DEPAUL UNIVERSITY

DePaul Journal of Health Care Law

Volume 14 Issue 2 *Spring 2012*

Article 5

October 2015

Accountable Care Organizations: A Response to Critical Voices

Wasif Ali Khan

Follow this and additional works at: https://via.library.depaul.edu/jhcl

Recommended Citation

Wasif A. Khan, *Accountable Care Organizations: A Response to Critical Voices*, 14 DePaul J. Health Care L. 309 (2012) Available at: https://via.library.depaul.edu/jhcl/vol14/iss2/5

This Article is brought to you for free and open access by the College of Law at Via Sapientiae. It has been accepted for inclusion in DePaul Journal of Health Care Law by an authorized editor of Via Sapientiae. For more information, please contact digitalservices@depaul.edu.

ACCOUNTABLE CARE ORGANIZATIONS: A RESPONSE TO CRITICAL VOICES

Wasif Ali Khan, Esq.*

ABSTRACT

The Patient Protection and Affordable Care Act creates the Shared Savings Program aimed at promoting accountability for a patient population, coordinating items under Medicare Part A and B, and encouraging investment in infrastructure and redesigned care processes.¹ The Shared Savings Program will give Accountable Care Organizations (ACOs) a share in any savings generated by incentivizing the reduction of healthcare costs associated with inefficiencies in and the ineffectiveness of the current healthcare delivery system. ACOs are expected to generate significant savings by requiring compliance with quality measures and healthcare infrastructure development.

This article advocates the speedy acceptance of ACOs as an innovative, profitable model of reducing healthcare costs. Section 1 provides background information on ACOs and the Shared Savings Program by discussing what an ACO is, what the Shared Savings Program is, and what the Center for Medicare and Medicaid Services (CMS) expects from an ACO. In Section 2, the paper highlights some of the criticisms directed at ACOs, and responds to those criticisms in Section 3. Finally, this paper reaches the conclusion that despite the criticisms, the Shared Savings Program and CMS-sanctioned ACOs can be a success, and urges providers who are considering joining an ACO to stop wasting time.

I would like to thank Professor Freeman Farrow, a mentor for whom I have an immeasurable amount of respect, for his incredible support while I wrote this article. In addition, I would like to thank Fatema Zanzi, Christopher Anderson and Feroze Khan for conversations that spurred some of the ideas present in this article. Finally, I would like to thank my wife, Nada Gomaa, for being incredibly patient with me during this process.

^{1.} Pub. L. 111-148; See Also, 42 U.S.C.A. 1395jjj (2011).

SECTION 1: BACKGROUND INFORMATION

What is an Accountable Care Organization?

ACOs are talked about frequently these days. Many commentators argue that they will (and should) be the new model for healthcare service delivery, while others suggest that they are not a viable model for the societal structure in America.² While the arguments on each side are compelling and very interesting, they are little more than passionate rhetoric and catchy phrases unless we know what an ACO is, and what is its intent. So, what is an ACO? In the early 1970s Dr. Elliot Fisher from Dartmouth Medical School led the Dartmouth Atlas Project.³ The Dartmouth Atlas project thoroughly researched and documented variations in medical care across the United States.⁴ The project's findings indicated that there was a wide variation in healthcare costs across the United States, and more importantly, that higher spending per patient does not equate to better outcomes for patients.⁵ In an effort to explain the anomaly, Dr. Fisher coined the term Accountable Care Organization to reflect an organization, virtual or otherwise, that provided accountability across the medical care spectrum.⁶ Given its design, it comes as no surprise that this new model has become an integral part of the future of American healthcare reform.

Ideally, an ACO is a healthcare delivery and cost-control model aimed at combining provider payment and delivery system reforms to deliver cost-effective care.⁷ Whereas prior healthcare reform measures have been sidetracked and derailed by the "chicken or the egg" conundrum,⁸—there was a general disagreement on whether the provider payment system or the delivery system should be addressed before the other⁹—an ACO avoids it altogether. The ACO model, by combining the two reforms, attempts to eradicate the "chicken or the egg" problem. Harold Miller, president and CEO for the Network for Regional

^{2.} See discussion infra Section Two.

^{3.} Jordan T. Cohen, A Guide to Accountable Care Organizations and Their Role in the Senate's Health Reform Bill, (March 11, 2010), http://www.healthreformwatch.com/2010/03/11/a-guide-to-accountable-care-organizations-and-their-role-in-the-senates-health-reform-bill/.

^{4.} Id.

^{5.} Id.

^{6.} Id.

^{7.} Kelly Devers & Robert Berenson, Can Accountable Care Organizations Improve the Value of Health Care by Solving the Cost and Quality Quandaries?, Urban Institute at 1 (2009), http://www.urban.org/UploadedPDF/411975_acountable_care_orgs.pdf.

^{8.} Id.

^{9.} Id.

Healthcare Improvement, describes an ACO best by equating it to buying a TV.¹⁰ He invokes the example of Sony, which combines the multiple component parts of a TV to sell individuals a whole TV.¹¹ Similarly, he states that an ACO combines the component parts of medical care (including primary care, specialists, hospitals, and home healthcare) to give people a complete "TV" rather than individual parts. Currently, we are accustomed to seeking out the component parts ourselves.¹²

Ultimately, an ACO is a network of doctors and healthcare providers from across the medical spectrum that share responsibility for efficiently providing quality medical care to patients.¹³ ACO proponents have identified the following three characteristics as essential elements of an ACO: (1) the ability to provide, and mange with patients, the continuum of care across different institutional settings, including ambulatory and inpatient hospital care, and possibly post acute care; (2) the capability of prospectively planning budgets and resource needs; and (3) sufficient size to support comprehensive, valid, and reliable performance measurement.¹⁴ The multiple industry definitions of an ACO are closely aligned with the government's expectations of a Center for Medicare and Medicaid Services ("CMS")-sanctioned ACO. CMS expects an ACO to be a legal entity that is recognized and authorized under state, federal, or tribal law and comprised of an eligible group of ACO participants¹⁵ that work together to manage and coordinate care for Medicare fee-for-service beneficiaries.

What are the Goals of an ACO?

The ultimate goal of having the ACO model is to provide quality medical care efficiently and effectively.¹⁶ This goal is accomplished "by focusing on the needs of patients and linking payment rewards to outcomes."¹⁷ As highlighted by the Patient Protection and Affordable Care

^{10.} Jenny Gold, Accountable Care Organizations, Explained, (January 18, 2011) http://www.kaiserhealthnews.org/stories/2011/january/13/aco-accountable-care-organization-faq.aspx.

^{11.} *Id*.

^{12.} *Id*.

^{13.} Cohen, supra note 2.

^{14.} Id. See also, Gold, supra note 10.

^{15. 76} Fed. Reg. 67,802, 67,973 (Nov. 2, 2011) (to be codified at 42 CFR §425.20).

^{16.} Healthcare.gov., Accountable Care Organizations: Improving Care Coordination for People with Medicare (March 31, 2011), http://www.healthcare.gov/news/factsheets/2011/03/accountablecare03312011a.html (last updated November 16, 2011).

^{17.} U.S. Department of Health and Human Services, Affordable Care Act to Improve Quality of Care for People with Medicare, HHS Press Release (March 31, 2011),

Act ("PPACA"), the CMS-sanctioned ACO must, in regards to quality improvement, include provisions to increase value-based purchasing.¹⁸ Value-based purchasing requires linking provider payment directly with quality of care by rewarding providers for delivering high-quality efficient clinical care.¹⁹ Accordingly, one of the main goals or purposes of the Shared Savings Program is to reduce healthcare costs by placing a focused emphasis on reducing excess expenditures and applying cost-saving redesigned care processes all while maintaining the quality of care.²⁰

Who Can Participate in an ACO in the Shared Savings Program?

CMS enumerated a list of individuals in the proposed rules that it sees as playing a critical role in establishing the ACO as a viable model for achieving efficiency in healthcare services delivery.²¹The list includes: (1) professionals in group practice arrangements, (2) partnerships or joint ventures between hospitals and "ACO Professionals,"²² (3) hospitals employing "ACO Professionals," and (4) other groups of providers of services and suppliers as the Health and Human Services (HHS) secretary ("Secretary") sees fit.²³ Other providers such as Federally Qualified Health Centers (FQHCs), Rural Health Centers (RHCs), Critical Access Hospitals (CAHs), long-term care hospitals, Skilled Nursing Facilities (SNFs), and nursing homes are included in the final rule as eligible participants.²⁴ However, the Secretary has the discretion to narrow or expand the list of eligible providers.²⁵

Specifically, for FQHCs and RHCs, the government lacked the specific data (service codes, physician, specialty, specific attribution of services to a rendering healthcare professional) to assign beneficiaries or determine the expenditures during the three-year benchmark period.²⁶ CMS requires FQHCs and RHCs participating in an ACO to identify

http://www.hhs.gov/news/press/2011pres/03/20110331a.html.

^{18. 76} Fed. Reg. 19528, 19530 (April 7, 2011).

^{19.} Id.

^{20.} HHS Press Release, supra note 17.

^{21. 42} CFR § 425.102 (2011).

