



# HEALTH CARE POLICY



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## **An Overview of the Administration's ACO Policy: Opportunities and Challenges**



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### **Introduction**

**F**or nearly a century, proponents of health reform have advocated for greater clinical integration to improve quality, promote efficiencies, and control costs. A seminal 1932 report issued by the Committee on the Costs of Medical Care called for the provision of care through group practice arrangements as part of a broader set of recommendations that included universal coverage, extension of public health services to the en-

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tire population, and a major investment in health professions education. Resistance to its findings was a key factor in convincing the Roosevelt Administration to abandon national health insurance in the original Social Security Act.<sup>1</sup>

The goal of clinical integration remains front and center today, as the nation confronts the consequences of a vastly larger and more complex medical care industry that for decades has operated in a political and policy environment willing to tolerate a high degree of business autonomy, even as evidence of inefficiency, waste, and poor quality has mounted.<sup>2</sup> In the current climate the stakes are much higher. Health expenditures stand at approximately 15 percent of GDP and the Congressional Budget Office projects that they will exceed 25 percent of GDP by 2035.<sup>3</sup> Employer-sponsored health insurance costs are rising at a rate that significantly exceeds growth in worker pay even as coverage shrinks; millions of workers and their families simply do without. Congress is poised to debate the future of Medicare and Medicaid, as well as the future of the Patient Protection and Affordable Care Act (the Affordable Care Act) and its financial commitment to affordability tax credits for the uninsured. As insured Ameri-

<sup>1</sup> Joseph S. Ross, "The Committee on the Costs of Medical Care and the History of Health Insurance in the United States," *Einstein Quart. J. Biol. Med.* (2002) 19: 129-134, at 130; Paul Starr, *The Social Transformation of American Medicine* (Basic Books, N.Y., N.Y. 1982) Book Two.

<sup>2</sup> David A. Hyman, "Health Care Fragmentation: We Get What We Pay For," *The Fragmentation of U.S. Health Care: Causes and Solutions* (Einer Elhauge, ed.) Ch. 2; Thomas Bodenheimer, "Coordinating Care—A perilous Journey Through the Health Care System," 358 *New Eng. Jour. Med.* 1064 (2008).

<sup>3</sup> Douglas W. Elmsdorf, "Economic Effects of the March Health Legislation (2010)" <http://www.cbo.gov/ftpdocs/119xx/doc11945/USC10-22-10.pdf> (Accessed May 2, 2011).

cans watch their insurance coverage slowly disintegrate, and as prospects for access by the uninsured are threatened with loss, the question of how to move health care toward a more sensible organizational and operational design grows more urgent.

The Affordable Care Act does not mandate system redesign but does contain a series of provisions aimed at setting this type of long term restructuring in motion. Chief among the law's restructuring elements is a move toward greater clinical integration of the type that experts have long associated with efficiency and quality.<sup>4</sup> The Affordable Care Act's legislative tools for achieving this result consist of a series of push/pull interventions such as payment reforms and investments in prevention and greater primary care access. Among these tools, two have drawn the most attention, not only because of their technical and legal complexity but because of their aspirational qualities, as well. The first is the Medicare Shared Savings Program (MSSP) whose purpose is to slow program growth while achieving quality reforms through the use of accountable care organizations (ACOs).<sup>5</sup> The second is the Center for Medicare and Medicaid Innovation (CMI)<sup>6</sup> whose mission is to spur, and rapidly diffuse, advances in patient care, particularly for higher cost populations.

Both strategies—the use of broad programmatic financial incentives to achieve greater organizational and operational integration, and direct investment in integrated delivery pilots—represent two dimensions of the same overarching goal. Indeed, the ACA essentially treats the MSSP program through ACOs as a companion to the CMI, specifically barring ACO participation by entities that participate in shared savings models administered by the CMI, as well as the Independence at Home medical pilot program.<sup>7</sup> The CMI's work will unfold through a series of pilots and demonstrations. The MSSP, on the other hand, represents a major effort at broad-based change in Medicare policy, and will be implemented through regulations of general applicability that ultimately will be more fully translated through sub-regulatory guidance and the agreements developed with participating ACOs.

The MSSP proposed rule published on April 7, along with a series of companion policy statements, not only sets out the legal standards that guide agency action but also offers insight into broad policy direction. The task of developing MSSP ACO policy was unusually challenging, because collectively these policies ultimately will affect the entire health care market. Because of Medicare's influence on U.S. health policy, its rules for ACO formation and operation will spill over into the interaction between payers and health care providers more generally, regardless of whether the relationship is part of the self-insured and state-regulated commercial market, the Medicaid market, or (ultimately) the market for qualified health plans sold in state health insurance exchanges. Federal policies in the fields of antitrust enforcement, tax, and fraud and abuse will affect

all forms of coverage as well as the shape of the health care system more generally. As new health care enterprises are formed, state laws governing the corporate practice of medicine and the regulation of risk-bearing health care entities will be drawn in as well. For these reasons, the Administration's collection of ACO-related policies (in the form of proposed rules and policy statements)<sup>8</sup> has attracted unusually great attention from the health care community.

