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Breaking Down Barriers to Creating Safety-Net Accountable Care Organizations: *Federal Statutory and Regulatory Issues*

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EXECUTIVE SUMMARY

The implementation of the Patient Protection and Affordable Care Act of 2010 (“PPACA”) is underway. A lively national debate on Medicare and Medicaid reform is also underway. No section of the PPACA straddles both of these events as well as section 3022 of the statute and its proposed implementing regulations, concerning accountable care organizations (“ACOs”). The effort to promote new forms of efficiently-integrated health care delivery and payment speaks to a two-fold desire to bend the health care cost curve while obtaining better health care outcomes. ACOs propose to do both.

Health care safety-net providers will have much of their world re-invented by the PPACA. Most remarkably, a substantial number of uninsured individuals now served by safety-net providers will become insured. The safety net’s commitment to serving the underserved will have to be both revised and refined in light of this.

ACOs offer a format in which health care providers and patients both benefit from systemic rewards for providing better, more integrated care and obtaining better health outcomes. ACOs are premised on the belief that providers and patients are aligned in their interests. Nowhere is this more true than in the safety net, where the underserved also should reap the benefit of health care reform’s emphasis on higher quality integrated health care.

Safety-net providers have not yet been as nimble as commercial insurance-funded providers in re-inventing themselves as integrated health care delivery systems. This is partially because venture capital is not available to these providers to stimulate planning for this transformation. It is also due to confusion over legal and regulatory barriers to safety-net ACO formation. In particular, uncertainty about federal legal and regulatory barriers to safety-net ACO formation has centered on provider compensation constraints, fair competition law and federal tax policy.

This policy brief addresses each of these issues and makes specific federal policy recommendations targeted at resolving the confusion surrounding these issues. We make specific recommendations about accommodating the needs and limitations of safety-net providers in the legal and regulatory framework for ACOs. Our strongest recommendation is that federal regulatory entities overseeing ACO rollout streamline the administrative responsibilities associated with complying with existing and modified legal and regulatory barriers. This would help to create breathing room for safety-net providers and other entities interested in forming ACOs. The most efficient way to do this would be to develop comprehensive program guidelines on safety-net ACO formation that cut across substantive regulatory areas. This policy brief makes the case for this approach while advancing specific proposals to clarify and rectify legal and regulatory barriers to ACO formation in the safety net.

Breaking Down Barriers to Creating Safety-Net Accountable Care Organizations: *Federal Statutory and Regulatory Issues*

INTRODUCTION

Accountable Care Organizations (“ACOs”) are one of several new forms of health care provider and delivery arrangements created under the Patient Protection and Affordable Care Act of 2010 (“PPACA”). Although the concept of organizing delivery and finance to provide more cost-effective health care is not new,¹ the federal government’s widespread promotion of ACOs is groundbreaking.² The goal is nothing less than to fundamentally restructure the way in which Americans receive health care services by creating financial incentives that reward quality and outcomes of care while restraining the growth in costs.

Accountable care incorporates both health care delivery and health care payment reform. An ACO is best understood as a group of health care providers and institutions that are collectively responsible for (and held accountable to measures of) the health of a population and that has an organizational structure that encourages improvements in quality and lower costs through payment incentives.³ Providers involved in accountable care must offer care that is integrated at a level that may be unfamiliar to their practice and to their patients. Providers that are independent may have to learn to cooperate to provide this integrated care. And new forms of provider cooperation and integration inevitably call into question old statutory and regulatory frameworks designed for a fragmented system.

Although the states and the federal government share concurrent regulatory authority over health care, the nature of government-funded health insurance renders much of the provision of health care within California’s safety net a matter of overlapping federal, state, county and local concern. Medicare in particular — as an exclusively federally funded program — illustrates the truism that all health care is local. Medicare is exclusively federally funded but almost all Medicare service delivery is local and sustained by information and other resources at local, state and federal levels.

¹ Stephen M. Shortell & Lawrence P. Casalino, *Health Care Reform Requires Accountable Care Systems*, 300 JAMA 95, 95-97 (2008) (explaining the ability of a coordinated and accountable system to improve the quality and decrease the costs of health care); Medicare Payment Advisory Commission (MedPAC), *Improving Incentives in the Medicare Program* (2009), available at http://www.medpac.gov/documents/jun09_entirereport.pdf.

² 42 U.S.C.A. § 1395cc-4 (West 2010) (creates Medicare pilot program to be set up under the new health reform law to test “bundled payments” for certain “applicable conditions” around a hospitalization).

³ Austin Frakt, *The Downside of ACOs*, *The Incidental Economist*, July 12, 2010, <http://theincidentaleconomist.com/wordpress/the-downside-of-acos>.

It is no accident, then, that the Centers for Medicare and Medicaid Services (“CMS”) have chosen to issue their first proposed ACO regulations⁴ in the Medicare program under an ACO project called the Medicare Shared Savings Program (“MSSP”). In Medicare, CMS has the funding, the utilization data and the leverage it needs to monitor a program that measures health care design and delivery success across many dimensions. Medicare serves a cross section of Americans, including the majority of Americans over the age of 65 and disabled individuals with sufficient work history.