^{22. 76} Fed. Reg. 67,802, 67,973 (Nov. 2, 2011) (to be codified at 42 CFR §425.20) (defining "ACO Professionals" as physicians, physician assistants, nurse practitioners, or clinical nurses).

^{23. 42} CFR § 425.102 (2011).

^{24.} *Id. See also* 76 Fed. Reg. 19538 (April 7, 2011) (Although, they were not specifically designated as eligible providers under the proposed rules because their unique claims billing systems, payment methodologies, and data-reporting requirements are not compatible with the Shared Savings Program's requirements and would pose additional challenges to the ACO model).

^{25. 76} Fed. Reg. 19538 (April 7, 2011).

^{26.} Id.

physicians who provide primary care services.²⁷ CAHs that adjust their billing methods to bill for both the facility and the professional service will also be eligible to participate according to the final rules.²⁸

How Does a CMS-Sanctioned ACO Function?

Industry experts understand an ACO to be a legal organization capable of receiving shared savings and disbursing those savings to its members.²⁹ CMS envisions a similar structure for ACOs.³⁰ After soliciting comments in the November 17, 2010 Federal Register, CMS proposed a two-track hybrid model that combines cost-savings with loss allocation.³¹ The final rules as established by CMSndicate that sanctioned ACOs will have the opportunity to participate in cost-saving measures by voluntarily electing one of two models for the initial mandatory three-year agreement.³² Track One is a model best suited for ACOs that are not yet able to share in the risks.³³ Under Track One, ACOs would not be responsible for any portion of the losses above the benchmark.³⁴

Under Track 2, ACOs that are ready to share in the losses with greater opportunity for reward can elect to immediately enter the twosided risk-sharing arrangement.³⁵ Participants in Track Two are eligible for higher sharing rates than those in the one-sided model.³⁶

Governance and Operational Requirements of an ACO

The Shared Savings Program recognizes that a change in the American healthcare system is not achieved simply by "fixing" physicians. The change to quality-driven healthcare that the Shared Savings Program emphasizes requires an institution-wide change. Consequently, the Shared Savings Program imposes strict governance and operational requirements on ACOs.³⁷ Eligible ACOs must have a governing body that can be held

^{27. 42} CFR § 425.404.

^{28. 42} CFR § 425.102. This would require CAHs to bill according to method II as mentioned in 42 CFR 413.70(b)(3).

^{29.} Fisher, et al., Fostering Accountable Healthcare: Moving Forward in Medicine, 28 HEALTH AFF. 219, 219-220 (2009).

^{30. 42} CFR § 425.104.

^{31. 76} Fed. Reg. 19603 (April 7, 2011).

^{32. 42} CFR § 425.600(a)(1)-(2).

^{33. 76} Fed. Reg. 19603 (April 7, 2011).

^{34.} Compare 76 Fed. Reg, 19603 (April 7, 2011) and 42 CFR § 425.604 (The final regulations do not contain loss calculation method for Track 1 ACOs).

^{35. 76} Fed. Reg. 19603 (April 7, 2011).

^{36.} Id.

^{37. 42} CFR § 425.106.

accountable for implementing specific processes aimed at improving the quality of medical care, such as promoting evidence-based medicine, reporting on quality and cost measures, and coordinating care amongst ACO members.³⁸ Aside from maintaining responsibility for oversight and strategic planning,³⁹ an ACO governing body must have a fiduciary duty to the ACO,⁴⁰ must provide for meaningful representation and participation of ACO members,⁴¹ and must be free of conflicts of interest.⁴²

Appropriate ACO management structures will align administrative and clinical systems to promote better individual and population healthcare and lower growth in healthcare expenditures.⁴³ The clinical aspect of the ACO must be managed by a state-licensed physician that is a participant within that ACO and who is physically present at an ACO office or clinical location on a regular basis.⁴⁴ In addition to requiring the clinical director/manager to be an active participant to the ACO, the Shared Savings Program requires each participating doctor to commit to the ACO.⁴⁵ Individual ACO providers/suppliers can show commitment by providing a sufficient amount of financial or human investment to ensure they remain motivated ACO participants.⁴⁶ Commitment can also be shown by agreeing to abide by mandatory ACO processes and being held accountable for meeting the ACO's performance standards for these processes.⁴⁷ Mandatory ACO processes include processes that promote evidence-based medicine,⁴⁸ promote patient-engagement,⁴⁹ develop an internal quality and cost reporting mechanism that allows for feedback and evaluation of ACO participants,⁵⁰ and coordinate care among ACO participants.51

Allocation of Savings/Losses

The main crux of the ACO Shared Savings Program is providing an

Id.
 Id. at 106(b).
 Id. at 106(b)(3).
 Id. at 106(c).
 42 CFR § 106(d).
 42 CFR § 106(d).
 42 CFR § 425.108(a).
 Id. at 108(c).
 Id. at 108(d).
 Id. at 108(d)(1).
 Id. at § 425.108(d)(2).
 42 C.F.R. § 425.112(b)(1).
 Id. at §425.112(b)(2).
 Id. at §425.112(b)(3).
 Id. at §425.112(b)(4).

incentive to participate in cost savings achieved by reducing expenditures. ACOs will be eligible to receive a portion of shared savings only if the estimate average per capita expenditures for Medicare Part A and B services for beneficiaries is a certain percentage below a benchmark established by the Secretary.⁵² The percentage amount, called the "minimum savings rate," will take into account the number of fee-forservice Medicare beneficiaries in the ACO.⁵³ CMS will determine the Minimum Savings Rate for a Track One ACO using a sliding scale based on the number of beneficiaries it serves.⁵⁴ For a Track Two ACO, the Minimum Savings Rate will be two percent.⁵⁵ The benchmark will be updated each year of the agreement period based on the flat dollar equivalent of the projected annual growth in national expenditures for Medicare Part A and Part B expenditures.⁵⁶ If a Track One ACO meets the quality performance standards set by the Secretary, it can recover up to fifty percent of all savings under the benchmark.⁵⁷ This sharing rate is subject to a cap, which places a limit on the total amount of shared savings payable to an ACO. The cap for a Track One ACO will be ten percent of its individual benchmark.⁵⁸ A Track Two ACO can recover up to sixty percent of savings generated, with a cap of recovering no more than fifteen percent of its total benchmark.⁵⁹ Similarly, costs incurred above and beyond the benchmark are considered losses, and will be allocated to similar percentage figures.⁶⁰

Performance and Quality Measures Under the Shared Savings Program

Section 1899(b)(3)(A) of PPACA requires the Secretary to determine appropriate measures to assess quality performance of an ACO. In keeping with this duty, CMS' proposed rules on the Shared Savings Program listed sixty-five measures to establish quality standards that must be met in order to qualify for shared savings for the first performance period.⁶¹ Under the proposed rules, quality measures for subsequent

^{52. 42} C.F.R. § 425.602.
53. Id.
54. 42 C.F.R. § 425.604(b).
55. Id. at § 425.606(b).
56. Id. at § 425.602.
57. Id. at § 425.604(d).
58. Id.
59. 42 C.F.R.§ 425.606.
60. Id.
61. 76 Fed. Reg. 67802-01, 67871 (November 2, 2011).

performance measures would have been released in future rulemaking.62 Many commenters suggested that CMS adopt a lower number of performance measures that are aligned with the goals of the Shared Savings Program.⁶³ In the final rules, CMS reduced the number of quality measures from sixty-five to thirty-three measures across four domains.⁶⁴ Patient/Caregiver domains Experience, The four are: Care Safety. Preventative Health. and At-Risk Coordination/Patient Populations.⁶⁵ ACOs will submit data to support their success in these quality measures through one of four ways: (1) patient surveys; (2) claims filed with CMS; (3) Electronic Health Record (EHR) Incentive Program Reporting; and (4) the Group Practice Reporting Option (GPRO) web interface.⁶⁶ The final rule is modified to score only reports of data in these measures for the first year (pay for reporting), and will phase in performance during years two and three (pay for performance).⁶⁷ The GPRO interface is an option in the Physician Quality Reporting System (PORS), and provides an incentive to group practices for reporting on performance measures under the PORS initiative.⁶⁸ The PORS initiative provides physicians who service Medicare beneficiaries with an incentive payment if they properly report on certain quality measures for certain covered services.69

ACO Models Under the CMS Shared Savings Program

Under CMS' proposed rules, an ACO can exist in a number of forms. Research indicates that there are at least five different viable models for an ACO to be in compliance with CMS.⁷⁰ The provision of quality medical care for serious illness requires coordinated longitudinal care and the engagement of multiple professionals across multiple institutional settings.⁷¹ The most serious gaps in the efficient provision of quality

^{62.} Id.

^{63.} *Id.* 64. *Id.* at 67889.

^{65.} *Id.* at 67889-90.

^{05.} *1a*. at 0/889-90.

^{66. 76} Fed. Reg. 67889-90 (November 2, 2011).

^{67.} Id. at 67891.

^{68.} Group Practice Reporting Option, CENTERS FOR MEDICARE & MEDICAID SERVICES, https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-

Instruments/PQRS/Group_Practice_Reporting_Option.html (last modified November 21, 2011).

^{69.} Physician Quality Reporting System, CENTERS FOR MEDICARE & MEDICAID SERVICES, https://www.cms.gov/PQRS/ (last modified October 17, 2011).