## Legislative Backdrop

It is helpful in understanding the major policy choices made by the Administration in ACO implementation to step back and consider the legislative backdrop against which this collection of policies has emerged. The Affordable Care Act's MSSP provisions empower the Department of Health and Human Services secretary not only to establish the program but to waive Medicare law, as well as certain federal fraud and abuse laws if necessary to implement the program.<sup>9</sup> At the same time, the Affordable Care Act did not alter antitrust law and doctrine but was enacted against a backdrop of longstanding antitrust policies in the field of health care. Similarly, the MSSP statute did not directly alter tax laws and doctrines applicable to participation in market enterprises by tax-exempt charitable entities; instead, implementation takes place within the existing legal framework. Thus, implementation of the MSSP through ACOs can be expected to trigger a series of downstream developments across many fields of law that extend beyond Medicare.

### *The MSSP Statute*

An ACO is essentially an enterprise that manages health care operations and financial arrangements for participating providers, with an eye toward improving performance quality and operational efficiency.<sup>10</sup> In an ACO arrangement, a corporate entity, through its participating providers, agrees to take responsibility for managing practice costs and patient care, and in return, participating providers can qualify for shared savings flowing from improved performance and efficiency. The MSSP statute contains extensive provisions regarding payment models, ACO operational structure, management and governance, and federal management powers. While the law is detailed, it also vests the HHS Secretary with broad and non-reviewable authority over implementation and key policy decisions. This means that the Secretary has the power to resolve am-

<sup>4</sup> Elliot Fisher, Mark McClellan, and John Bertko, *Fostering Accountable Health Care: Moving Forward in Medicare Health Affairs* 28:2 w219-w231 (January 2009); MedPAC, *Accountable Care Organizations*, in *Report to Congress: Improving Incentives in the Medicare Program* (June 2009).

<sup>5</sup> SSA § 1899, added by PPACA § 3022.

<sup>6</sup> SSA § 1115A, added by PPACA § 3021.

<sup>7</sup> § 1899(b)(4), added by PPACA § 3022.

<sup>8</sup> 76 Fed. Reg. 19528. Also published on April 7 was a joint Notice from the Centers for Medicare and Medicaid Services and the Office of the Inspector General regarding waivers of federal fraud and abuse laws in connection with the Medicare Program and the Innovation Center. 76 Fed. Reg. 19655. Related materials were published separately. The Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program was published on April 19 (76 Fed. Reg. 21894). A separate IRS Notice regarding the applicability of the Internal Revenue Code to tax exempt organizations participating in the Medicare Shared Savings Program can be found at <http://www.irs.gov/pub/irs-drop/n-11-20.pdf> (Accessed May 11, 2011).

<sup>9</sup> § 1899(f), added by PPACA § 3022.

<sup>10</sup> See, e.g., Stephen Shortell, Lawrence Casalino, and Elliot Fisher, *Implementing Accountable Care Organizations* (BerkeleyLaw Policy Brief May 2010. p. 2.

biguities raised by the statute itself (an inevitable consequence of legislative policies whose implementation is entrusted to agencies with policy and management expertise).

*ACO payment models.* The statute specifies a basic payment model; under this model “payments shall continue to be made to providers of services and suppliers participating in an ACO under the original Medicare fee-for-service program . . . in the same manner as they would otherwise be made, except that a participating ACO is eligible to receive payment for shared savings”<sup>11</sup> if its quality meets performance standards, and estimated ACO expenditures for assigned patients fall below an estimated spending benchmark developed by the Secretary. In addition, the statute gives the Secretary an “option to use other payment models” that the Secretary deems appropriate, including a partial capitation model as well as “any payment model that the Secretary determines will improve the quality and efficiency”<sup>12</sup> of care. The statute is ambiguous as to whether “other payment models” chosen by the Secretary are intended to supplement the basic approach or can supplant the basic model altogether. This is crucial for two reasons. First, the basic model is designed to maintain the existing payment Medicare fee-for-service payment structure while simply adding in a bonus; by contrast, other models could be risk-based. Second, the “other payment model” approach is subject to budget neutrality requirements that do not apply to the basic payment system.<sup>13</sup>

*ACO size and maturity.* The statute specifies that ACOs must have at least 5,000 beneficiaries assigned in order to participate in the MSSP.<sup>14</sup> In the Physician Group Practice Demonstration program, 5,000 lives were shown to translate into some 50 physicians, making the ACO model established by Congress one that envisions a group enterprise of considerable size. By 2004-2005, less than 5 percent of physicians practiced in medical groups of 50 or greater;<sup>15</sup> this means that ACOs not built on single large practice groups will span multiple independent practices in order to reach the required assigned patient threshold. This 5,000-patient threshold for market entry also was a feature of earlier Medicare HMO statute, suggesting that although the MSSP statute contemplates payment arrangements not tied to risk of loss, Congress nonetheless anticipated a size sufficient to produce reliable estimates of both savings and loss.

