is tasked with coordinating the patient’s healthcare needs with other specialists, hospitals, etc. There is no central coordinator in the ACO option. Instead the ACO involves the network of providers working together for the benefit of the patient. Additionally, the PCMH model does not typically involve a fee-for service model. Rather it utilizes “comprehensive payment for services that [extend] beyond the face-to-face visit with the personal physician...”³⁰

That said, the lines may soon be blurring. During a recent Medicare Payment Advisory Commission (MedPAC) meeting, one Commissioner commented that he couldn’t see “how a straight ACO without something that keeps people together [like a medical home] is going to work.”³¹ In other words, he expects that ultimately the Shared Savings (ACO) program will require some sort of ACO/medical home hybrid.

CMS plans as part of PPACA to conduct a number of demonstration projects to advance the PCMH model. The entity within CMS handling these tasks will be the newly created Center for Medicare and

Medicaid Innovation. In fact, on the very date the Center was launched in November 2010, it announced as one of its first projects the Multi-Payer Advanced Primary Care Practice Demonstration, which is anticipated to include up to 1,200 PCMHs serving as many as one million Medicare beneficiaries.³² More than 22 states are already conducting medical home pilot projects.³³

One recent study, by Reid *et al.* (2010), found that “within the Group Health system in Seattle that a medical home demonstration was associated with 29% fewer emergency visits, 6% fewer hospitalizations, and total savings of \$10.30 per patient per month over a twenty-one month period.”^{34, 35} The results of the one year project also experienced 11 percent fewer hospitalizations that primary care could prevent. Reid stated that “the findings are important because they provide proof-of-concept that investments in the medical home can achieve relatively rapid returns across a range of key outcomes.”³⁶

Another PCMH project involving Community Care of North Carolina reportedly saved the state between \$77 and \$85 million in 2005 and between \$154 and \$170 million in 2006. Additionally, Boeing conducted a pilot of the model that found that the model “reduced emergency room visits and hospital admissions among Boeing employees. This led, in turn, to a 20 percent net savings in medical costs among patients in the medical home. The project also led to increased employee and physician satisfaction rates, and it reduced the number of days employees missed because of illnesses...”³⁷ The Commonwealth Fund projects that savings of \$194 billion could be saved over a ten year period by assigning Medicare beneficiaries to medical homes.

Also, data from several PCMH demonstrations have also shown that the projects can be financially beneficial to physician practices. One example is provided by the Chronic Care Initiative, a collection of medical homes serving southeast Pennsylvania financed by Medicaid and three private payers, resulted in an additional \$85,500 per participating physician.

III. Role of Pathologists in ACOs and PCMHs

The ACO and the medical home are generally viewed as emphasizing the role of primary care physicians. That said, both of these reforms present opportunities for certain specialists to become leaders in the quest to improve care, reduce cost, and improve accountability. Given the importance of laboratory results to patient diagnosis and treatment, pathology could assume a key role in ACOs and PCMHs.³⁸ Though under these models laboratory information is expected to have increased importance, “it is not clear that the benefits of either readily accessible lab information or closer collaboration between pathologists and primary care physicians is readily understood. Consequently, pathology is in the difficult position of having to demonstrate its relevance and importance to these health care models. This is particularly challenging in light of the fact that the current fee-for-service payment structure does not recognize the value of pathologist collaboration the primary care physicians or “the collection and management of population-specific data by the pathologist.”³⁹

Pathology’s ability to serve a central role in these patient care delivery models is linked to “the importance of laboratory data in the diagnosis and treatment of disease and the ability of pathologists to serve as partner physicians to primary care doctors...”⁴⁰ Pathology services and clinical laboratory testing plays an indispensable role in the delivery of quality health care, providing physicians, nurses, and other health care providers with objective information needed to prevent, diagnose, treat, and manage disease.

Pathology helps in identifying risk for developing disease, detecting disease early, planning disease management strategies, selecting safe and effective treatments, monitoring treatment response, pinpointing threats to patient safety and public health, protecting the blood supply and transplant

recipients from harmful pathogens, and testing for drugs of abuse to support clinical care and ensure public safety.⁴¹ It is estimated that laboratory data has an impact on over 70 percent of medical decisions, yet spending on laboratory services accounts for only 2.3 percent of U.S. health care expenditures and 2 percent of Medicare expenditures.^{42, 43} These functions, when properly coordinated, can lower the cost of patient care substantially.

Another factor that could help pathology assume a central role within ACOs and PCMHs is the increasing importance and functionality of health information technology and electronic health records. For ACOs and PCMHs to be effective coordinators of care, they need the structural capability and systems necessary to carry out these tasks.⁴⁴ This requires the assistance of informatics systems. Given the robust state of laboratory informatics, the increasing importance of laboratory data to coordinated care and the fact that the bulk the patient's EHR is expected to be laboratory data, pathology is well positioned to advocate for a central role in ACOs and PCMHs.