^{70.} Stephen M. Shortell & Lawrence P. Casalino, Accountable Care Systems for Comprehensive Health Care Reform, (March, 2007), at 9, available at http://www.fresh-thinking.org/docs/workshop_070301/ShortellCasalinoDeliverySystemModelsRevise9.pdf.

^{71.} Elliot S. Fisher, Creating Accountable Care Organizations: The Extended Hospital Medical Staff, 26

healthcare are a result of poor coordination and faulty transition.⁷² A recent Institute of Medicine report noticed the flawed coordination and transition of healthcare between providers, and called for efforts to foster shared accountability for quality and cost of care among providers.⁷³ While this call for a higher standard in healthcare delivery is attractive in theory, practical challenges exist in identifying the appropriate nexus for shared accountability and responsibility.⁷⁴

Model One - The Extended Medical Staff

The "Extended Medical Staff" model enforces accountability among hospital[s] and physicians that work in or around them.⁷⁵ This model takes into account the notion that all physicians are directly or indirectly affiliated with a local acute care hospital, whether through inpatient work or through care patterns of patients they serve.⁷⁶ An ACO under the Extended Medical Staff model would essentially be a hospital-associated, multispecialty group practice that is empirically defined by direct or indirect referral patterns to a hospital.⁷⁷ Under this model, patients and physicians would be assigned to a particular hospital[s].⁷⁸

Physicians who are inpatient providers are assigned to the hospital where they do most of their inpatient work.⁷⁹ Research indicates that approximately sixty-two percent of physicians perform inpatient work, and of those performing inpatient work, sixty percent work only at one hospital.⁸⁰ Of the physicians performing in-patient services at multiple locations, seventy-five percent of their work is at a primary hospital.⁸¹ Consequently, of those who do inpatient work, ninety percent or more of the work is done at the physician's primary hospital.⁸² For non-inpatient providers, the model would identify Medicare beneficiaries they served during the last three-year period, and assign those physicians to the hospital where the plurality of their Medicare patients were admitted.⁸³

HEALTH AFF., no.1 (2007) at w44, w45.

^{72.} Id.

^{73.} Id.

^{74.} Id

^{75.} Fisher, supra note 71 at w45.

^{76.} Id.

^{77.} Id.

^{78.} Id. at w46.

^{79.} Id. at w47.

^{80.} Fisher, supra note 71 at w47.

^{81.} *Id*.

^{82.} Id.

^{83.} Id. at w46.

Patients would be assigned to the physician, primary or specialty care, which provides the most amount of care in an ambulatory setting to that particular patient.⁸⁴ The patient would then be assigned to the hospital where their physician is assigned.⁸⁵ This method of assigning patients reflects research indicating that Medicare beneficiary care is highly concentrated within the defined "Extended Medical Staff."⁸⁶ Seventy-two percent of physician visits for evaluation and management services ("E&M services") and nearly sixty-four percent of admissions are done by physicians within the "Extended Medical Staff" and primary hospital.⁸⁷ If you consider the primary and secondary hospitals together, the percentage of E&M services rises to just over seventy-six percent and admission to nearly eighty-two percent.⁸⁸ The overall patterns reveal a high degree of care concentration, even in rural areas.⁸⁹

A review of the data shows that there is a significant difference between the best and worst performing "Extended Medical Staff."⁹⁰ The study used in Dr. Fisher's article divided hospitals and Extended Medical Staffs into five groups.⁹¹ The study showed that the top quartile, consisting of high-performance hospitals with risk-adjusted, one-year mortality rates, and risk-adjusted, one-year costs in the bottom quartile, provided better ambulatory care; and preventative screenings, such as mammography and diabetes screening, are done more consistently in highperformance hospitals.⁹² High-performing Extended Medical Staffs showed a lower use of institutional facilities and displayed fewer hospital discharges, skilled nursing facility discharges, and reimbursable institutional days.⁹³

This model has a number of advantages that make performance measurement much easier.⁹⁴ The FULL NAME (IOP) suggests that performance measurement should include both longitudinal care (including costs and health outcomes), *and* measurements that directly address the current fragmentation of care.⁹⁵ Aggregating performance

^{84.} Id.

^{85.} Fisher, supra note 71 at w46.

^{86.} Id. at w.48

^{87.} Id.

^{88.} *Id*.

^{89.} Id.

^{90.} Fisher, supra note 71 at w49.

^{91.} Id.

^{92.} Id.

^{93.} Id. (All of which indicate a lower institutional admittance rate).

^{94.} Id.

^{95.} Fisher, supra note 71 at 52.

measurements to the level of large physician groups, such as the "Extended Medical Staff," does exactly that.⁹⁶ Under this proposed model, we can get all the physicians assigned to an Extended Medical Staff and we can conduct performance measurements that will result in larger sample sizes and a broader scope of potential measures. These performance measurements could feasibly include all physicians that provide care to a population within the framework of measurements.⁹⁷ Additionally, focusing on the Extended Medical Staff will foster accountability for care by emphasizing capacity measures.⁹⁸ This model inherently makes the argument that higher healthcare spending is attributable to a greater use of discretionary supply sensitive services such as: visits, specialist consultations, tests, imaging, and the use of institutional, rather than outpatient, settings for care.⁹⁹ Physicians tend to adapt their practice to locally available resources, thus, local decisions that influence capacity-capital investments, physician recruitment, and choice about practice location-are the first links in the chain leading to an increase in the quantity of care provided and the overuse of supply sensitive services.¹⁰⁰ The use of performance measures on a large scale would bring this issue to light, and hopefully decisions to invest in care management, reduce acute care capacity, reduce unnecessary specialist recruitment, or to engage in effective management of post acute care would result in improved quality and lower costs.¹⁰¹ Finally, since most physicians remain in solo or small practices that lack the capital necessary to make large investments for implementation of better care management protocols and health information systems, a large ACO, such as the Extended Medical Staff, could make those investments.¹⁰²

As effective as this model may seem at providing the necessary largescale investments, performance data, and accountability, there are several issues that could limit its effectiveness.¹⁰³ Namely, the older model of capitated payments (define) has been replaced by fixed-price care.¹⁰⁴ With doctors getting a lower fee for their services, they tend to perform more services to offset their losses. The Extended Medical Staff model would

- 102. Id.
- 103. Id.
- 104. Id. at 54.

^{96.} Id.

^{97.} Id.

^{98.} Id. at 53.

^{99.} Id.

^{100.} Id.Fisher, supra note 71 at w53.

^{101.} Id. at 53.

have to keep this in mind when creating performance measurements to accurately determine any cost-savings.¹⁰⁵ Physicians also exhibit a strong culture of individual responsibility and professional autonomy for the patients they see, and they may be hesitant to be accountable to patients within the ACO that they do not personally treat.¹⁰⁶ A more practical concern about large-scale accountability is the highly charged decision-making environment.¹⁰⁷ Questions arise such as who would make decisions about data collection, auditing, and deciding what levels of achievement merit reward?¹⁰⁸ Finally, legal obstacles such as how this model would function under the current antitrust and anti-kickback laws could prevent the efficiencies often realized under an ACO from ever being realized.¹⁰⁹

Model Two - Multi-Specialty Group

The second model would create ACOs that incorporate and reflect multi-specialty practice groups. Cite Of the 718,000 practicing physicians in the United States, between seventeen percent and twenty-six percent are associated with a multi-specialty group practice of 100 or more physicians.¹¹⁰ These large multi-specialty group practices present an opportunity to deliver coordinated care to a defined group of patients.¹¹¹ Additionally, these large practice groups are more likely to implement and use healthcare IT and electronic health records, work in collaborative healthcare teams, and use evidence-based care processes.¹¹² Multi-specialty practice groups are also better situated to provide long-term care and handle multiple payment methods including related bundled payment, episodic payment, and capitation.¹¹³

In addition to being expensive to create,¹¹⁴ sometimes the size and lack of cooperation amongst physicians make large multi-specialty

^{105.} Fisher, supra note 71 at 54.

^{106.} *Id*.

^{107.} Id.

^{108.} *Id.*

^{109.} Id. (The Department of Justice along with CMS have amended rules pertaining to antitrust provisions and Stark and Anti-kickback laws, respectively. It remains to be seen whether the proposed changes would result in the desired efficiency).

^{110.} Lawrence P. Casalino, Physicians and Corporations: A Corporate Transformation of American Medicine?, 29 J. HEALTH POL'Y, POL. & L. 869 (2004).

^{111.} Stephen M. Shortell & Lawrence P. Casalino, Accountable Care Systems for Comprehensive Health Care Reform, (March, 2007), at 9, available at http://www.fresh-thinking.org/docs/workshop 070301/ShortellCasalinoDeliverySystemModelsRevise9.pdf.

^{112.} Francis J. Crosson, The delivery System Matters, 24 HEALTH AFF. 1543, 1544 (2005).

^{113.} Shortell, supra note 110, at 10.

^{114.} Id.

practice groups a difficult practice model.¹¹⁵ Additionally, while they have the capacity and money to hire effective and skilled leadership, the governance protocols in many multi-specialty practice groups can be complex and time-consuming due to size and conflicts among the different specialty groups.¹¹⁶ Even if multi-specialty practice groups don't become the most prevalent model for ACOs they exhibit valued characteristics such as working on teams and data generation that should be implemented in ACO models.