Safety-net providers are a varied group with a common purpose – to provide health care services to the underserved. The health care safety net has no standardized definition, a legacy of its lack of formal structure.⁵ “Generally, though, the safety net includes public hospitals and health systems, health care districts, community health centers and clinics and for-profit and nonprofit health care organizations that provide free or discounted care.”⁶ More specifically, the Institute of Medicine has defined the health care safety net as: “those providers that organize and deliver a significant level of health care and other related services to uninsured, Medicaid, and other vulnerable patients.”⁷ Health care safety-net providers are distinguished by an explicit mandate or mission to serve patients regardless of their ability to pay and by the fact that a substantial share of their patient mix is uninsured or Medicaid eligible. This means public hospital systems, federal, state, and locally supported community health centers or clinics, special service providers, community hospitals, private physicians, and ambulatory care sites may all fall within the definition of safety-net provider. All of these entities are touched in some way by the promise of ACOs in the safety net.

Core safety-net providers typically target a Medicaid population as part of their service to the underserved, but may also serve lower income Medicare beneficiaries. Indeed, Medicare provider participation in the safety net is on the rise.⁸ This is particularly true in California’s rural and medically under-served counties where socioeconomic stratification of health care delivery is not as pronounced as elsewhere and it is possible to see an entire cross-section of a community receive health care at a community clinic.

Medicare experimentation is often the bellwether for Medicaid⁹ and commercial insurance experimentation. Indeed, the MSSP proposed regulations specifically contemplate that much of what is eventually promulgated for Medicare ACOs may hold true for Medicaid ACOs as well as ACOs in the commercial insurance arena.¹⁰ For this reason alone, safety-net providers interested in safety-net ACO participation need to focus on the MSSP program and CMS needs to focus on the implications of the MSSP program for safety-net providers.

⁴ The final regulations are expected to be released in early fall, 2011.

⁵ Megan McHugh et al., *Understanding the Safety Net: Inpatient Quality of Care Varies On How One Defines Safety-Net Hospital*, 66 Medical Care Research and Review 590, 590-604 (April 27, 2009), available at <http://mcr.sagepub.com/content/66/5/590.full.pdf>.

⁶ Elizabeth Saviano, California Healthcare Foundation, California’s Safety-Net Clinics: A Primer 2 (2009), available at <http://www.chcf.org/~media/Files/PDF/S/PDF%20SafetyNetClinicPrimer.pdf>.

⁷ Institute of Medicine. 2000. *America’s Health Care Safety Net*. Washington, DC: National Academy Press.

⁸ Saviano, *supra* note 6.

⁹ Medicaid is federally funded but administered by the states. California’s version is called Medi-Cal.

¹⁰ Medicare Program: Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. at 19,592 (proposed April 7, 2011) (to be codified at 42 C.F.R. pt. 425).

CMS's intent to paint with a broad brush across the ACO landscape is praiseworthy for its acknowledgement that efficiency may demand consistency in program design and operation across product markets. However, the proposed regulations (and comments thereon) that have emerged do little to identify and respond to the specific concerns of safety-net entities interested in forming ACOs. Safety-net providers interested in ACO formation must confront questions about participant eligibility, financial viability, and conflicts between the pre-existing health care legal and regulatory framework and the guidelines being developed to shape ACO formation.

This set of policy briefs attempts to fill this gap. This brief, the first in the series, will focus on the federal legislative and regulatory barriers to safety-net ACO formation. A second brief will focus on the state legislative and regulatory barriers to safety-net ACO formation. The final policy brief in this series will annotate and expand on the project's Safety-Net ACO Readiness Instrument. All three policy briefs, together, are designed to identify and clarify legal and regulatory barriers – federal, state, county and local – to ACO formation in the safety net.

Legal and Regulatory Barriers to ACO Development in the Safety Net: A Snapshot of the Present

Section 3022 of the Patient Protection and Affordable Care Act (“PPACA”) outlines a new form of integrated health care delivery and finance designed to coordinate care by aligning provider, patient and payer incentives for improved, cost-effective care. ACOs represent only a fraction of the total text of the PPACA, but they have been occupying much of the integrated care discussion of the PPACA – because of the promise of a new form of integrated care delivery across payers and because of the speed with which the Center for Medicare and Medicaid Services (“CMS”) proposes to roll them out.¹¹

On March 31, 2011, CMS released proposed regulations for the MSSP.¹² In addition, and as part of the inter-agency collaborative administrative process, other ACO-related guidelines were issued:

- CMS and HHS Office of Inspector General (OIG) jointly issued a notice with comment period outlining proposals for waivers of certain Federal laws—the physician self-referral law, the anti-kickback statute and certain provisions of the civil monetary penalty law—in connection with the Shared Savings.¹³
- The Federal Trade Commission and the Department of Justice jointly issued a “Proposed Statement of Enforcement Policy Regarding Accountable Care

¹¹ See, e.g., NPR, Accountable Care Organizations Explained, January 18, 2011, <http://www.npr.org/2011/04/01/132937232/accountable-care-organizations-explained>.

¹² Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. at 19,528, (proposed March 31, 2011) (to be codified at 42 C.F.R. pt. 425).

¹³ Medicare Program; Waiver Designs in Connection With the Medicare Shared Savings Program and the Innovation Center, 76 Fed. Reg. 19,655 (proposed April 7, 2011).

Organizations Participating in the Medicare Shared Savings Program” (Antitrust Policy Statement).¹⁴

- The Internal Revenue Service (IRS) issued a Notice (“IRS Notice”) requesting comments regarding the need for guidance on participation by tax-exempt organizations in the Shared Savings Program through ACOs.¹⁵

Even before the early June close of the comment period, two other Medicare ACO initiatives were introduced by the Center for Medicare and Medicaid Innovation (“CMMI”) – the introduction of the Pioneer ACO Program¹⁶ and the Advance Payment ACO Model,¹⁷ both designed to broaden the opportunity for varied health care providers to participate in the development of ACOs. The Pioneer ACO Program, in particular, confirmed what many had suspected – that the health care delivery model found in the Medicare Physician Group Practice Demonstration Project¹⁸ would meet the requirements of a Pioneer Project ACO program participant.¹⁹ This was heartening news for those looking for real world examples of ACO-like organizations. None of the participants in the Medicare Physician Group Practice Demonstration Project was exclusively safety-net-focused, however.