Beyond size, the statute envisions entities that possess considerable capabilities. An ACO must have a legal structure robust enough to engage in governance and financial management, including the ability to receive and distribute shared savings, which in turn means the existence of considerable financial management capabilities. An ACO must also be able to imple-

ment quality and reporting requirements covering the enterprise. Furthermore, an ACO, by statute, must be able to govern, not merely implement. That is, the statute requires that an ACO “define processes to promote evidence-based medicine and patient engagement, report on quality and cost measures, and coordinate care . . .” [emphasis added].<sup>16</sup> Notably however, the ACO statute does not designate the ability to manage financial risk as a core requirement.

*Quality performance and reporting.* The statute is clear that however paid, ACOs cannot share in savings unless their quality performance and reporting capabilities meet tests established by the HHS secretary.<sup>17</sup> At the same time, the statute appears to envision an incremental approach to quality performance, specifying that the “Secretary shall seek to improve the quality of care furnished by ACOs over time by specifying higher standards, new measures, or both . . .”<sup>18</sup>

*ACO participation and beneficiary assignment.* The statute permits participation by a broad array of groups of Medicare providers and suppliers; the law identifies as “participants” “ACO professionals,” which in turn are defined as physicians, physician assistants, clinical nurse specialists, and nurse practitioners<sup>19</sup> in both group practices or as members of networks of individual practices. The statute also encompasses hospitals (either employing ACO professionals or in partnership with them) and “such other groups of providers of services and suppliers as the Secretary determines appropriate.”<sup>20</sup>

The statute accords the Secretary similarly broad discretion where patient assignment is concerned, directing her to “determine an appropriate method to assign Medicare fee-for-service beneficiaries to an ACO based on their utilization of primary care services provided . . . by an ACO professional described in [§ 1899] (h) (1) (A)”<sup>21</sup> [emphasis added].

The MSSP statute contains several important ambiguities requiring resolution. First, there is the apparent disconnect between provider assignment and patient participation. Where participation is concerned, the legislation contemplates broad inclusion of health professionals beyond physicians; included in the participating groups and individuals are all Medicare suppliers (including federally qualified health centers and rural health clinics) as well as physician assistants, nurse practitioners, and clinical nurse specialists. At the same time, the assignment provisions of the statute reference one particular type of health care (i.e., primary care services) and one particular provider class (physicians), tying assignment to how beneficiaries use primary care “provided by” physicians. The meaning that will be ascribed to both “primary care services” and “provide” thus becomes highly important. In addition, the statute gives the Secretary broad powers to define how “assignment” works, with the authority to weigh the essential economic and performance dimensions of the model against Medicare’s core freedom-of-choice guarantee, which avoids the choice-limiting effects of the

<sup>11</sup> SSA § 1899(d), added by PPACA § 3022.

<sup>12</sup> § 1899(i)(1)-(3).

<sup>13</sup> Compare SSA § 1899(d), which does not address budget neutrality, to § 1899(i) the other payment model authority, that does contain two express budget neutrality provisions (§ 1899(i)(2)(B) and § 1899(i)(3)(B)). See also, 76 Fed. Reg. 19533.

<sup>14</sup> § 1899(b)(2)(D).

<sup>15</sup> Allison Lieber and Joy Grossman, Physicians Moving to Mid-Size Single Specialty Practices, *Tracking Report #18* (Center for Studying Health Systems Change, 2007) <http://www.hschange.com/CONTENT/941/> (Accessed May 2, 2011).

<sup>16</sup> § 1899(b)(2)(C).

<sup>17</sup> § 1899(b)(3)(B) and (C).

<sup>18</sup> § 1899(b)(3)(C).

<sup>19</sup> § 1899(h)(1)(A) and (B).

<sup>20</sup> § 1899(b)(1)(A)-(E).

<sup>21</sup> § 1899(c).

modern network approach to health insurance coverage that controls other markets.

*Avoiding at risk patients.* Whether through bonuses or shared risk of loss, the ACO model incentivizes expenditure reductions. In order to guard against cherry-picking the healthiest patients, the statute gives the HHS secretary power to sanction ACOs if she determines that the ACO has “taken steps to avoid patients at risk in order to reduce the likelihood of increasing costs to the ACO . . .”<sup>22</sup> The HHS secretary’s discretion extends to both setting the method for determining whether avoidance is taking place and fashioning the sanction.