Model Three - Hospital Medical Staff Organizations

Hospital Medical Staff Organizations are very similar to the Extended Medical Staff Model explained above. The ACO would consist of the hospital and the physicians on its medical staff.¹¹⁷ The medical staff is an area of high physician concentration with an emphasis on developing professional and referral relationships.¹¹⁸ Hospitals have the capacity to invest in large-scale efficiency projects, generate date on performance, adopt electronic medical/health record technology, and assist with providing quality improvement support.¹¹⁹ Additionally, this model could respond better to incentives based on specific payment models such as bundled payments for specific medical conditions or episodic-illness based payment methods, because these payment models would require the hospital and medical staff to collaborate at a much higher level.¹²⁰

Nevertheless, hospital medical staff organizations have historically faced several problems. Many physicians under these organizations view the hospital as a competitor for medical services and show general discomfort with involvement in such large organizations due to the challenges of reconciling divergent physician interests, long-standing conflicts between the hospital and physicians, and legal obstacles to gain-sharing.¹²¹

Model Four - Physician Hospital Organization

The Physician-Hospital Organization (PHO) is a variation of the

^{115.} Lawrence P. Casalino et al., Benefits of and Barriers to Large Medical Practice in the United States,163ARCH.INTERNALMED.1958,1961(2003)availableathttp://www.ftc.gov/ogc/healthcarehearings/docs/030925lawrencebb.pdf.

^{116.} Shortell, supra note 110, at 10.

^{117.} Id. at 11.

^{118.} Id.

^{119.} *Id.*

^{120&}lt;sup>.</sup> ^{Id.}

^{121.} Shortell, supra note 110 at 12.

multi-specialty practice group and Hospital Medical Staff Model.¹²² Currently, there are 1,000 PHOs in the United States, and approximately thirty-seven percent of physicians in the U.S. belong to them.¹²³ PHO's will typically involve those members of the medical staff whose economic interest are best aligned with the hospital; meaning, those physicians that can provide the hospital with the needed geographic network for contracting purposes and are the most cost-effective providers.¹²⁴ This model has the ability to manage the cost and quality of care because hospitals can use cost and quality criteria as standards for membership in addition to measuring efficiency.¹²⁵ Hospitals can reevaluate membership annually to ensure that participating providers will help the hospital maximize cost-savings and efficiency.¹²⁶

In addition to controlling costs, limited membership also restricts the size and bureaucracy of the organization.¹²⁷ This could result in an easier transfer of information and a better ability to manage change.¹²⁸ Despite the inherent advantages of this double-incentive model, many first generation PHOs have failed.¹²⁹ PHOs require significant clinical integration and raise significant antitrust concerns.¹³⁰ And with the FTC's past success in bringing cases against PHOs that, while not clinically integrated, were trying to negotiate contracts with health plans that did not involve risk-sharing by physicians and hospitals, legal concerns about an integrated model involving hospital and physician risk sharing are to be expected.¹³¹

Model Five - Health Plan Provider and Interdependent Physician Organizations

The Health Plan-Provider Organization and the Interdependent Physician Organization are interesting ACO models. A Health Plan-Provider Organization would aggregate ACO physicians based on the health plans they service.¹³² The deep pockets of the health plan could

^{122.} Id.

^{123.} Id.

^{124.} *Id.*

^{125.} Denis Cortese & Robert Smoldt, Taking Steps Towards Integration, 26 HEALTH AFF. w70 (2007).

^{126.} Shortell, supra note 110, at 12-13.

^{127.} Id.

^{128.} Id.

^{129.} *Id.*

^{130.} Id.

^{131.} Lawrence P. Casalino, The Federal Trade Commission, Clinical Integration, and the Organization of Physician Practice, 31 J. HEALTH POL'Y, POL. & L. 569-568 (2006).

^{132.} Shortell, supra note 110 at 14.

provide a significant boost to necessary capital-heavy investments such as overhauls of electronic medical/health record systems and quality improvement/care-management systems.¹³³ Some health plans already have developed capabilities in the area of electronic medical record systems.¹³⁴ However, while they can manage data and provide technical assistance, these health plans can only have a limited impact on care management and changes in physician practices.¹³⁵ A Health Plan-Provider Organization ACO model would need leadership from local physicians, who may or may not possess adequate leadership skills.¹³⁶

Interdependent Physician Organizations are a variation on currently existing Independent Physician Organizations.¹³⁷ Interdependent Physician Organizations, however, have a stronger governance structure, shared knowledge capabilities, and enough patients to support investment.¹³⁸

Regardless of which models ACOs falls under, they generally need three things to succeed: information, infrastructure, and incentive.¹³⁹ The success of any model, as the Institute of Medicine highlights, relies on a national performance measurement system.¹⁴⁰ National performance measurement systems and evidence-based medicine allow for a multi-disciplinary group of physicians, engineers, researchers, and managers to continually identify areas of improvement and rapidly spread those to ACOs across the country.¹⁴¹

SECTION TWO: ANALYSIS

Criticisms of ACOs

ACOs have the potential to trigger a massive shift in healthcare delivery in the United States. However, critics wonder if they can really improve the value of healthcare. Despite significant modifications and changes from the proposed rules to the final rules, critics remain skeptical of whether ACOs will receive a warm welcome by the healthcare community and whether ACOs can actually deliver on the promise of a

^{133.} Id.

^{134.} Id.

^{135.} Id. at 15.

^{136.} Id.

^{137.} Shortell, supra note 110 at 13.

^{138.} Id. at 14.

^{139.} Victor R. Fuchs, Health Care Expenditures Reexamined, 143 ANN. INTERNAL MED. 76, 77 (2005).

^{140.} Institute of Medicine, Performance Measurement: Accelerating Improvement (2006).

^{141.} Id.

reformed system.¹⁴² The crux of the commentary seems to be focused on three main areas of concern: complexities and costs of reporting requirements; internal coordination; and the external impact ACOs may have on the healthcare market and whether ACOs can actually deliver on the promise of a reformed system.

Reporting Complexities and Costs

The original proposed rules were called a bureaucratic nightmare and commentators found the need to report on sixty-five quality measures to be quite intrusive and burdensome.¹⁴³ The final rules adjusted the reporting requirements in the proposed rules by reducing them to thirty-three measures.¹⁴⁴ Yet, thirty-three separate reporting requirements spread over four domains is no easy task.¹⁴⁵ The design of the program, including its reporting requirements, could lead to steep start-up costs averaging around \$1.8 million per ACO.¹⁴⁶ These reporting requirements will require new data warehouses and substantial staff to manage the process.¹⁴⁷ For an ACO consisting of a 200-bed hospital, 80 primary care physicians and 150 specialists, it would have to spend at least \$75,000 in reporting requirement related start-up costs.¹⁴⁸ For a larger five-hospital ACO with 1,200 beds, 250 primary care physicians, and 500 specialists, the average reporting requirement start-up costs are expected to be at least \$100,000.¹⁴⁹

Internal Coordination Issues

The high cost of burdensome reporting requirements and the relatively low financial incentive for the amount of work and internal adjustment necessary to create a fully-functional ACO led the American Medical Group Association to declare that the ". . .incentives are too

^{142.} John Cummins, *ACOs Seen as Tough Sell, Despite Concessions*, HEALTHLEADERS MEDIA (October 24, 2011), http://www.healthleadersmedia.com/content/LED-272403/ACOs-Seen-As-Tough-Sell-Despite-Concessions## (follow article to page 2 link).

^{143.} Robert Samuelson, *How NOT to Control health Costs*, WASHINGTON POST (June 7, 2011), http://www.washingtonpost.co m/blogs/post-partisan/post/how-not-to-control-health-spending/2011/06/07/AGrnjDLH_blog.html?hpid=z3.

^{144. 76} Fed Reg 67,889 (November 2, 2011).

^{145.} Id.

^{146.} Ann Wilde Matthews, *Health-Care Initiative Draws Fire*, WALL STREET JOURNAL (June 3, 2011), http://online.wsj.com/ article/SB100 01424052702303654804576349794068956906.html.

^{147.} Keith D. Moore, *The Work Ahead: Activities and Costs to Develop an Accountable Care Organization*, MCMANIS CONSULTING, 10 (April, 2011), http://www.mcmanisconsulting.com/pdfs/Cost_of_Developing_ACO_White_Paper.pdf.

^{148.} Id. at 13.

^{149.} Id. at 16.

difficult to achieve to make this voluntary achievement attractive."¹⁵⁰ The internal coordination issues primarily relate to coordination between ACO participants and, on a moral level, between the types of patients an ACO participant treats.