Therefore, through the rulemaking process now underway, CMS and CMMI have already made progress in identifying some of the legal and regulatory barriers that may dampen enthusiasm for safety-net ACO formation. We highlight these developments, where useful. But not all safety-net ACO legal and regulatory barriers have been completely resolved. Chief among the federal legislative and regulatory barriers to safety-net ACOs are three areas in need of further amplification or clarification.

Focusing on the primary federal legislative and regulatory barriers to safety-net accountable care formation and operation, this policy brief will address:²⁰

- Provider compensation constraints
- Fair competition law
- Federal tax policy

These are all issues relevant to safety-net providers interested in ACO formation.

¹⁴ Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 21,894 (Fed. Trade Comm’n proposed Apr. 19, 2011) [hereinafter *Antitrust Policy Statement*].

¹⁵ Notice 2011-20, Internal Revenue Service, available at <http://www.irs.gov/pub/irs-drop/n-11-20.pdf>. [hereinafter *IRS Notice*].

¹⁶ The program announcement and application form may be found at <http://innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/pioneer-aco>.

¹⁷ The program announcement may be found at <http://innovations.cms.gov/areas-of-focus/seamless-and-coordinated-care-models/advance-payment>.

¹⁸ Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108–173, 117 Stat. 2066 (2003) (Established Medicare Physician Group Practice).

¹⁹ *Id.*

²⁰ A later policy brief will focus on state legislative and regulatory barriers to safety-net ACO formation.

Provider compensation constraints are important because they raise the question of whether specific safety zones contemplated in the federal fraud and abuse laws open enough room for safety-net entity participation in ACO formation and whether safety-net entities will be able to comply with the financial and organizational demands of these safety zones. Similarly, fair competition law constraints are important because they raise the question of whether the antitrust safety zones carved out for ACO formation will be accessible to safety-net ACOs and whether safety-net entities will be able to garner the resources²¹, when necessary, to make the data driven case for safety zone exemption. Finally, federal tax policy relating to business relationships between non-profit health care entities and for profit health care entities are implicated by ACO formation that extends beyond conventional in-patient and out-patient settings, something that will likely be of particular interest to less well capitalized safety-net ACOs.

Safety-Net ACO Formation and Operational Requirements Relating to Provider Compensation

Safety-net ACOs may take many forms. The MSSP proposed regulations specifically decline to limit the possible organizational forms of nascent ACOs. Safety-net ACOs may have to be particularly entrepreneurial in their design if the participating entities have no culture of integrated care across venues. This makes understanding the applicability of the federal Stark Law,²² Anti-Kickback Statute,²³ and Civil Monetary Penalty Statute²⁴ to safety-net ACO formation and operation more pressing because it is these fraud and abuse statutes and regulatory scheme that will shape shared savings agreements in all types of ACOs. The particular relevance of provider compensation constraints for safety-net ACOs is that the formidable monitoring and compliance burden the MSSP requires may disproportionately burden safety-net ACOs. And while this section of the policy brief focuses on the implications of provider compensation constraints on safety-net ACOs, the problem is larger. Much, if not most, of the broader fraud and abuse risk lies in material non-compliance with the structure and process requirements of an ACO and the accompanying data reporting requirements.²⁵ And it is these requirements that also disproportionately burden safety-net entities.

Medicare's existing fraud and abuse laws are overwhelmingly unchanged by the MSSP program. Carefully-tailored exceptions have been proposed by the Office of the Inspector General ("OIG") and CMS to create enough room inside the general prohibitions on physician self-dealing to allow a new form of health care delivery and finance to flourish

²¹ The role of limited capital and administrative resources in inhibiting safety-net ACO formation is a reality that cuts across every issue discussed in this policy brief. Safety-net providers, operating at lower costs, may find it even more difficult to demonstrate the level of shared savings required by ACO participation. Although this issue brief does not specifically address capitalization constraints, their existence looms over the entire discussion.

²² 42 U.S.C.A. § 1395nn (West 2010).

²³ 42 U.S.C.A. § 1320a-7b(b) (West 2010).

²⁴ 42 U.S.C.A § 1320a-7a (West 2010).

²⁵ Kathleen McDermott, Medicare ACOs: Fraud and Abuse Perspectives, 23, <http://www.morganlewis.com/index.cfm/eventID/454786a3-d721-4408-8f8b-5543cfe66fab/fuseaction/event.detail>.

– one premised on providers sharing a financial stake in outcomes. While Fraud and abuse laws play a vital role in the Medicare system, waiving them for MSSP payments and in other circumstances, as CMS has proposed, is equally essential to the success of the MSSP.

Shared Savings within the Safety-Net ACO – Stark Law Breathing Room

Stark Law generally prohibits a physician or family member with a financial relationship in a health care entity from making a referral to that entity for certain Medicare-funded health services. This strict liability statute raised some early concerns over ACO formation.

Most safety net providers are not in a position to establish ownership or financial interests as health care referral recipients. Fraud and abuse laws, overwhelmingly designed to police these interests, are, as a result, of less relevance to safety-net providers.