*Administrative and judicial review.* The statute limits administrative and judicial review of virtually all major aspects of the HHS secretary’s implementation of the statute, thereby further augmenting her considerable powers. The statute bars review of certain decisions, whether under certain specified review authorities within the Social Security Act, “or otherwise”: specification of quality performance standards; measurement of ACO quality performance; Medicare beneficiary assignment; determinations of whether an ACO is eligible for shared savings including determinations of estimated expenditures for assigned beneficiaries and the ACO’s average benchmark; the percent of shared savings and limits on such savings; and ACO termination.<sup>23</sup>

#### *Antitrust, Fraud, and Tax Considerations*

The statute explicitly anticipates the legal questions related to federal fraud laws that can arise under an ACO model, while remaining silent on the questions of tax and antitrust law that ultimately surfaced as well.

*Fraud.* A series of federal laws are aimed at curbing fraud and abuse in federal programs and carry implications for ACO formation and operation. The Physician Self-Referral Law prohibits physicians from making referrals for Medicare “designated health services” to entities with which they or their immediate family members have a financial relationship, unless they are operating under an exception.<sup>24</sup> The Anti-Kickback Statute,<sup>25</sup> imposes criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration to induce or reward the referral of business reimbursable under a federal health care program. Violation of the statute also can result in the imposition of civil money penalties, program exclusion, and liability under the federal False Claims Act, since every claim arising out of a kickback arrangement becomes implicated as a false claim.<sup>26</sup> Finally, federal law prohibits hospital payments to physicians to induce reduction or limitation in services (known as “gainsharing”).<sup>27</sup> Over the years, the HHS Office of the Inspector General and CMS have developed a series of safe harbors that, consistent with the laws themselves, recognize certain exceptions to these general prohibitions,

thereby leading to the inclusion of express waiver authority in the HHS secretary.<sup>28</sup>

*Antitrust.* While the original Medicare program operates as an administered payment system that does not turn on price negotiation, ACOs can be expected to pursue contracts in other markets where price negotiation is the norm. The nation’s physicians have a long history of opposition to insurance arrangements that threaten their incomes and autonomy.<sup>29</sup> Following the United States Supreme Court’s landmark 1982 ruling against what it judged to be *per se* unlawful price-fixing by physician cartels in *Arizona v Maricopa County Medical Society*,<sup>30</sup> the antitrust enforcement agencies have been engaged in an extended effort to define what constitutes permissible market conduct, as well as which standard—the strict *per se* test or the more lenient “rule of reason” test—will be used to reviewing medical care joint ventures.<sup>31</sup>

Statements of Antitrust Enforcement Policy issued in 1994 and revised in 1996<sup>32</sup> allow avoidance of scrutiny under the *per se* rule (which classifies certain types of market conduct as illegal without further proof of anti-competitive effects) in situations in which there exists sufficient evidence of shared commitment to a common enterprise so as to permit otherwise independent competitors to negotiate with purchasers as a single entity. The revised Statements recognize as falling within a clear safety zone joint ventures that involve full financial integration (through, for example, a single global payment to the venture). As modified in 1996, the Statements also recognize arrangements that lack financial integration while possessing sufficient indicia of clinical integration to promote quality and efficiency so as to justify treatment as a single venture for price negotiation purposes. Of particular importance in the latter instance are accountability of a group’s members for quality and efficiency, the threat of dismissal from the group for substandard conduct, and the investment of human and financial resources in a shared enterprise.<sup>33</sup>

Enforcement agency rulings on joint ventures issued over the years suggest that the prior Statements may have been broad enough to cover ACO formation and operation.<sup>34</sup> However, both during and following the health reform debate, questions arose regarding the extent to which the existing Statements fully addressed ACO scenarios. Furthermore, ACO proponents sought a more streamlined approach to the oversight process in order to speed and standardize resolution.

*Tax exemption policy for nonprofit health care corporations.* Nonprofit entities that enjoy tax-exempt status under the Internal Revenue Code are expected to seek to become ACO participants; this is particularly true for hospitals, three-quarters of which operate as nonprofit corporations. As with antitrust concerns, the applicability of existing tax policy to ACO formation

<sup>22</sup> § 1899(d)(3).

<sup>23</sup> § 1899(g).

<sup>24</sup> SSA § 1877, 42 U.S.C. § 1395nn. See 76 Fed. Reg. 19656 (April 7, 2011).

<sup>25</sup> SSA § 1128B.

<sup>26</sup> 76 Fed. Reg. 19657.

<sup>27</sup> SSA § 1128A(b)(1) and (2), 76 Fed. Reg. 19657.

<sup>28</sup> SSA § 1899(f), added by PPACA § 3302.

<sup>29</sup> Thomas Greaney, *Thirty Years of Solitude: Antitrust Law and Physician Cartels*, 7 *Hous. J. Health L. and Policy* 189-226 (2007) at 192-195.