A primary example of physician coordination revolves around physician autonomy. ACOs create a rather unique situation for physicians, who are taught that medicine is an interaction between an individual physician and an individual patient.¹⁵¹ ACOs need to give physicians the room to work and achieve the best results in the diverse clinical settings they face today.¹⁵² Historically, physicians have proven inept when it comes to working together in large numbers—nearly seventy-five percent of office-based physicians, representing nearly ninety-five percent of all U.S. practices, work in groups of five or fewer physicians.¹⁵³

Additionally, ACOs are expected to promote and implement the use of Electronic Health Records (EHR), however, ACO participants may be using different EHR software.¹⁵⁴ In hospital-run ACOs, it is likely that the participating physicians will have to switch over to the hospital's EHR software.¹⁵⁵ These coordination issues pale in comparison to the issue of splitting profits. Ideally, an ACO participant (primary care physician or specialist) uses the financial incentives to generate savings, which in turn create profits for the ACO. Cite How can we expect physicians to be honest about the value they bring to an ACO? Because much of the profits generated by an ACO will be from the shared savings, does a physician determine his portion by counting the number of tests or scans he didn't order?¹⁵⁶

ACOs present a larger philosophical and moral question that remains unanswered. The classical version of the Hippocratic Oath states, "I will apply dietetic measures for the benefit of the sick according to my ability and judgment; I will keep them from harm and injustice."¹⁵⁷ With the

^{150.} American Medical Group Association, Letter on Medicare Shared Savings Program, (May 11, 2011).151. Tom Walsh, Balancing Physician Autonomy with Team-Based ACO Models, MASSACHUSETTSMEDICALSOCIETY,MEDICALSOCIETY,Methy://www.massmed.org/AM/Template.cfm?Section=Home6&TEMPLATE=/CM/ContentDisplay.cfm&C

http://www.massmed.org/AM/Template.cfm?Section=Home6&TEMPLATE=/CM/ContentDisplay.cfm&C ONT ENTID =51821.

^{152.} Id.

^{153.} Robert Kocher, MD & Nikhil R. Sahni, Physicians Versus Hospitals as Leaders of Accountable Care Organizations, 363 NEW ENG. J. MED. 2579, 2580 (2010).

^{154.} Robert Rowley, MD, *More About ACOs: Care Coordination*, PRACTICE FUSION, (April 21, 2011), http://www.practicefu sion.com/ehrbloggers/2011/04/more-about-acos-care-coordination.html. 155. *Id.*

^{156.} Kocher, *supra* note 152, at 2580.

^{157.} Peter Tyson, *The Hippocratic Oath Today*, PBS, (March 27, 2001), http://www.pbs.org/wgbh/nova/body/hippocratic-oath-today.html (citing Ludwig Edelstein, *The*

requirement to protect the sick by applying their skill and judgment and the requirement to be just, how do physicians treat an ACO patient compared to a non-ACO patient? If motivated by the wrong reasons, namely greed, a physician may tend to over-test and over-treat the non-ACO patient, and under-treat and under-test the ACO patient.

External Impact of the ACO

Undoubtedly, bringing together hospitals, primary care physicians, specialists, and other suppliers/providers under one umbrella is bound to create issues. Aside from the internal problems created by the ACO healthcare delivery model, it seems unavoidable for ACOs to experience some external issues as well. External issues relate directly to how an ACO, once formed, will interact with other non-ACO healthcare providers, and whether it runs afoul of longstanding laws and government policy affecting its operation.

After PPACA was passed, the movement toward healthcare provider consolidation into ACOs raised antitrust concerns among commentators, mainly that consolidation may lead to increased prices and defeat the spirit of lowering healthcare costs.¹⁵⁸ While the Shared Savings Program rules were being written, CMS administrators recognized the potential for manipulation noting that healthcare entities could reorganize to call themselves ACOs and use the new clout to raise prices against consumers.¹⁵⁹ Of particular concern is the potential impact of ACOs on solo practitioners and small group practices that cannot make the necessary investment to join an ACO.¹⁶⁰ Some argue that ACOs will result in the extinction of community-based solo practices and the crowding out of smaller hospitals and independent physicians ultimately resulting in decreased competition and lessened innovation.¹⁶¹

Besides antitrust concerns, ACOs raise significant Medicare fraud and abuse issues. The type of coordination and consolidation needed to operate an ACO implicates the Stark Law and the Anti-kickback Statute the primary mechanisms for limiting fraud and abuse. Cite ACOs are

Hippocratic Oath: Text, Translation, and Interpretation (1943)).

^{158.} Merrill Goozner, *Monopolies Threaten Healthcare Cost Controls*, THE FISCAL TIMES (February 3, 2011), http://www.th efiscaltimes.com/Articles/2011/02/03/Monopolies-Threaten-Health-Care-Cost-Controls.aspx#page1.

^{159.} Id.

^{160.} Update - Accountable Care Organizations, HEALTH AFFAIRS, (August 13, 2010), http://www.healthaffairs.org/healthpoli cybriefs/brief.php?brief_id=23.

^{161.} Randall S. Bock, *How an ACO Will Effect the Relationship Between a Doctor and a Patient*, KEVINMD.COM, http://www.kevinmd.com/blog/2011/05/aco-affect-relationship-doctor-patient.html.

structured to "achieve the efficiency and quality gains of formally integrated delivery systems (Geisinger, Mayo Clinic) through contractbased aggregation of providers."¹⁶² This type of structure calls into question the ability of a "virtual organization" to meet the integration requirements of PPACA without running afoul of laws prohibiting physician self-referral (Stark) and kickbacks (Anti-kickback Statute).¹⁶³

The Stark Law prohibits a physician who has a direct or indirect financial relationship with an entity, or who has an immediate family member who has a direct or indirect financial relationship with an entity, from making a referral to that entity for the furnishing of designated health services paid for by Medicare.¹⁶⁴ ACOs will require referrals between individuals that are tied together in a financial relationship. Financial relationships, as defined by Stark Law, include direct or indirect ownership, investment, or compensation arrangements.¹⁶⁵ An ACO is supposed to be a legal entity capable of distributing shared savings payments to its members.¹⁶⁶ Clearly, the two need to be reconciled.

We need to consider how valid the aforementioned concerns are and whether they are significant enough to abandon what could be a monumental change in healthcare delivery in the United States.

Critics' Concerns are Over-Exaggerated or Miss the Point Altogether

Discourse is important. It stimulates discussion and forces society to think seriously about policy choices. Thus far, ACO critics have done a great job of stimulating discussion. However, their concerns are drastically overstated and exaggerated. The Medicare Shared Savings Program itself, Office of Inspector General, Department of Justice, and Center for Medicaid and Medicare Services waivers, and other regulations mitigate if not eradicate some concerns altogether.

Reporting Requirements are Easy to Satisfy and will Facilitate ACO Success

Many critics are apprehensive about the reporting requirements,

^{162.} John V. Jacobi, ACOs: OIG Guidance, CMS Regulations, and Interpretive Tasks, HEALTH REFORM WATCH (April 5, 2011), http://www.healthreformwatch.com/2011/04/05/acos-oig-guidance-cms-regulations-and-interpretive-tasks/.

^{163.} Id.

^{164. 42} CFR § 411.353(a).

^{165. 42} CFR § 411. 354(a)(1)(i)-(ii).

^{166. 42} CFR § 425.104.

stating that they will be overly burdensome, and prohibit the success of ACOs.¹⁶⁷ In response to the overwhelming comments to the proposed rules, CMS has reduced the number of quality measures from sixty-five over five domains to thirty-three over four domains.¹⁶⁸ Will the reporting requirements really overburden ACO participants? The answer is no. The thirty-three measures will get reported to CMS through the following four methods: (1) patient surveys; (2) EHR (Full name) Incentive Program Reporting; (3) the GPRO (Group Practice Reporting Option) web interface; and, (4) claims filed with CMS.¹⁶⁹

Of the four domains being tested, the Patient/Caregiver Experience domain is the only one that requires its performance measures to be assessed via a survey.¹⁷⁰ CMS believes that the survey should be based on the Consumer Assessment of Healthcare Providers and Systems model because no survey model currently exists for ACO assessment.¹⁷¹ For the years 2012 and 2013, CMS will fund the survey portion of the reporting requirements for ACOs.¹⁷² Starting in 2014, ACOs will have to pay for and conduct their own surveys, but CMS will make this much easier by providing a number of CMS-certified vendors to conduct the survey.¹⁷³ ACO participants have a preapproved survey model to use, will receive funding in 2012 and 2013 to conduct it, and starting in 2014 can outsource the survey to a certified vendor—it doesn't get easier than that.

A number of data measures overlap with the data measures used in the EHR Incentive Program found in the Health Information Technology for Economic and Clinical Health Act (HITECH Act).¹⁷⁴ As originally submitted, the proposed rules had twenty-two reporting requirements that were identical to the HITECH Act's EHR Incentive Program.¹⁷⁵ In fact, one of the data measures in the ACO final rules specifically takes into account how many ACO primary care physicians qualify for an incentive payment under the EHR Incentive Program.¹⁷⁶

170. Id.

^{167.} Samuelson, supra note 142.

^{168. 76} Fed. Reg. 67889 (November 2, 2011).

^{169.} Id. at 67889-90.

^{171.} Id. at 67891.

^{172. 76} Fed. Reg. 67891 (November 2, 2011)

^{173.} Id.

^{174.} Compra 76 Fed. Reg. 19571-19591(HER Incentive Program) with 75 Fed. Reg. 44315 (HITECH Meaningful Use Rules).

^{175.} Amy K. Fehn, The Importance of Health Information Technology for Accountable Care Organizations, ABA HEALTH ESOURCE (June, 2011 Spec. Ed.), Available at http://www.americanbar.org/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1 106_aco_fehn.html.

^{176. 76} Fed. Reg. at 67889 (November 2, 2011).