In response, OIG and CMS have proposed a waiver of the Stark Law’s general prohibition on physician self-dealing for the distribution of shared savings received by ACOs to their participants for activities necessary for and directly related to the ACO’s operation.²⁶ In addition, Stark Laws already include an exception for direct compensation arrangements.²⁷

Policy Recommendation:

Further guidance is needed on how to identify the ACO self-dealing waiver and the pre-existing exception for direct compensation arrangements, for reporting requirements. CMS and the cooperating agencies also need to consider the disproportionate burden new fraud and abuse law reporting and compliance requirements place on safety-net entities considering ACO formation.

Shared Savings Within the Safety-Net ACO – Anti-Kickback Statute Breathing Room

The federal anti-kickback statute prohibits knowing payment to another in order to induce referrals for Medicare health services. This statute also raised early questions about the scope of permissible ACO shared savings payments.

In response, OIG and CMS have proposed to waive the Anti-Kickback Statute’s prohibition on rewarding referring providers by the waiver of the statute for any financial relationship between and among ACO participants, providers and suppliers that is necessary for and directly related to the ACO program and that implicates a Stark Law exception.²⁸

Gain Sharing and Safety-Net ACOs

The Civil Monetary Penalty (“CMP”) Statute’s prohibitions on gain sharing present the strongest and clearest contrast to the ACO premise. A broad prohibition on an

²⁶ 42 U.S.C.A. § 1395nn (West 2010).

²⁷ 42 C.F.R. 411.35(c)(2).

²⁸ 42 U.S.C.A. § 1395nn (West 2010).

individual sharing in the increased profits of an organization – at the heart of the Civil Monetary Penalty Statute – finds its Waterloo at ACO design. The ACO concept rejects the Civil Monetary Penalty Statute’s formative assumption that providers rewarded for improved benefit to the organization would violate Medicare’s mandate to provide reasonable and necessary medical services.²⁹

CMS and the OIG have proposed waiver of the Civil Monetary Penalty Statute’s gain sharing provisions for the distribution of sharing savings generated by an ACO so long as the payments are not made to induce limitations on medically necessary services.³⁰ In short, the proposed guidelines remove accusations of stinting from the definition of Civil Monetary Penalty Statute violations, so long as the gain sharing payments are to reward compliance with the Medicare statute and the quality and performance measures required by the MSSP.

Policy Recommendation:

CMS and OIG should offer further clarification on the CMP waiver’s applicability to providers and suppliers outside the ACO. Drawing on resources outside of the ACO may be particularly important for smaller, less well-capitalized ACOs, such as safety-net ACOs.

Physician Compensation Constraints for Safety-Net ACOs – Administrative Burden

CMS specifically solicited comments on the necessity of waivers for arrangements related to ACO formation, compliance with MSSP regulations, or building IT and administrative capacity. As with any legal issue, safety-net ACOs will struggle with capacity. Not only does the proposed regulations’ requirement of an added compliance official³¹ potentially drain safety-net providers’ coffers, but the addition of new regulations that require research and advice could also mean an increased financial burden for the safety net. The proposed fraud and abuse waiver designs are no exception. Therefore, CMS should consider whether safety-net providers should be permitted to substitute another professional, such as a general counsel or head of administration, in the compliance official role.

There will be substantial legal work to do in the initial years of the program. For example, the phrase “necessary for and directly related to” will no doubt require interpretation by CMS, OIG and providers themselves before a working definition emerges. In a larger example, financial relationships other than shared savings payments must meet an existing exception to the Stark laws in order to be legal under the proposed waivers. Many such exceptions exist, such as bona fide employment relationships, personal service relationships and indirect compensation arrangements. However, obtaining sound legal advice about the new types of financial relationships under the MSSP may require more legal resources than safety-net providers have previously enlisted. Thus, there is a chance that in

²⁹ 42 U.S.C.A. § 1395x(ddd)(1) (West 2010).

³⁰ 42 U.S.C.A. § 1395x(ddd)(1) (West 2010).

³¹ 42 C.F.R. § 425.5(d)(10)(i)(A).

spite of the proposed waiver designs, legal issues like fraud and abuse may prove to be obstacles or disincentives to safety-net ACO formation.

Policy Recommendation:

CMS should consider whether it can offer technical legal assistance, such as CMS or HHS-OGC attorneys, to assist safety-net providers in navigating this facet of the MSSP.

Overview: Fair Competition Concerns and ACOs

The success of Medicare ACO initiatives, whether through the Medicare Shared Savings Program or the Pioneer ACO Program, will be judged in part by whether they involve provider groups of all types, not only large integrated group practices with affiliated hospitals or large practice groups affiliated with large commercial insurers. Moreover, health care providers are more likely to integrate their care delivery for Medicare beneficiaries through ACOs if they can also use the ACOs for commercially insured patients.³² “[P]roviders’ main purpose in forming ACOs may not be to achieve cost savings to be shared with Medicare but to strengthen their market power over purchasers in the private sector.”³³

The success of all of CMS’s ACO initiatives should also be measured by the opportunity they present to providers, patients and payers in the safety net to reap the benefits of more fully-integrated health care.

Fair competition concerns relevant to safety-net ACO formation and operation are two-dimensional: concerns with increased provider or insurer concentration inhibiting safety-net ACO formation or operation, and concerns with satisfying ACO fair competition requirements for safety-net ACO formation.