Other factors that lend support to the argument that pathology should have a central role in the administrative and clinical structure of ACOs and PCMHs is the role of the Chronic Care , a model which encourages patient self-management,⁴⁵ in these care delivery models and the rise of molecular testing and personalized medicine.⁴⁶

Ronald L. Weiss noted during a 2010 ASCP panel discussion on pathology's future, that pathology "must educate health care providers on effective utilization of our complex and costly resources, including the importance of pathologist-directed consultation and comparative effectiveness research."⁴⁷ One way the value of pathology could be demonstrated may be to help integrate "clinical testing into decision support systems in electronic medical record systems. Showing a reduction in duplicate testing would demonstrate value and increase physician satisfaction."⁴⁸

IV. Legal Impediments

There are a host of potential legal issues surrounding the establishment and operation of ACOs, and to a lesser extent PCMHs.^{49, 50, 51} At the federal level, the gain sharing and provider alignment may conflict with federal anti-trust, anti-kickback, physician self-referral (Stark), and Civil Monetary Penalties laws. At the state level, these entities may conflict with State Corporate Practice, Self-Referral, and anti-trust laws. With regard to federal law, the Secretary of Health and Human Services has the authority to, and likely will, waive applicable federal laws for qualified ACOs. Indeed, HHS will have to find an appropriate balance in waiving these requirements so as "not to create unintended loopholes."⁵² In addition, the Federal Trade Commission will have to determine how ACO and PCMH arrangements can be structured to avoid Anti-Trust prohibitions.⁵³

The application of these laws to the structure, operations and arrangements of ACOs is complex and beyond the scope of this policy statement. Individuals interested in a thorough discussion of the application of these laws to ACOs may wish to review the Accountable Care Organization Toolkit, produced jointly by the Brookings-Dartmouth ACO Learning Network.⁵⁴ For ASCP detailed concerns about self referral and other inappropriate arrangements, see ASCP's policy statement on [Self Referral and related practices](#).

V. ASCP's Principles for ACOs/PCMHs

The ASCP outlines the following principles that are focused on the patient care models advanced by PPACA:

1. Principles Concerning Organizational Issues

- ASCP believes that ACOs and PCMHs should be physician-led, patient-centric organizations utilizing voluntary physician and patient participation.
- ASCP believes that only true multispecialty organizations, not administratively dominated by any singular physician specialty, that are able to treat the full continuum of patient care should be eligible for ACO and PCMHs designation under the Medicare program.
- Representatives of all physician specialties, including pathologists, should have representation in the administrative structure, policy development and decision-making processes of ACOs and PCMHs.
- ASCP believes that organizational relationships and relevant clinical and administrative processes within the ACO and PCMHs should be clearly defined and transparent, particularly with regard to reimbursement, quality management, and assessment delivery system performance review.
- ASCP believes that ACOs and PCMHs should strive to ensure administrative simplification for participating physicians.
- ASCP believes that when allocating shared savings or other bonus/incentive payments, ACOs and PCMHs should not only consider the efforts of physicians to provide direct patient care but also the role of physicians to reduce the overutilization of health care services. For example, pathologists working in either a consultative, organizational leadership or other capacity to reduce the use of unnecessary pathology or laboratory testing should be eligible for shared savings.

2. Principles Concerning Quality/Performance Measures

- ASCP believes that quality measures are important to ensuring quality patient care. To ensure quality, ACOs and PCMHs should rely on appropriate, nationally recognized quality measures where available.
- In cases where appropriate, nationally recognized, specialty-specific quality measures are absent, this should not adversely affect or penalize individual physicians or specialty group practices, either in terms of documenting quality or participating in shared savings.
- ACOs and PCMHs should be allowed to utilize alternative metrics to demonstrate progress towards improving quality, such as efforts to reduction in the overutilization or duplication of services.

3. Principles Concerning Systems Issues

- ASCP believes that the widespread adoption of health information technologies is imperative to the success of ACOs and PCMHs and that if these entities provide incentives to participating physicians and physician practices for investments in these systems that incentives should be based on the actual costs of purchasing EHR systems and for their costs of making these systems or their modules accessible to other physicians or care providers.

4. Principles Concerning Waivers of Federal Law

- ASCP believes that any relief provided from federal and state anti-trust, physician self referral laws, anti-kickback statutes, etc., should be limited to ACOs or PCMHs that are true multi-specialty organization able to provide the full continuum of patient care.

- ASCP believes that CMS should ultimately impose a “two-sided” risk model to minimize the incentive for volume increasing behavior that may be brought about by such practices as self referral.

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