A substantial amount¹⁷⁷ of ACO reporting will also be done via the Group Practice Reporting Option (GPRO) web interface.¹⁷⁸ The GPRO reporting medium will be an upgraded version of the GPRO tool currently used in the Physician Quality Reporting System (PQRS).¹⁷⁹ In the proposed rules. CMS mentioned its intent to develop the GPRO tool to interface with EHR technology, so that EHR data could directly fill in GPRO quality measures.¹⁸⁰ Moving forward, CMS is aiming to increase reporting efficiency for ACO participants by reducing redundancy. While ACO participants cannot take advantage of both the Shared Savings Incentive and the PQRS incentive,¹⁸¹ CMS has built in a smaller PQRS incentive in the Shared Savings Program.¹⁸² For physicians already participating in the PQRS initiative, ACO participation is a smart choice. The physicians get to earn a PQRS initiative, albeit a smaller one, while potentially earning a Shared Savings Initiative without having to drastically change data-reporting activities.

Of the thirty-three reporting measures in the final rules, three measures will be satisfied by data submitted through CMS claims.¹⁸³ These measures focus on patient readmissions for all conditions and ambulatory sensitive admissions for congestive heart failure and chronic obstructive pulmonary disease.¹⁸⁴ The data for these measures will be gathered by claims submitted for the respective services and do not require any additional reporting on the ACO's part.¹⁸⁵ Besides satisfying reporting requirements, CMS claims can provide ACOs with critical information necessary to ACO success under the Shared Savings Program.¹⁸⁶ ACOs will need to complete a Data Usage Agreement (DUA) and submit a formal request to access claims data, which they can do on a monthly basis.¹⁸⁷ The availability of such claims data will only help the ACO in

- 181. 42 CFR §425.504(a)(4)
- 182. 42 CFR §425.504(a)(5).

^{177.} Id. (22 of 33 Reporting Measures).

^{178. 76} Fed. Reg. at 67889-90 (November 2, 2011).

^{179. 76} Fed. Reg. 19592 (April 7, 2011) (The PQRS is a system originally authorized to provide financial incentives for eligible professionals who satisfactorily report on a designated set of quality measures. The 2011 PQRS Final Rule can be found at 75 Fed. Reg. 73169 (January 11, 2011)).

^{180. 76} Fed. Reg. 19593 (April 7, 2011).

^{183. 76} Fed. Reg. 67889 (November 2, 2011).

^{184.} Id.

^{185.} Melanie Phelps, ACO Proposed Rule Review- Part 10: Quality and Performance, (May 6, 2011), http://www.ncmedsoc.org/blog/index.php/archives/11284.

^{186. 42} CFR § 425.704 (ACOs can request access to beneficiary identifiable claims data for preliminary prospective assigned beneficiaries and other beneficiaries who receive primary care services from an ACO participant upon whom assignment is based during the agreement period).
187. 42 CFR §425.704(a).

tweaking its policies and procedures to ensure maximum efficiency and quality in the delivery of coordinated care. Beneficiaries reserve the right to opt-out of data sharing,¹⁸⁸ and they will be notified in writing of how the ACO will use the information.¹⁸⁹

Most Internal ACO Concerns are Easily Resolved

The main internal ACO coordination concerns raised by critics revolve around physician independence,¹⁹⁰ division of ACO profits,¹⁹¹ technology integration,¹⁹² and disparate treatment between ACO and non-ACO patients. Most of these concerns are resolved by referring to the Shared Savings Program itself or other existing legislation. However, the disparate treatment of patients is a more difficult issue to resolve.

Physicians have been described as a "track team of individuals rather than a soccer team"¹⁹³ and have grown to enjoy their autonomy. Though the Shared Savings Program places a heavy emphasis on developing and promoting evidence-based medicine,¹⁹⁴ it does not remove a physician's ability to make autonomous clinical decisions. On the contrary, some specialists believe that ACOs will let doctors engage in their practice without clinical interference because the crux of the cost-control measures come from better coordination of care and technological improvement.¹⁹⁵ CMS requires an ACO governing body to have enough clout to influence or direct clinical practice "to improve efficiency in processes and outcomes."196 The American Medical Group Association (AMGA) indicated that more than 100 member medical groups across the country are well-positioned to become accountable care organizations.¹⁹⁷ These organizations already have in place multi-specialty group practices, partnerships with hospitals, well-functioning clinical information systems, and established physician leadership.¹⁹⁸ ACO success is not dependent on reducing physician clinical autonomy, but rather from adopting protocols

^{188. 42} CFR §425.708

^{189. 42} CFR §425.704(d)(2).

^{190.} Walsh, supra note 150.

^{191.} Kocher, supra note 152.

^{192.} Rowley, supra note 153.

^{193.} Walsh, supra note 150.

^{194. 42} CFR §425.112(a)(1)(i)

^{195.} OrthoSuperSite, *Questions Loom Regarding the Future and the Implementation of ACOs*, (August 2011), http://www.orthosupersite.com/view.aspx?rid=86531.

^{196. 42} CFR §425.108(b).

^{197.} Francis J. Crosson, The Accountable Care Organization: Whatever Its Growing Pains, The Concept Is Too Vitally Important to Fail, 30 HEALTH AFF. 1250, 1252 (2011).

^{198.} Id.

to reduce the growth in Medicare spending.¹⁹⁹ The AMGA statistics also indicate that physicians can work together in larger group settings.

Harmony amongst ACO participants will be most important when it comes to dividing the shared savings. As part of its application, a CMSsanctioned ACO is required to submit documentation describing how it plans on using any shared savings it generates, including the criteria it will employ when distributing shared savings to member participants.²⁰⁰ ACO participants will not be blindly joining an ACO without first being able to determine whether the proposed distribution scheme is to their liking. It is expected that whoever controls the ACO will capture the largest portion of the shared savings.²⁰¹ ACOs can either be physician-run or hospital-run, and each control model has its own benefits and drawbacks.²⁰² For physicians to take control of an ACO they will need to be ready to make significant investments in EHR technology and infrastructure development.²⁰³ If they don't want to make large capital investments, they should let hospitals take the lead. Hospitals, on the other hand, must be willing to sacrifice short-term profit for long-term savings and forego some profit from admissions and procedures by shifting to an outpatient care model.²⁰⁴ When it comes to profits, ACO participants cannot expect a windfall. Ultimately any profits made will be distributed according to a pre-established criteria. If, as a potential participant, a physician does not like the distribution scheme he or she can always participate in another ACO or not participate in any ACO.

The disparate treatment between ACO and non-ACO patients by participating providers is a valid concern.²⁰⁵ In a first-of-its-kind model program, the Medicare Physician Group Practice Demonstration Project, the results were mixed.²⁰⁶ The program provided bonuses to the ten participating groups if they met quality standards and reduced costs.²⁰⁷ While some groups were able to generate savings, some groups faced growing healthcare costs for their patient population compared to

^{199.} David Newman, Accountable Care Organizations and the Medicare Shared Savings Program, Congressional Research Service, (November 4, 2011) at pg. 18, available at https://www.aamc.org/download/161172/data/crs_acos.pdf.

^{200. 42} CFR § 425.204(d)(1). 201. Kocher, *supra* note 152, at 2580.

^{201.} Köcher, *supra* note 152, at 25-202. *Id*.

^{202.} *Id.* 203. *Id.*

^{205.} IU.

^{204.} Id. at 2580-81.

^{205.} Mark Merlis, *Health Policy Brief: Accountable Care Organizations*, (July 27, 2010), http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=20.

^{206.} Id.

^{207.} Id.

comparable Medicare beneficiaries in the same area.²⁰⁸ Possible explanations for this result include the inability to manage the care of nonenrolled patients and the fact that payment was still on a fee-for-service basis.²⁰⁹ This proves that some groups will be more likely to apply CMS quality standards to all of their patients, while some will be less likely to treat all patients the same. However, if private payers implemented CMS equivalent quality standards and bonus payments, providers will be more likely to apply quality standards and cost-cutting measures evenly.²¹⁰ Considering the growing interest in expanding the ACO models to the private sector—private payers have already started ACOs with their providers²¹¹— it may not be a bad idea for private payers to strongly consider mimicking CMS quality standards and bonus payment mechanisms.

Waivers Resolve the "Problematic" External Impact of ACOs

ACOs require a significant amount of collaboration and integration in order to deliver healthcare cost savings.²¹² Health law attorneys indicate that a number of existing laws are specifically aimed at preventing this level of integration and collaboration.²¹³ A main concern has been how ACOs can function under the preexisting antitrust laws.²¹⁴ Similarly, "[another] glaring issue affecting all ACOs intending to participate in the Medicare Sharing Savings Program ("MSSP") include (sic) application of the current Fraud and Abuse laws that prohibit the fundamental purpose of the MSSP – distribution of shared savings among hospitals, physicians, and other individuals and/or entities."²¹⁵ Mindful of these legal obstacles,

^{208.} Id.

^{209.} Id.

^{210.} Merlis, supra note 204.

^{211.} J. Kersten Kraft & Aldo De La Torre, Northern California ACO to be a Model for National Efforts, 2 Accountable Care News, No.11, Oct., 2011.