Provider and Insurer Concentration Issues in the Safety Net: The Problem of Access to Specialists

Safety-net providers are typically not motivated by the drive to strengthen their market power over purchasers in the private sector. They will, however, run the risk of failure to be competitive in an increasingly concentrated market for specialists. If a safety-net provider’s ultimate ACO goal is a “publicly sponsored health care delivery system that combine[s] a primary care base built around community health centers with safety-net hospitals and the specialists that serve them,”³⁴ then specialists will need to play a major role in safety-net ACO formation. The availability of specialists for safety-net ACO participation

³² Fed. Trade Comm’n & Dep’t of Health and Human Serv., Workshop Regarding Accountable Care Organizations, and Implications Regarding Antitrust, Physician Self-Referral, Anti-Kickback, and Civil Monetary Penalty (CMP) Laws (Oct. 5, 2010).

³³ Clark C. Havighurst & Barak D. Richman, *The Provider Monopoly Problem in Health Care*, 89 OR. L. REV. 847, 872 (2011).

³⁴ John Zweifler et al., *Creating an Effective and Efficient Publicly Sponsored Health Care Delivery System*, 22 J. HEALTH CARE POOR UNDERSERVED 311, 316 (2011).

may be diminished by the “growing frenzy of mergers involving hospitals, clinics and doctors’ groups eager to share costs and savings, and cash in on the incentives.”³⁵ Equally remarkable, though less noted, is the recent spate of insurer and hospital acquisitions of physician groups.³⁶ We are in the midst of what has been labeled a “post-reform merger wave.”³⁷ But what is optimal for commercial insurance companies and hospitals may be far from optimal for ACOs in the safety net. Insurance companies and hospitals are pursuing doctors in response to increasing financial pressure to control costs. One way to control costs is to attempt to control physicians through the employment relationship.³⁸ Whatever the merits of such an approach for commercial insurers and hospitals, nascent safety-net ACOs will need access to a robust roster of specialists ready, willing and able to participate in a safety-net ACO through either the MSSP or the Pioneer Program.

Great care has been given in the Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program Antitrust Policy Statement to limit the safety zones³⁹ of independent ACO participants (such as physician group practices) to a combined share of 30 percent or less of each common services in each Primary Service Area.⁴⁰ However, the calculation of the ACO’s share of services, as outlined in the document’s Appendix, relies on the identification of Primary Service Areas based on retrospective ZIP code data. The PSA is a backward looking method. It tells us nothing about the willingness of important groups, like specialty physicians, to participate in Medicare going forward and whether those continuing to participate in Medicare are willing to serve a safety-net population. A number of California specialty physicians, for example, accept Medicare only with the supplement of a substantial Medicare patient annual fee,⁴¹ a requirement unlikely to make them accessible to the safety-net patient population. CMS should counter this potential obstacle with rewards and/or incentives for specialists who participate in ACOs with safety-net providers.

³⁵ Havighurst & Richman, *supra* note 31, at 850 n.7, citing Robert Pear, *Consumer Risks Feared as Health Law Spurs Mergers*, N.Y. TIMES, Nov. 20, 2010, available at

<http://www.nytimes.com/2010/11/21/health/policy/21health.html>.

³⁶ Christopher Weaver, *Managed Care Enters the Exam Room as Insurers Buy Doctor Groups*, Kaiser Health News, July 1, 2011, <http://www.kaiserhealthnews.org/Stories/2011/July/01/unitedhealth-insurers-buy-doctors-groups.aspx>.

³⁷ Tim Greaney, *Accountable Care Organizations and Antitrust: A New PSA Test* (April 1, 2011); available at <http://www.healthreformwatch.com/2011/04/01/a-new-psa-test>.

³⁸ All physician employment relationships must also comply with federal fraud and abuse rules as well.

³⁹ Special “dominant provider” rules limiting exclusive contracts may supply some relief in specialty physician starved areas. An ACO with a participant holding greater than 50 percent share in a given PSA for any service that no other ACO participant provides to patients in that PSA, requires that the dominant provider must be non-exclusive to the ACO to fall within the safety zone. These non-exclusivity rules do not apply outside these safety zones.

⁴⁰ *Antitrust Policy Statement*, *supra* note 13.

⁴¹ Christopher Weaver, *As Medicare Pay Shrinks, Some California Docs Hike Patient Fees* (March 16, 2010), http://www.npr.org/blogs/health/2010/03/calif_heart_docs_hike_patient.html.

Policy Recommendation:

Nothing done to establish the program should worsen pre-existing problems with safety-net Medicare provider participation. Therefore we recommend incentives and/or rewards for specialists who collaborate with safety-net providers. We also recommend the enactment of a rule that excludes all Medicare providers who require supplemental annual fees from the calculation of available specialists by authorities performing fair competition analysis.

Safety-Net ACOs and Compliance with Fair Competition Law

Fair competition law protects competition, not competitors.⁴² As a practical matter, this means that fair competition law offers no favored treatment to particular competitors in the health care marketplace. The premise of fair competition law is that consumer welfare is maximized through free and open competition. This is as true in health care markets as elsewhere, though health care markets are acknowledged to be imperfect.⁴³ This is particularly so with regard to the presence of information asymmetries as to third-party payers that make it difficult for some consumers to choose between competing health care providers. There has, as a result, grown up a specialized body of fair competition law in the area of health care acknowledging the existence of information asymmetries and the significant role of third party payers.

Since the rise of nationwide managed care, multi-state health insurance firms and large physician practice groups, federal fair competition law has focused on the amount of provider and payer concentration allowed in integrated care and finance delivery models.⁴⁴ The United States Department of Justice and the Federal Trade Commission, exercising their concurrent authority over federal fair competition law in the health care arena, cooperated to issue joint Statements of Antitrust Authority in Health Care⁴⁵ in 1996. Guideline Eight, on Physician Network Joint Ventures, has been of particular interest to those developing fair competition law guidance for ACOs. Guideline Eight's interpretation has been a subject of considerable dispute – both in advisory opinions and enforcement actions.⁴⁶ Although it has been clear that clinically integrated providers may be protected from fair competition law enforcement actions, there was uncertainty about the scope of this protection to providers organizing ACOs.⁴⁷

⁴² See generally, Robert Bork, *The Antitrust Paradox* (1993).