<sup>30</sup> 457 U.S. 332 (1982).

<sup>31</sup> Greaney, *op. cit.* note 30.

<sup>32</sup> <http://www.justice.gov/atr/public/guidelines/0000.htm> (Accessed May 5, 2011).

<sup>33</sup> Taylor Burke and Sara Rosenbaum, *Accountable Care Organizations: Implications for Antitrust Policy* (BNA Health Law Reporter, March 11, 2010).

<sup>34</sup> *Id.*

and operation by charitable entities emerged as an important issue in the wake of passage of the Affordable Care Act. This emergence took two forms. First, questions arose as to whether participation in ACOs might expose a nonprofit corporation to loss of its § 501(c)(3) tax-exempt status because shared savings could be understood as inuring to the benefit of private participants or as a substantial activity not in furtherance of an organization's charitable purposes. Second, questions arose as to whether nonprofit entities would be liable for taxes on "unrelated business income" as a result of the shared savings realized from MSSP distributions.<sup>35</sup>

### Key Elements of the CMS Proposed Rule

In implementing the MSSP program, CMS made a number of policy decisions that have the potential to carry considerable downstream effects.

*Payment models.* The CMS rule essentially jettisons the statute's basic payment model, which envisions coupling Medicare Part A and B fee-for-service payments with bonuses for savings and high quality performance. In its place, the proposed rule establishes two payment models both of which can be considered "other" payment models, thereby subjecting the ACO program in its entirety to the law's budget-neutrality test.

Under the proposed rule, an ACO can elect between a one-sided or two-sided model, known as Track 1 and Track 2, respectively.<sup>36</sup> Track 1 nominally begins as a basic shared savings approach, while Track 2 encompasses financial risk from the outset. Yet from its inception, Track 1 also creates financial risk beyond, of course, the risks that any ACO incurs in deciding to invest in formation. The first form of risk is liability for risk of loss by Year Three, even in the shared savings model. The second and equally serious risk of loss is a 25 percent withhold against the share of savings otherwise due to Track 1 ACO participants, with no procedures or timetable spelled out for calculating losses or refunding the withheld amount in the event that losses are avoided.<sup>37</sup> Instead the regulation simply provides that "[t]he withheld amount will be applied towards [sic] repayment of an ACO's losses."<sup>38</sup> With no timetable or recovery process, the length of time the government can retain shared savings otherwise due is unclear; indeed, since Track 1 ACOs are not liable for losses until year three, it is possible that retention of savings could span years, costing ACOs financing that presumably will be needed to offset initial investment costs.

Third, all ACOs (whether Track 1 or Track 2) must obtain reinsurance, place funds in escrow, obtain surety bonds, establish a line of credit or maintain another "appropriate repayment mechanism in order to ensure repayment of any losses to the Medicare program in advance of entering into a period of participation in the Shared Savings Program under the two-sided model,"<sup>39</sup> with un-repaid losses carried forward into future years.<sup>40</sup> Presumably a Track 1 ACO would need to secure financial backing either before or soon after initi-

ating its agreement, given the risk-of-loss requirement by year three.

In sum, rather than implementing the statute as a choice between the basic payment model and an "other" model involving financial risk of loss, the proposed rule uses a payment structure that creates financial risk in both models, compelling shared losses by year three and withholding shared savings otherwise due to a Track 1 ACO for an indefinite time period. Because both models are essentially "other payment" models, they presumably would both be subject to the budget neutrality requirements of the statute.

*ACO size and maturity, including quality measurement, performance, and reporting.* The statute itself contemplates ACOs of considerable size, since the law establishes a 5,000 patient minimum. The CMS rule further emphasizes size and strength by imposing risk of loss requirements on all ACOs and by establishing performance requirements that include extensive quality performance reporting and a requirement that 50 percent of all primary care physicians be meaningful users of electronic health records.<sup>41</sup> This final requirement is particularly significant given the nascence of EHR adoption as of 2012 when ACOs are to become certified and begin operations. Essentially the rule uses the incentives created by the ACO statute to further leverage extensive quality reporting, along with broad-based EHR adoption and meaningful use. These requirements apply to ACOs of all sizes, not only the largest entities.

The proposed rule favors size and maturity in other ways. First, the greatest opportunities for shared savings inure to ACOs capable of taking a risk of financial loss from the outset (i.e., Track 2 ACOs).<sup>42</sup> Second, the proposed rule establishes considerable staffing requirements. For example, an ACO must employ a "full-time senior" medical director<sup>43</sup> who is physically present in an ACO location and must have substantial management capabilities.<sup>44</sup> The model envisioned by Congress—at least 5,000 Medicare patients—thus has (inevitably perhaps) led to an agency implementation approach that emphasizes size, strength, and financial maturity.