^{212.} Brandi White, ACO Proposed Rule Outlines Risks and Rewards for Doctors and Hospitals, AAFP BLOG (Apr. 11, 2011, 4:28 p.m.),

http://blogs.aafp.org/fpm/noteworthy/entry/aco_proposed_rule_outlines_risks.

^{213.} Jesse Berg, *Health Law Alert: CMS Issues Proposed ACO Regulations*, GRAY PLANT MOOTY LAW FIRM (April 13, 2011), http://www.gpmlaw.com/resources/newsletters/health-law-alert-cms-issues-proposed-aco-regulations.aspx. (ACOs will impact Stark Law, the Anti-Kickback Statute, the Civil Monetary Penalty, Anti-Trust laws, and IRS Rules).

^{214.} Melissa Maleske, Accountable Care Organizations May Raise Antitrust Concerns: FTC and DOJ Issue Guidance on Accountable Care Organizations' Intersection with Antitrust Laws, INSIDE COUNSEL MAGAZINE (June 2011), available at http://www.insidecounsel.com/2011/06/01/accountable-careorganizations-may-raise-antitrust.

^{215.} Conrad Meyer, Proposed Waiver for Application of Fraud and Abuse Laws, ABA HEALTH ESOURCE, (Apr. 2011),

http://www.americanbar.org/newsletter/publications/aba_health_esource_home/aba_health_law_esource_l 104 aco meyer.html.

government agencies decided to implement waivers to excuse certain ACO activities that would seemingly violate these laws.²¹⁶ The waivers provide ample protection for ACO activity and will facilitate long-term ACO success.

"Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce . . . is declared to be illegal."²¹⁷ A contract, agreement, or conspiracy to unreasonably restrict trade that impacts interstate commerce is in violation of the Sherman Act.²¹⁸ An ACO involves numerous healthcare providers agreeing to cooperate and coordinate the delivery of their services, and clearly violates the Sherman Act. The Department of Justice and the FTC have created a waiver that will allow CMS-sanctioned ACOs to get around this legal hurdle.²¹⁹

The final antitrust waiver establishes three main antitrust policies that the FTC and DOJ will adhere to: (1) use of rule of reason analysis; (2) the creation of an antitrust safety zone; (3) and an expedited voluntary antitrust review process for ACOs.²²⁰ Typically, antitrust laws treat naked price-fixing²²¹ and market-allocation agreements among competitors as per se illegal; however, joint price agreements between competitors are evaluated under the rule of reason if the providers are financially or clinically integrated.²²² To withstand an antitrust review under the rule of reason, an agreement's potential efficiencies must outweigh its potential anti-competitive effects.²²³ The FTC and DOJ determined that CMS' ACO eligibility criteria are more or less aligned with their requirement for financial or clinical integration.²²⁴

The FTC and DOJ created an antitrust safety zone for ACOs in which independent participants do not exceed thirty-percent market share in common services for each participant's primary service area.²²⁵ Hospitals

^{216.} Joint FTC/DOJ Antitrust Policy, 76 Fed. Reg. 67026 (Oct. 28, 2011); CMS/OIG/HHS waivers, 76 Fed. Reg. 67992 (Nov. 2, 2011).

^{217. 15} U.S.C.§1 (2011).

^{218.} Lee v. Life Ins. Co. of North America, 829 F. Supp. 529, 535 (D.R.I. 1993), aff^{*}d, 23 F.3d 14 (1st Cir.), cert. denied, 513 U.S. 964 (1994).

^{219.} Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67026 (Oct. 28, 2011).

^{220. 76} Fed. Reg. 62027-31 (Oct. 28, 2011).

^{221.} Where the main purpose of an agreement is to fix prices, divide the market, or generally eliminate the competition.

^{222.} Id. at 62027.

^{223.} Id.

^{224.} Id.

^{225.} Id. at 67028 (The primary service area is the lowest number of zip codes from which an ACO participant draws seventy-five percent of its patients).

and ambulatory surgical centers, in order to qualify for the safety zone, must be non-exclusive members of the ACO.²²⁶ ACOs that exceed the thirty-percent market share can still qualify for the safety zone, if they exceed the threshold due to the inclusion of rural providers/participants.²²⁷ ACOs that have participating members that exceed fifty percent of the market share (dominant providers) in their Full name (PSA) will qualify for the safety zone if no other ACO participant provides that service and the dominant provider participates in the ACO on a non-exclusive basis.²²⁸ For ACOs that do not qualify for the safety zone, the FTC and DOJ recommend avoiding the following activities: (1) Improper sharing of competitively sensitive information; (2) preventing private payers from incentivizing patients to choose certain providers through contractual clauses; (3) tying sales²²⁹; (4) entering into exclusive contracts with ACO participants; and, (5) preventing private payers from disseminating information to their beneficiaries on the efficiency and quality of the ACO.230

The antitrust waivers are reasonably tailored to promote ACO growth and success without significant market monopolization. Specifically, the thirty-percent market share ceiling for the safety zone ensures that an ACO cannot become too large so as to prevent independent solo practitioners from being able to compete in the marketplace. The rural and dominant provider exceptions require the rural participant or the participant with a dominant market share to be a non-exclusive member of the ACO. Similarly, hospitals and ambulatory surgical centers must be non-exclusive members of ACOs. Cite This proves that the spirit behind ACO participation is to create an efficient healthcare delivery model, not to eliminate independent physician practices or reduce healthcare costs through market dominance. Solo practitioners in many communities are banding together to form IPAs (Independent Physician Associations),²³¹ and they can continue to do that to combat any perceived ACO threat.

To resolve legal concerns over ACOs' implication of the Medicare fraud and abuse laws, CMS, the OIG, and HHS have issued waiver guidelines for ACOs to protect them from violating the Physician Self-Referral Law (Stark), the Anti-kickback Statute (AKS), and the Civil

^{226. 76} Fed. Reg. 67028-29 (Oct. 28, 2011).

^{227.} *Id.* at 62029 (Rural hospitals must participate in the ACO on a non-exclusive basis). 228. *Id.*

^{229.} Conditioning the sale of a wanted product to the sale of another, unwanted product.

^{230. 76} Fed. Reg. 62029-30 (Oct. 28, 2011).

^{231.} Merlis, supra note 204.

Monetary Penalty (CMP).²³² Stark, AKS, and CMP provision, addressing inappropriate compensation arrangements and beneficiary inducement to reduce or limit services, are vital tools used to protect patients and the federal healthcare programs from fraud, improper referral payments, unnecessary utilization, underutilization, and other questionable practices.²³³ There are five waivers in total that address the Medicare fraud and abuse laws: (1) ACO pre-participation waiver; (2) ACO participation waiver; (3) shared savings distributions waiver; (4) Stark compliance waiver; and (5) a patient incentive waiver.²³⁴

The pre-participation waiver applies to ACO related start-up arrangements in anticipation of participating in the Shared Savings Program.²³⁵ This waiver waives the applicability of Stark, AKS, and CMP to start-up arrangements that occur before an ACO officially starts participating in the shared savings program.²³⁶ ACOs must meet the following criteria to qualify: (1) the arrangement must be undertaken with a good faith intention to develop an ACO that will participate in the Shared Savings Program in a target year and to submit a completed application to participate for that year; (2) parties to the arrangement must take diligent steps towards developing an eligible ACO; (3) the ACO governing body must make and authorize a bona fide determination that the arrangement is reasonably related to the purposes of the Shared Savings Program; and (4) the ACOs must contemporaneously document all efforts to satisfy the first three requirements.²³⁷ The waiver would start one year prior to the ACO application due date for the target year and end on the start date of an ACO's participation agreement with CMS.²³⁸

The ACO participation waiver waives the same fraud and abuse laws for ACOs that: (1) entered into a participation agreement with CMS and remain in good standing; (2) meet the governance, leadership, and management requirements of the Shared Savings Program; (3) made and authorized a bona fide determination that the agreement is reasonably related to the provisions of the Shared Savings Program; (4) document the arrangement and its authorization by the ACO governing body; and, (5) publicly disclose the arrangement in a manner acceptable to CMS.²³⁹ The

^{232. 76} Fed. Reg. 67992 (Nov. 2, 2011).

^{233.} Id. at 68008.

^{234. 76} Fed. Reg. 67993 (Nov. 2, 2011).

^{235.} Id.

^{236.} Id. at 68000.

^{237.} Id.

^{238.} Id.

^{239. 76} Fed. Reg. 67801 (November 2, 2011).

waiver takes effect on the start date of the participation agreement with CMS and ends six months after the expiration of the agreement (including any renewals) or the voluntary termination of an ACO.²⁴⁰

The shared savings distribution waiver protects the distribution of shared savings earned by the ACO to member participants or the use of the savings towards activities reasonably related to the shared savings program if the ACO has a signed agreement with CMS, remains in good standing, and the savings were earned during the participation period.²⁴¹ The Stark compliance waiver protects the ACO, its participants, and its providers/suppliers from implicating AKS and CMP provisions if: (1) the ACO has a signed participation agreement and is in good standing, (2) the financial relationship is reasonably related to the purposes of the Shared Savings Program, and (3) the financial relationship complies with an existing Stark exception.²⁴² The patient incentive waiver will not be discussed in detail for the purposes of this article.