⁴³ See generally, FTC and DOJ, *Improving Health Care: A Dose of Competition* (2004), available at <http://www.ftc.gov/reports/healthcare/040723healthcarerept.pdf>.

⁴⁴ FTC and DOJ, *Statements of Antitrust Enforcement Policy in Healthcare*, 75 (1996), available at <http://www.justice.gov/atr/public/guidelines/0000.htm> [hereinafter *Guideline Eight*].

⁴⁵ *Id.*

⁴⁶ See, e.g., FTC Formal Commission Action regarding Brown and Tolland Medical Group, available at <http://www.ftc.gov/os/2003/07/caadmincmp.pdf>, FTC Advisory Opinion regarding MedSouth, available at <http://www.ftc.gov/bc/adops/medsouth.shtm> and available at <http://www.ftc.gov/bc/adops/070618medsouth.pdf> (a subsequent follow-up letter to MedSouth).

⁴⁷ *Antitrust Enforcement in the Health Care Industry: Hearing Before the Subcomm. On Courts and Competition Policy and the H. Comm. on the Judiciary*, 111th Cong. (2010) (statement of Richard A. Feinstein, Director of the Bureau of Competition at the FTC), available at <http://www.ftc.gov/os/testimony/101201antitrusthealthcare.pdf>.

Responding to this uncertainty, the Federal Trade Commission and the Antitrust Division of the Department of Justice (“the agencies”) issued the Antitrust Policy Statement regarding ACOs participating in the MSSP on March 31, 2011.⁴⁸ This Antitrust Policy Statement built on the earlier Guidelines but offers specific guidance relevant to ACOs. In particular, the Antitrust Policy Statement indicates that competing health care providers seeking to form integrated care organizations will be evaluated under fair competition law’s rule of reason analysis. This would apply if the providers are financially or clinically integrated and if the joint agreement is reasonably necessary to accomplish the procompetitive benefits of the integration. Rule of reason analysis is less stringent, intended to evaluate whether collaboration is likely to have substantial anticompetitive effects, and if so, whether it has potential procompetitive efficiencies likely to outweigh those effects. The greater the likely anticompetitive effects, the greater or more likely the efficiencies must be to pass muster under fair competition law.

Although this announcement of a less stringent standard of review for ACOs creates breathing and growing room for nascent ACOs, these assurances are not as useful to those seeking to launch an ACO as the announcement of ACO fair competition enforcement safety zones. Safety zones, by their very nature, offer prospective guidelines on permissible activity and represent the most cost effective and prospective guidance on how to organize an ACO that will not offend federal fair competition law.

The Antitrust Policy Statements’ antitrust safety zone is designated for ACOs that meet CMS’s eligibility criteria to participate in the MSSP and are highly unlikely to raise significant competitive concerns. The agencies will not challenge ACOs that fall within these safety zones, absent extraordinary circumstances. The ACO fair competition safety zones include:

- Provider groups, such as physician group practices, that provide the same service⁴⁹, so long as they have a combined share of 30% or less of each common service in each participant’s primary service area, unless they are in a rural area.⁵⁰
- Hospital or ambulatory surgery centers that are non-exclusive participants in an ACO

⁴⁸ *Antitrust Policy Statement*, *supra* note 13.

⁴⁹ *Id.* at 21,898, *supra* note 13 (“For example, if two physician group practices form an ACO and each includes cardiologists and oncologists, cardiology and oncology would be common services. If, on the other hand, one physician group practice consists only of cardiologists and the other only of oncologists, then there are no common services and the ACO falls within the safety zone regardless of its share, subject to the dominant provider limitation.”).

⁵⁰ *Antitrust Policy Statement*, *supra* note 13. at 21,897 (defines the rural exception as allowing an ACO to include “one physician per specialty from each rural county (as defined by the U.S. Census Bureau) on a non-exclusive basis and qualify for the safety zone, even if the inclusion of these physicians causes the ACO’s share of any common service to exceed 30 percent in any ACO participant’s PSA for that service. Likewise, an ACO may include Rural Hospitals on a non-exclusive basis and qualify for the safety zone, even if the inclusion of a Rural Hospital causes the ACO’s share of any common service to exceed 30 percent in any ACO participant’s PSA for that service.”).

In addition, dominant providers – those with greater than a 50% market share in the PSA of any service – must be non-exclusive to ACOs to fall within the fair competition safety zones.

The implications of these guidelines and safety zones relating to provider concentration are different for commercial and for safety-net ACOs. Most safety-net providers at present do not approach the size and scale of dominant providers. And there is a specific exemption for entities that grow to the larger market share once an ACO is established.⁵¹ Rural safety-net providers may approach the 50% dominant provider definition and will need to accumulate sufficient data to determine, as a threshold matter, whether the threshold has been met and whether non-exclusivity is an easy fix. This is not a simple matter, however, as many public health clinics do not collect the patient origin data needed to calculate market share. Generating patient origin data from existing patient files or billing records may be possible only at considerable investment of time and money, once again highlighting the substantial burden the administrative requirements of ACOs may place on safety net providers.