*ACO participation and patient assignment.* Taking a broad approach to its statutory powers, the proposed rule enables broad participation in ACOs.<sup>45</sup> At the same time, the proposed rule takes a narrow approach to the question of assignment of Medicare beneficiaries, excluding as assignable all Medicare beneficiaries who receive primary care through individual health professionals other than physicians, as well as patients who receive care through clinical care teams, one of whose members is a physician.<sup>46</sup>

The exclusion of potentially millions of beneficiaries from ACO assignable status is in one sense an outgrowth of the terms of the statute, which defines assignment based on "utilization of primary care services by

<sup>41</sup> 42 C.F.R. § 425.11(b).

<sup>42</sup> 42 C.F.R. § 425.7(d).

<sup>43</sup> 42 C.F.R. § 425.5(d)(9)(iii).

<sup>44</sup> 42 C.F.R. § 425.5(d)(9)(ii).

<sup>45</sup> 42 C.F.R. § 425.5(b).

<sup>46</sup> Sara Rosenbaum and Peter Shin, Medicare's Accountable Care Organizations: How Will Medicare Beneficiaries Who Reside in Medically Underserved Communities Fare? [http://www.gwumc.edu/sphhs/departments/healthpolicy/dhp\\_publications/pub\\_uploads/dhpPublication\\_6EFAAA15-5056-9D20-3DBE579D20C06F05.pdf](http://www.gwumc.edu/sphhs/departments/healthpolicy/dhp_publications/pub_uploads/dhpPublication_6EFAAA15-5056-9D20-3DBE579D20C06F05.pdf) (Accessed May 3, 2011).

<sup>35</sup> See discussion in the IRS Notice, cited n. 7, supra, pp. 2-6.

<sup>36</sup> 42 C.F.R. § 425.5(d)(6)(A) and 425.7(c).

<sup>37</sup> 42 C.F.R. § 425.5(d)(6)(iii).

<sup>38</sup> Id.

<sup>39</sup> 42 C.F.R. § 425.5(d)(6)(iv).

<sup>40</sup> 42 C.F.R. § 425.5(d)(6)(vi).

an ACO professional [who is a physician].”<sup>47</sup> But CMS has interpreted the statute literally to reach only services provided *directly* by a physician rather than the provision of care in its fullest sense under state medical practice law, which recognizes physicians as providers of care when they have legal accountability for care under state medical practice acts. The proposed rule also excludes care arrangements in which nurse practitioners and physician assistants share duties for the plurality<sup>48</sup> of primary care (as required under the law) in partnership with a physician. As a result, the proposed rule excludes patients cared for in nurse-managed clinics, federally qualified health centers (FQHCs), and rural health clinics (RHCs) that together disproportionately account for the care of millions of low-income and medically underserved beneficiaries, whose Medicare-sanctioned primary care models involve the use of health care teams in order to overcome the problem of primary care shortages.

*Avoiding at risk beneficiaries.* The problem of health care organizational and payment models with the potential to exacerbate rather than reduce health disparities is well recognized.<sup>49</sup> The proposed rule defines the term “at risk” beneficiaries relatively broadly, to include persons with high risk scores on the CMS risk adjustment model, persons considered high cost as a result of two or more hospitalizations each year, dual eligible beneficiaries, beneficiaries with high utilization patterns, and those with diagnoses expected to result in high cost.<sup>50</sup> Of particular concern are individuals who are Medicare beneficiaries based on disability (these individuals presumably would be included as individuals with anticipated high-cost diagnoses), as well as beneficiaries who are viewed as clinically challenging because of personal characteristics not related directly to a diagnosis (e.g., primary language other than English, perceived low health literacy, mental disabilities that impair cognition and thus the potential for compliance). The CMS standards do not directly address this latter group, nor does the proposed rule suggest monitoring of beneficiaries who, having been notified of the ACO participant status of their health care provider,<sup>51</sup> decline assignment or change physicians. A key question may be the characteristics of patients who refuse to be part of practices that, after all, are charged with paying much greater attention to health care quality.

More importantly, perhaps, the proposed avoidance rule is silent on what may be the most obvious way to avoid at risk beneficiaries, namely by redlining certain providers within the ACO’s primary service area out of participant status by simply not inviting them in. This problem of redlining has long been of concern in the managed care network context,<sup>52</sup> and while assignment is not mandatory under the law, ACOs enjoy broad discretion to select their participants virtually without

oversight under equity standards. The monitoring regulation indicates that the agency will look for “trends and patterns suggestive of at-risk beneficiaries” using techniques that consist of (i) analysis of specific financial and quality measurement data reported by the ACO; (ii) site visits; (iii) analysis of beneficiary and provider complaints; and (iv) audits of claims, chart reviews, and beneficiary surveys.<sup>53</sup> No monitoring is suggested for comparing ACO participants to potential participants within the ACO’s primary service area, to determine whether health professionals and clinics that disproportionately treat more at-risk patients are under-represented in an ACO’s network. The absence of a more vigorous monitoring effort for selective inclusion of participating professionals is not mitigated by the fact that assignment is retrospective, since prospective or retrospective (an issue that has attracted considerable debate and that is discussed extensively in the proposed rule)<sup>54</sup> the more significant risk-related question for ACOs may be which providers get to participate at all.

