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## The Stark Physician Self-Referral Law and Accountable Care Organizations: Collision Course or Opportunity to Reconcile Federal Anti-Abuse and Cost-Saving Legislation?

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# THE STARK PHYSICIAN SELF-REFERRAL LAW AND ACCOUNTABLE CARE ORGANIZATIONS: COLLISION COURSE OR OPPORTUNITY TO RECONCILE FEDERAL ANTI-ABUSE AND COST-SAVING LEGISLATION?

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I.	INTRODUCTION .....	315
II.	OVERVIEW OF ACCOUNTABLE CARE ORGANIZATIONS .....	316
	A. <i>What is an Accountable Care Organization?</i> .....	316
	B. <i>Structure and Operations</i> .....	318
	C. <i>Preliminary Cost and Quality Findings</i> .....	325
III.	CONFLICT WITH FEDERAL STARK PHYSICIAN SELF-REFERRAL LAW .....	327
	A. <i>Potential Implication of Stark</i> .....	327
	B. <i>Purpose of Stark</i> .....	330
	C. <i>Stark and ACO Approaches to Achieving Shared Goals</i> .....	332
IV.	CMS' WAIVER APPROACH AND ALTERNATIVES .....	337
	A. <i>Current Waiver</i> .....	337
	B. <i>Public Comments Received on CMS' Interim Final Waiver Rule</i> .....	340
	C. <i>Alternative Approaches</i> .....	343
V.	RECOMMENDATION .....	344
VI.	CONCLUSION .....	347

## I. INTRODUCTION

Scholars and legal practitioners have long debated the virtues and vices of integrated models of health care delivery and financing. Few such models have been as promising or as rapidly adopted as Accountable Care Organizations (“ACOs”), the latest concept in delivering cost-effective, high-quality health care. Implementation of pre-ACO models, however, never required extensive grants of immunity to providers and suppliers from the federal Stark physician self-referral

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law (“Stark”) and other fraud and abuse laws.<sup>1</sup> The broad waivers issued by the Centers for Medicare & Medicaid Services (“CMS”) for implementing ACOs raise unprecedented legal questions concerning Stark’s application to these hospital/physician arrangements designed to decrease costs. Furthermore, the waivers represent new opportunities to reconcile, through rulemaking, the cost savings of ACOs with their attendant risks of physician abuse or patient harm accomplished through Stark-proscribed self-referral.

This Article discusses: the ACO model and how it works (Part I); the specific areas of conflict between Stark regulations and ACOs and their respective approaches to regulating health care cost and quality (Part II); CMS’ current interim waiver of Stark for ACO arrangements, including stakeholder reactions through public comment and alternative approaches to resolving ACO-Stark conflict (Part III). Part IV analyzes the costs and benefits of addressing ACO-Stark conflict through a temporary waiver versus *ex ante* reconciliation of the two regimes. It recommends that CMS maintain the current waiver with additional safeguards to mitigate Stark risks, and consult findings from the 2012 empirical data collected before taking further action.

## II. OVERVIEW OF ACCOUNTABLE CARE ORGANIZATIONS

This section provides a general survey of Accountable Care Organizations (“ACOs”). It discusses what an ACO is, how it is structured and operated, and current empirical results regarding ACOs’ effects on cost and quality of health care services delivered.

### A. *What is an Accountable Care Organization?*

An Accountable Care Organization (“ACO”) is a group of medical providers and suppliers that work together to manage and coordinate care for a patient population.<sup>2</sup> The Medicare Shared Savings Program (“MSSP”), authorized under the Affordable Care Act (“ACA”), gives providers and suppliers the option to create such a structure for Medicare fee-for-service beneficiaries.<sup>3</sup> In exchange for reducing medical costs and maintaining quality of care at or beyond a level specified by CMS, the ACO providers and suppliers receive a share of cost savings realized through voluntarily implementing various service delivery reforms.<sup>4</sup> These include processes to promote evidence-based medicine, sharing of electronic health records (“EHR”), joint decision-making and governance, and care coordination processes.<sup>5</sup> More generally, the ACA statute outlines ACO objectives, which are to: promote accountability, encourage investment in infrastructure, coordinate provision of

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<sup>1</sup> See Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992, 67999 (Nov. 2, 2011) (to be codified at 42 C.F.R. ch. IV & 42 C.F.R. ch. V).