Policy Recommendation:

The FTC and DOJ should consider creating special fair competition safety zones for ACOs in rural areas. Everything about the formation requirements needs tailoring to the realities of rural health care if the benefits of safety-net ACOs are to be available to the citizens, providers and payers in rural areas. Specifically, expanding the fair competition safety zones for safety-net ACOs would particularly invite these entities to participate.

Safety-Net ACOs and Compliance with the Federal Tax Code

Tax-exempt institutions that join safety-net ACOs may need to carefully structure their participation to maintain tax-exempt status. A good case can be made that accountable care’s goal of transforming health care will require activity spanning both the public and private health care sectors – which will in turn commingling of organizations of diverse tax status.⁵² Additionally, safety-net ACOs themselves may or may not be tax exempt; the Internal Revenue Service (“IRS”) has not been clear on this point.

The Tax Status of Both ACOs and Constituent Tax-Exempt Participants

The PPACA is silent on the tax status of ACOs. In addition, the IRS has not directly addressed the tax status of ACOs. ACOs, by nature of distributing shared savings to physicians, could potentially be inherent private benefit vehicles, something 501(c)(3) non-profit organizations must take steps to avoid. Further, physicians employed by a health

⁵¹ *Antitrust Policy Statement*, *supra* note 13, at 21,897.

⁵² Robert Wood Johnson Foundation CMS MSSP Comments, June 6, 2011, 4, <http://www.rwjf.org/files/research/72485aco201106.pdf>.

organization may be considered “insiders” and subject the organization to the implication it violated the prohibition on private inurement, jeopardizing non-profit status.⁵³ Although the IRS Notice addresses private inurement and private benefit with regard to the constituent organizations, it is silent how such rules would work for the ACO itself.

Policy Recommendation:

Some ACOs, such as safety-net ACOs, are natural candidates for tax exemption. The IRS should provide specific guidance on this point.

Tax-Exempt Health Care Institutions Must Avoid Private Inurement and Private Benefit to Maintain Their Exemption

A tax-exempt institution’s participation in a safety-net ACO is premised on the receipt of shared savings, a cornerstone of ACO organization. These same shared savings, however, could imperil the exempt institution’s preferential tax treatment if the shared savings are distributed in a way that creates private inurement or benefit to private parties. This principle has developed over a long and storied history of federal tax-exempt status for some health care providers and institutions.

Anticipating this problem, the IRS issued Notice 2011-20, as part of the MSSP ACO formation guidelines. In the IRS Notice, the IRS specifies the requirements under which it “expects that it will not consider a tax-exempt organization’s participation in the MSSP through an ACO to result in inurement or impermissible private benefit to the private party”.⁵⁴

- The terms of the tax-exempt organization’s participation in the MSSP through the ACO (including its share of MSSP payments or losses and expenses) are set forth in advance in a written agreement negotiated at arm’s length
- CMS has accepted the ACO into, and has not terminated the ACO from, the MSSP
- The tax-exempt organization’s share of economic benefits derived from the ACO (including its share of MSSP payments) is proportional to the benefits or contributions the tax-exempt organization provides to the ACO. If the tax-exempt organization receives an ownership interest in the ACO, the ownership interest received is proportional and equal in value to its capital contributions to the ACO and all ACO returns of capital, allocations and distributions are made in proportion to ownership interests
- The tax-exempt organization's share of the ACO's losses (including its share of MSSP losses) does not exceed the share of ACO economic benefits to which the tax-exempt organization is entitled

⁵³ Treas. Reg. § 53.4958-3.

⁵⁴ *IRS Notice*, *supra* note 14.

- All contracts and transactions entered into by the tax-exempt organization with the ACO and the ACO's participants, and by the ACO with the ACO's participants and any other parties, are at fair market value⁵⁵

These rules are as applicable to safety-net ACOs as to those outside the safety net.

Thus, while the IRS Notice gives specific guidance, it stops short of a blanket safe harbor for tax-exempt institutions, instead favoring a case-by-case determination, based on all the facts and circumstances.⁵⁶ ACOs formed by safety-net hospitals may have a particular need to attract physicians with below-market-cost benefits such as electronic health record training, administrative assistance and above-market-rate salary to compensate for initial anticipated losses to practice revenue.⁵⁷ It may also be difficult to set forth the actual payments or losses in advance. Rather, ACOs may be limited to setting forth the methodologies in advance, depending on the savings achieved, to align incentives properly for maximum savings.

Policy Recommendation:

Safety-net ACOs face a uniquely difficult proportionality determination because they are likely to capitalize themselves with grants, making it less clear still how to allocate shared savings properly. Further, this requirement may go beyond CMS's Notice of Proposed Rulemaking, in that it requires shared savings of losses proportionately. The IRS should clarify what the proportionality determination requires of those backed not by venture capital but by foundation grant money or government funds. As previously stated, while the proposed regulations state MSSP payments will be distributed to parties in proportion to savings realized, the IRS suggests such payments be distributed to capital ownership interests in the ACO, a different approach. The IRS should consider revising this requirement entirely, or in the alternative, clarify how it will operate in tandem with the requirements in the final MSSP regulations.

Joint Ventures Necessary to Form ACOs Could Imperil Tax-Exempt Participants' Exemption

ACOs formed out of joint ventures may bring together non-profit and for-profit entities.⁵⁸ A non-profit hospital, for example, may enter a joint venture with a large for-

⁵⁵ *Id.* at 7-8.

⁵⁶ *IRS Notice*, *supra* note 14, at 7.

⁵⁷ Physician recruitment practices are also the concern of the fraud and abuse laws.