*Review of agency action.* As expected, the proposed rule implements the bars to administrative and judicial review while at the same time attempting to balance this unilateral power to act against certain due process considerations. Thus, the rule permits reconsiderations of some but not all of the initial agency decisions that can result in termination, suspension, or an order to repay shared savings.<sup>55</sup> Why certain actions merit a reconsideration and others do not is not immediately obvious. For example, findings of avoidance of high risk beneficiaries can be taken to a reconsideration, while the results of quality assessments cannot. Why one type of action merits a second look and the other does not is hardly evident.

### **The Proposed Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the MSSP**

In view of the agencies’ prior policy positions regarding enforcement of antitrust laws in a health care context, their proposed ACO policy statements are hardly surprising, since CMS’s proposed ACO clinical integration standards parallel the indicia of clinical integration identified under the agencies’ 1996 Statements and subsequent rulings.<sup>56</sup> Indeed, the proposed Statement appears to not only permit but encourage ACO formation, thereby underscoring the agencies’ conclusion that in a competitive health care system, the benefits of clinical integration may be fairly said to outweigh the risks of collusive financial behavior within a market.

In a departure from the prior Statements, the agencies adopt a clear, prospective, and expedited approach to agency review, a broad safety zone that makes review technically unnecessary, and extension of the 1996 Safety Zones to multi-provider networks in which independent ACO participants providing the same service have a combined service share of less than 30 percent of each ACO’s Primary Service Area (PSA).<sup>57</sup> Limita-

<sup>47</sup> § 1899(c).

<sup>48</sup> 42 C.F.R. § 425.6(b)(5).

<sup>49</sup> Craig E. Pollack and Katrina Armstrong, *Accountable Care Organizations and Health Disparities*, 305 *JAMA* 16 (April 27, 2011) 1706-1707.

<sup>50</sup> 42 C.F.R. § 425.4.

<sup>51</sup> 42 C.F.R. § 425.6(c).

<sup>52</sup> Sara Rosenbaum and Joel Teitelbaum, *Civil Rights Enforcement in the Modern Health Care System: Reinvigorating the Role of the Federal Government in the Aftermath of Alexander v Sandoval*, 3 *Yale Jour. Health Pol. L. & Ethics* 215 (2002).

<sup>53</sup> 42 C.F.R. § 425.12(a) and (b).

<sup>54</sup> 76 Fed. Reg. 19565-19566.

<sup>55</sup> 42 C.F.R. §§ 425.14 and 15.

<sup>56</sup> These rulings are reviewed in Taylor and Rosenbaum, *supra*, note 34.

<sup>57</sup> 76 Fed. Reg. 28197 (April 19, 2011).

tions on ACO demands for participant exclusivity apply to “dominant” providers (those with more than a 50 percent market share of any service that no other ACO participant providers. At the same time, broad leeway is given to physicians and hospitals that participate in rural ACOs and whose market share exceed the 30 percent threshold for the safety zone to apply. Mandatory review prior to CMS approval is required under the Proposed Statement for ACOs that have a PSA share that exceeds 50 percent of the common services that two or more independent ACO participants provide within a single PSA;<sup>58</sup> at the same time, an agency can provide a letter indicating that it has no present intention to challenge the ACO or to recommend such a challenge, and approval.<sup>59</sup>

The Proposed Statement also addresses situations in which the ACO’s market percentage falls between 30 percent and 50 percent of common services provided by two or more independent participants. Even here, the Proposed Statement permits ACO approval to move forward without Agency review.<sup>60</sup> ACOs whose participants’ share of common services within their PSA fall within this market share range are advised to refrain from engaging in certain types of conduct in order to avoid review: attempting to steer payers away from other providers; tying sales of the ACO’s services to the purchase of certain other non-ACO services; attempting to enter into exclusive specialty contracting arrangements; trying to restrict a payer’s ability to disclose quality and cost data; and sharing competitive information inappropriately among ACO members.<sup>61</sup>

## Issues Related to Tax-Exempt Status and Fraud and Abuse

The Treasury Department and the OIG policies similarly reflect a favorable view regarding the formation and operation of ACOs.