<sup>2</sup> BARRY R. FURROW ET AL., HEALTH CARE REFORM: SUPPLEMENTARY MATERIALS 211-12 (West 2012).

<sup>3</sup> See *id.*; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67814-15 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425).

<sup>4</sup> See FURROW, *supra* note 2, at 212-14.

<sup>5</sup> See FURROW, *supra* note 2, at 215; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67815-16 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425).

Medicare services, and redesign care processes for high quality and efficient service delivery.<sup>6</sup>

ACOs have adopted a variety of innovative methods for integrating care and reducing costs for specific patient populations. Studies based on ACO pilot demonstrations present a plethora of qualitative findings of provider-specific approaches to accomplishing ACO goals.<sup>7</sup> These include registries reminding providers to follow-up with at-risk patients, telephone monitoring to check-up on at-risk patients, care management to individualize and coordinate services for specific at-risk individuals, EHR implementation and utilization, and reviewing clinical dashboards to track and measure quality and cost performance.<sup>8</sup>

There are a number of legal requirements for ACOs, including that they have an established mechanism for shared governance providing all ACO participants with proportionate control over decision-making.<sup>9</sup> Additionally, prospective ACOs must apply to CMS to receive approval for operation, and must operate at least three years following approval with the option for renewal.<sup>10</sup> ACO performance in the areas of cost reduction and quality of care is reported and evaluated on an annual basis.<sup>11</sup>

Within an ACO, individual Medicare beneficiaries are “attributed” to the primary care physician from whom they receive most of their primary care services.<sup>12</sup> CMS creates a list of patients likely to receive care from the ACO based on recent utilization patterns.<sup>13</sup> Beneficiaries do not receive advance notice of their attribution to an ACO but providers must provide signage in their facilities to notify these patients.<sup>14</sup> However, ACO beneficiaries may always choose to receive health benefits from providers outside the ACO to which they are attributed.<sup>15</sup> These costs are nonetheless considered in calculating the ACO’s total cost savings and quality performance.<sup>16</sup>

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<sup>6</sup> 42 U.S.C.A. § 1395jjj (West 2012) (outlining statutory goals for providers).

<sup>7</sup> See Ctrs. for Medicare & Medicaid Servs., *Medicare Physician Group Practice Demonstration: Physicians Groups Continue to Improve Quality and Generate Savings Under Medicare Physician Pay-for-Performance Demonstration 1-6* (2011), available at [http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/PGP\\_Fact\\_Sheet.pdf](http://www.cms.gov/Medicare/Demonstration-Projects/DemoProjectsEvalRpts/downloads/PGP_Fact_Sheet.pdf); Bridget K. Larson et al., *Insights from Transformations Under Way At Four Brookings-Dartmouth Accountable Care Organization Pilot Sites*, 31 HEALTH AFFAIRS 2395, 2396 (2012).

<sup>8</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 6-9.

<sup>9</sup> See FURROW, *supra* note 2, at 213.

<sup>10</sup> See FURROW, *supra* note 2, at 213.

<sup>11</sup> See FURROW, *supra* note 2, at 213, 215.

<sup>12</sup> See FURROW, *supra* note 2, at 213.

<sup>13</sup> See FURROW, *supra* note 2, at 213.

<sup>14</sup> See FURROW, *supra* note 2, at 213.

<sup>15</sup> See FURROW, *supra* note 2, at 213.

<sup>16</sup> See FURROW, *supra* note 2, at 214.