CMS has indicated that the shared savings distribution waiver applies to activities or financial relationships "reasonably related to the purposes of the Shared Savings Program."243 It defines "purposes of Shared Savings Program" as promoting accountability for the quality, cost, and overall care for a Medicare population; managing and coordinating care for Medicare beneficiaries through an ACO; and encouraging investments in infrastructure and redesigned care processes.²⁴⁴ To be reasonably related to the purposes of the Shared Savings Program, an activity or arrangement need only be reasonably related to one of the purposes of the Shared Savings Program.²⁴⁵ This departure from the "necessary for and directly related to ACO purposes" language of the proposed rules is aimed at making compliance with waiver requirements easier.²⁴⁶ This language change is a significant relaxation of what constitutes a waived activity or relationship. So long as anargument could be made that a particular activity is reasonably related to the enumerated purposes of the Shared Savings Program, it will be protected by the waivers. Additionally, the Stark compliance waiver reduces the regulatory analysis ACO participants need to conduct when engaging in activities that meet an existing Stark

^{240.} Id. (Involuntary terminations result in the immediate revocation of the waiver).

^{241.} Id.

^{242.} Id.

^{243.} Id. at 68002.

^{244.} Id.

^{245.} Id.

^{246. 76} Fed. Reg. 68002.

exception.²⁴⁷ As it stands right now, satisfying a Stark exception does not immunize conduct under the AKS,²⁴⁸ providers have to satisfy both laws independently to ensure compliance. CMS is deviating from this long-standing, restrictive rule.²⁴⁹

Being amongst the first batch of ACOs has the advantage of getting "grandfathered" in to the current waiver requirement.²⁵⁰ CMS indicated that it will closely monitor ACOs entering the program between 2012-2013 (the first year of the Shared Savings Program) and, if need be, plan to narrow the waivers for ACO applicants beyond 2013.²⁵¹

Health law experts note that the final ACO waivers are a significant departure from the requirements of existing fraud and abuse laws.²⁵² For example, in order to meet Stark Law exceptions, provider agreements must be in writing, signed by the parties, and must be commercially reasonable arrangements at fair market value.²⁵³ None of the waivers, except the Stark compliance waiver aimed at protecting existing Stark arrangements, requires an arrangement to be at fair market value.²⁵⁴ The waivers themselves are immediately effective and self-implementing, which means that ACOs, their member participants, and their providers/suppliers will not need to apply to CMS or OIG to utilize a particular waiver.²⁵⁵

The protections afforded by the waivers are extensive and will permit many relationships that are currently prohibited.²⁵⁶ These waivers will allow for larger EHR and connectivity donations from hospitals to ACO participating physician as they are currently only subject to the Stark EHR donation exception, which expires at the end of 2013.²⁵⁷ Additionally, hospitals could begin making compensation payments to physicians based on reductions in patient length of stay, patient readmission, use of standard low-cost supplies, and hospital efficiencies—such payments are currently prohibited under the fraud and abuse laws.²⁵⁸ The relaxed waivers could

251. Id.

253. 42 C.F.R. § 411.357, et seq.

2011), at http://www.mwe.com/info/news/wp1111a.pdf at 2.

257. Id. at 10.

^{247. 76} Fed. Reg. 68006 (November 2, 2011).

^{248.} Id.

^{249.} Id.

^{250.} Id. at 68008.

^{252.,} ACO Update: Overview of Final Waivers, HARRIS BEACH, PLLC (Nov. 22, 2011), at www.harrisbeach.com/print/media-news/9196.

^{254.} See 42 C.F.R. § 411.357; ACO Update, supra note 249.

^{255.} Id.

^{256.} ACOs Get Broad Waivers From the Fraud and Abuse Laws, MCDERMOTT, WILL & EMERY (Nov. 10,

^{258.} Id.

allow for compensation arrangements between ACO members, which are likely to influence referral trends.²⁵⁹ If the data from the first batch of ACOs shows rampant fraud and abuse, CMS will most likely modify the waivers. However, the first batch of ACOs will be grandfathered into the current waiver requirements and can take advantage of compensation arrangements that may not be allowed after 2013.

Health Care Delivery Moving Toward a Pay For Quality Model

It is unequivocally true that subpar healthcare quality is a national issue.²⁶⁰ Policymakers have recognized that the catalyst for healthcare change is incentivizing the delivery of high-quality care at low costs.²⁶¹ Policymakers have recognized that the catalyst for healthcare change is incentivizing the delivery of high-quality care at low costs.²⁶² Additionally, CMS identified four criteria for implementing value-based purchasing of healthcare: (1) developing quality/efficiency measures; (2) payment system redesign through demonstration projects or statutory/regulatory authority; (3) resources to develop and implement value-based purchasing payment; and (4) developing data infrastructure.²⁶³ In large part, CMS has followed through with its initiative to move healthcare in the direction of value-based purchasing (pay for quality).

A cursory review of CMS initiatives shows that, as a society, we have started down the path of value-based purchasing. Recent changes to the Stark Law included an exception for donations of EHR and e-Prescribing technology by hospitals to physicians.²⁶⁴ In 2009, The HITECH Act provisions implemented an incentive program for physicians who engage in the meaningful use of EHR.²⁶⁵ The Physician Quality Reporting System provides incentives to CMS-certified physicians who report on various quality measures to CMS.²⁶⁶ Over the last six years, these three major incentive programs have been unveiled by CMS and emphasize the shift toward value-based purchasing.

^{259.} Id. at 7.

^{260.} J. Frank Wharam & Daniel Sulmasy, Improving the Quality of Health Care: Who is Responsible for What?, 301 no. 2 JAMA 215 (2009).

^{261.} Department of Health and Human Services, Roadmap for Implementing Value Driven Health Care in the Traditional Medicare Fee-for-Service Program, CENTERS FOR MEDICARE AND MEDICAID SERVICES, *at* https://www.cms.gov/QualityInitiativesGenInfo/downloads/VBPRoadmap_OEA_1-16_508.pdf at 1.

^{262.} Id.

^{263.} HHS, supra note 259, at 4.

^{264. 42} C.F.R. § 411.357(v), (w).

^{265. 42} C.F.R. § 495.2.

^{266.} Physician Quality Reporting Service Overview, Centers for Medicare and Medicaid Services, at https://www.cms.gov/PQRS/ (last modified Mar. 30, 2012).

CMS initiatives are expected to substantially impact private payers as well.²⁶⁷ and in the area of ACOs, private payers have already started ACO programs.²⁶⁸ Anthem Blue Cross and the Individual Practice Association Medical Group of Santa Clara County (SCCIPA) started a private ACO in California.²⁶⁹ Anthem Blue Cross members will be included in the program if they have received the majority of their medical care from the participating physicians in the past.²⁷⁰ In 2010, the ACO reported over \$3.5 million in savings.²⁷¹ In Illinois, Advocate Physician Partners, a physician-hospital organization representing approximately 3.500 physicians, signed its first ACO contract with Blue Cross Blue Shield, which went into effect on January 1, 2011.²⁷² The growth of private ACOs can only be expected to continue, especially considering the federal government's support of the ACO model.

SECTION 3: CONCLUSION

ACOs are here to stay. By incentivizing the reporting of quality measures, infrastructure changes, and actual performance, the model is capable of starting a revolution in healthcare delivery. The criticism that the ACO model has received is greatly exaggerated. Critics have cited burdensome reporting requirements, issues with internal ACO cooperation, and external ACO impact as the reasons for their hesitation in supporting the new CMS Shared Savings Program. However, after considering the different structural models for ACOs, the multiple ways to divide profits, the existing cooperation between physicians and local hospitals by way of EHR technology, the reasonably tailored antitrust waiver, the favorable fraud and abuse waivers, and the trend in healthcare policy, it becomes increasingly clear that there is no need to wait. The ACO model of healthcare delivery has received significant support from federal agencies and has been implemented by a handful of private payers as well. Waiting to participate in this revolutionary model will not result in additional

269. Kraft, supra note 210; Anderson supra note 265.

^{267.} Stephen M. Weiner & Garrett G. Gillispie, CMS Proposes New Hospital Value-Based Purchasing Program, HEALTH CARE REFORM ADVISORY (Jan. 18, 2011), at http://www.mintz.com/newsletter/2011/Advisories/0875-0111-NAT-HCR/web.html.

^{268.} Kraft, *supra* note 210; *See also* Chris Anderson, Anthem Blue Cross, Provider Group Launch ACO in Silicon Valley, HEALTHCARE FINANCE NEWS, (Aug. 11, 2011), *at* http://healthcarefinancenews.com/print/34907.

^{270.} Anderson *supra* note 265. (The assignment mechanism is very similar to CMS-sanctioned ACO beneficiary assignment mechanism found at 42 C.F.R. § 425.402).

^{271.} Id.

^{272.} Mark C. Shields, et al., A Model For Integrating Independent Physicians into Accountable Care Organizations, 30 no. 1 HEALTH AFF. 161 (2010).

340 DEPAUL JOURNAL OF HEALTH CARE LAW [VOL. 14.2:309

benefits in fact waiting may result in potential ACOs' inability to take advantage of current relaxed waivers. Healthcare providers should consider the shift toward pay-for-quality delivery models, take advantage of the favorable waivers, and dive head first into the ACO pool.