*Tax policy.* After reviewing a series of comparable situations dealing with inurement and benefit to private parties as well as unrelated income, the IRS signals its support for nonprofit involvement in ACOs without fear of loss of Section 501(c)(3) tax-exempt status. The IRS Notice states that “[b]ecause of CMS regulation and oversight of the MSSP, as a general matter the IRS 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 provide party ACO participants.”<sup>62</sup> The Notice sets forth steps that ACOs can take to assure favorable IRS response, including the use of arms length agreements, CMS approval of the ACO, assuring that the organization’s share of economic benefits derived from the ACO is proportional to its contributions and assuring that its share of losses does not exceed the share of benefits to which it is entitled from the ACO.<sup>63</sup>

Furthermore, the IRS notes that “absent inurement or impermissible private benefit,” MSSP payments would be consistent with the entity’s charitable purpose of “lessening the burdens of government within the

meaning of Treasury rules.”<sup>64</sup> The IRS does leave the door open to a finding of unrelated business income derived from negotiations with private payers, because in its view, these negotiations are not related to the MSSP; even so, the agency specifically notes that participation in a Medicaid shared savings program would constitute related income because they share the MSSP charitable purpose of lessening the burden on government.

*Fraud and abuse laws.* CMS and the OIG propose to waive application of provisions of the physician self-referral and anti-kickback laws to permit distribution of shared savings among the participants. At the same time, the agencies are clear that exchange of payments *outside the boundaries* of the ACO in the context of self-referrals, kickbacks, and gainsharing, will receive a far different level of scrutiny.<sup>65</sup> As with the antitrust enforcement agencies’ willingness to tolerate large, multi-practice networks with significant market presence, the CMS/OIG position suggests the agencies’ emphasis on the formation and operation of broadly inclusive ACOs whose reach spans the full spectrum of primary and specialty health care. Throughout the proposed waiver policy the agencies draw the line at distributions outside the scope of an ACO’s participant group itself, unless the payments are for “activities necessary for and directly related to the ACO’s participation in and operations under” the MSSP. This concept remains undefined in the law, and presumably the burden falls on the ACO to make such a showing. How ACOs will know what such a showing entails in the absence of further definitional regulation or more extensive sub-regulatory guidance is unclear.

## Conclusion

Taken as a whole, the Administration’s policies on ACO formation and operation, both within the MSSP and beyond, suggest a high eagerness on its part to move ACOs forward, but with a strong orientation—at least in the early phases of the program—toward large, mature entities that from the outset are capable of taking risk of both loss and reward. By building risk into the MSSP program through the use of withholds and ultimate acceptance of risk of loss even among Track 1 ACOs, the proposed MSSP rule effectively eliminates the very payment model that was assumed by Congress to be the basic approach to the program, one that uses the standard fee-for-service payment system coupled with bonus payments to ACOs whose expenditures beat their benchmark.

Also evident is the MSSP rule’s policy tilt toward networks comprised of “traditional” primary care practice arrangements, meaning physicians. Although clinics in rural and urban underserved areas and nurse-led practices can participate, the proposed MSSP rule’s strict construction of the term “provide” effectively excludes from ACO networks all Medicare patients whose primary care—no matter how high quality—might be considered non-traditional. Since these patients disproportionately may be lower income and medically underserved persons, with a higher likelihood of dual Medicare/Medicaid enrollment, the policy ironically may perpetuate the very avoidance of high risk patients that CMS seeks to deter.

<sup>58</sup> Id.

<sup>59</sup> 76 Fed. Reg. 28198 (April 19, 2011).

<sup>60</sup> Id.

<sup>61</sup> Id.

<sup>62</sup> IRS Notice 2011-20.

<sup>63</sup> Id.

<sup>64</sup> Id. pp. 7-8.

<sup>65</sup> 76 Fed. Reg. 19655 (April 7, 2011).

Similarly absent is any policy for addressing avoidance techniques that entail the avoidance of high risk patients through the avoidance of their providers. The lack of any strategy for addressing redlining of potential ACO participants is notable, since this type of practice that has long been a focus of concern in networked efficiency models and among civil rights experts.

The proposed MSSP regulation's policy toward bigger, stronger, and more mature physician group practices that tend not to serve underserved and low income patients in large numbers stands in contrast, perhaps, to the FTC/DOJ policy of inclusion and incentivization that encourage smaller practices that band together to form networks, even networks that surpass a certain size threshold in historically underserved communities. Similarly, the IRS rule on nonprofit involvement seemingly encourages ACO entry by charitable hospitals that

possess relatively strong track records of reaching lower income and medically underserved patients through partnerships with FQHCs and RHCs. What happens to these partnerships in the wake of exclusion of their patients from assignable status is unclear.

Finally, the OIG/CMS proposed standards for waiving the federal fraud laws emphasizes ACOs of considerable size and scope, spanning the full range of primary and specialty care practices and capable of sharing savings within the ACO rather than over the corporate "wall" surrounding the ACO.

How these broad policies complement or contrast with one another, and how strongly they collectively nudge the health care system down the road of full integration, will be one of the most closely watched questions for health policy researchers in the years ahead.