⁵⁸ 42 U.S.C.A. § 1899(b)(1) (West 2010) (This is not the only way to form an ACO. The ACA amended §1899 of the Social Security Act to include examples of how shared governance in an ACO might work: (1) ACO professionals in group practice arrangements; (2) networks of individual practices of ACO professionals; (3) partnerships or joint venture arrangements between hospitals and ACO professionals; (4) hospitals employing ACO professionals; and (5) such other groups of providers of services as suppliers as the Secretary determines appropriate).

profit practitioner group or with a for-profit skilled nursing facility to coordinate care across venues. Such a joint venture, if improperly planned, could affect the tax exemption of the non-profit entity. As indicated above, the IRS maintains a facts and circumstances test of such ventures, in which control tends to be quite important.

The IRS Notice itself takes apparently conflicting positions. It points to Rev. Rul. 98-15 as valid precedent (establishing that a facts and circumstances investigation was necessary to determine if a tax-exempt institution retained sufficient control in a joint venture with a for-profit entity). However, the IRS Notice also cites Rev. Rul. 2004-51 as valid (establishing that equal voting control in a joint venture between a for-profit and a non-profit entity may be acceptable, provided certain safeguards exist in the governing documents to retain key charitable functions by the non-profit entity). It is possible to read these consistently to mean that the formal control rule may not be an absolute requirement for ACOs.

Some responses to the IRS Notice point to a contradiction between the IRS's guidelines regarding joint ventures and the PPACA and the subsequent proposed MSSP regulations.⁵⁹ Specifically, the PPACA requires that ACOs govern themselves with proportional representation from all participating providers.⁶⁰ By contrast, the IRS has traditionally required the tax-exempt institution to retain control. However, it is not clear that the two stances are truly incompatible. For example, in a joint venture between a non-profit hospital and a skilled nursing facility, the hospital may rightly retain voting control, particularly if it provides the majority of care through its existing network of physicians and acute care facilities. Many non-profit hospitals that are good candidates to form ACOs already operate outpatient clinics as well, particularly among safety-net providers. Even in the event of an even split of board votes among for-profit and non-profit entities, the founding documents could be written to address what happens in the event of a tie so as to favor the non-profit entity for certain key charitable matters. Alternatively, the tax-exempt hospital could potentially take sole responsibility for certain exempt functions, as in Rev. Rul. 2004-51, and leave the rest to the board.

The governing situation potentially becomes much more complex when a non-profit hospital or clinic collaborates with multiple for-profit entities, such as a physician group and a skilled nursing center. If governance were shared 40% for the hospital and 30% each for the other two entities, such a joint venture could conflict with the control requirements in that the exempt entity would lose its majority. This issue is not likely to be a problem for

⁵⁹ See, e.g., AHCA comments to Notice 2011-20, 2, obtained by emailing notice.comments@irs.counsel.treas.gov.

⁶⁰ 42 U.S.C.A. § 1395j(j)(b)(1) (West 2010) (ACO participants must “establish[] a mechanism for shared governance.”).

safety-net ACOs formed from previously integrated health care organizations. It is hard to see, however, how a safety-net ACO could integrate with a skilled nursing facility without confronting these issues. Roughly half of all nursing homes in the United States are for-profit facilities⁶¹ and some states, such as California, have relatively few non-profit nursing homes.⁶²

Policy Recommendation:

The IRS should provide greater clarity as to how tax-exempt institutions can avoid private inurement and private benefit to maintain their exemption. This issue is, of course, larger than ACOs, but of pressing importance to tax-exempt entities who will need to form relationships with commercial health insurance entities in order to form safety-net ACOs.

⁶¹ CMS Nursing Home Data Compendium (2009) Table 1.2.B, 22, http://www.cms.gov/CertificationandCompliance/Downloads/nursinghomedatacompendium_508.pdf.

⁶² *Id.*

CONCLUSION

One measure of the success of the PPACA will be in how well it improves more cost-effective health care outcomes for diverse groups of Americans by the promotion of integrated care across venues. This will also be one of the PPACA's greatest challenges. Just as health care is fragmented, health care finance is also fragmented. ACOs are designed to integrate both the delivery of and the payment for care in a way that recognizes that neither can be integrated successfully without the other.

Our health care safety net is as fragmented as the rest of our health care system. And its chief sources of funding for patient care, reimbursement for government funded health insurance recipients, are also fragmented. The decision to launch a safety-net ACO is, as a result, not a simple one. The complexities of the legal and regulatory barriers involved are reflected in the length of the MSSP proposed regulations and in the volume of discussion and debate surrounding the regulatory process.

Many of the challenges involved in ACO formation require reform internal to safety-net organizations. But many others will require collaborative effort between and among the governmental entities that regulate health care. It is a sign of significant foresight that, as a result, CMS has initiated unprecedented cross-agency collaboration in the regulatory process to usher in the MSSP. Adoption of any of the policy recommendations in this policy brief will similarly require cross-agency collaboration.

Safety-net providers will need to marshal their administrative and financial resources wisely to form an ACO. This makes it all the more important to address the need for a streamlined, tailored process for complying with the MSSP's fair competition, fraud and abuse and federal tax concerns.

Advice relevant to safety-net entities interested in ACO formation is found scattered throughout the collaborative proposed regulations and policy guidelines issues for the MSSP. Safety-net entities, particularly those with fewer administrative resources, could assimilate the final MSSP regulations more easily if the legal and regulatory guidance were provided in a focused, comprehensive format targeted to safety-net ACO formation. Such tailored, streamlined guidance targeted to ACO formation in the safety net, presented in one comprehensive document (cross-referencing others, as needed) would do much to advance the real goal of encouraging ACO formation in the safety net.

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