### B. Structure and Operations

ACOs may be legally formed under a myriad of state law entities, including: limited liability corporations (“LLCs”), professional corporations, and not-for-profit 501(c)(3) organizations.<sup>17</sup> Regulations make it clear that any state authorized entity is sufficient so long as it can perform ACO functions and incorporate all participants in decision-making.<sup>18</sup> The legal choice is closely related to the practical structure of the organization. For example, an LLC, with its more flexible rules on allocating members’ liabilities and income and pass-through tax benefits, might make more sense for a loose confederation of physicians, whereas a 501(c)(3) might be best for a large, centralized hospital system.<sup>19</sup>

In an attempt to avoid unnecessary costly restructuring, many ACOs choose to retain an existing legal status adopted prior to its formation rather than to create a new entity.<sup>20</sup> Notably, CMS regulations indicate that an ACO formed between two or more *otherwise independent* participants, such as a hospital and independent physician groups, must nonetheless establish a separate legal entity and obtain a Tax Identification Number (“TIN”) to qualify as an ACO.<sup>21</sup> This provides a mechanism by which to distribute savings to all participants and ensure that all participants have access to the organization’s governance. Such entities would not, however, be required to obtain or bill through a Medicare provider number.<sup>22</sup>

Distinct from the legal choice of entity, ACOs may be organized and structured in a number of different ways. An ACO may be a single independent medical practice association of physicians with no owned hospitals. For example, Monarch HealthCare in Irvine, CA operates as an independent practice association ACO.<sup>23</sup> It is incorporated as a professional corporation and serves 172,000 patients annually.<sup>24</sup> Less than 2% of the physicians are employed by the ACO; the remaining physicians,

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<sup>17</sup> See Larson, *supra* note 7, at 2397-98.

<sup>18</sup> See Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67815-16 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425).

<sup>19</sup> Janet E. Gitterman & Marvin Friedlander, *Health Care Provider Reference Guide*, EXEMPT ORGANIZATIONS CONTINUING PROFESSIONAL EDUCATION TEXT 2-3 (2004), <http://www.irs.gov/pub/irs-tege/eotopic04.pdf> (last visited May 26, 2013); Dennis Murray, *S Corp, C Corp, LLC, LLP – Which Is Best?*, MEDICAL ECONOMICS (Mar. 5, 2004), <http://www.modernmedicine.com/news/s-corp-c-corp-llc-llp%2097which-best> (last visited May 26, 2013).

<sup>20</sup> In a recent study of non-MSSP ACO pilot demonstrations from the Brookings-Dartmouth Collaborative, three of the four ACOs evaluated elected to retain an existing legal status. See Larson, *supra* note 7, at 2397-2398.

<sup>21</sup> See Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67815 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425).

<sup>22</sup> See Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67814 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425).

<sup>23</sup> Please note all the ACOs referenced for organizational structure were participants in the Brookings-Dartmouth Accountable Care Organization (ACO) Pilot Series and are not MSSP ACOs, which are being implemented and studied in 2012. The observations are based on a study conducted by Larson. Larson, *supra* note 7, at 2396.

<sup>24</sup> Larson, *supra* note 7, at 2397-98.

roughly 98%, are affiliated with the organization.<sup>25</sup> All the physicians participating in the ACO are primary care practitioners.<sup>26</sup> All the organization's revenues are derived from outcomes-based contracts.<sup>27</sup>

Alternately, an ACO may consist of an affiliated group of medical providers working together such as a multi-specialty group practice. For example, HealthCare Partners in Torrance, CA operates as a medical group practice ACO.<sup>28</sup> It is incorporated as a limited liability company and is physician-owned and governed.<sup>29</sup> The ACO serves 675,000 patients annually.<sup>30</sup> Nearly one quarter, 23%, of the physicians practicing there are employed by the ACO; the remaining 77% are affiliated with the organization.<sup>31</sup> Of the physicians in the ACO, 37% are primary care physicians and 63% are specialty practitioners.<sup>32</sup> Nearly all the organization's revenues, 94%, are derived from outcomes-based contracts.<sup>33</sup>

An ACO might also be an entire regional hospital system that itself owns all participating hospitals and physician practices. For example, Tucson Medical Center in Tucson, AZ operates as a community hospital system ACO.<sup>34</sup> It was initially incorporated as a 501(c)(3) not-for-profit organization governed through a board of trustees, of which 25% were physicians.<sup>35</sup> However, to partner with physicians in the ACO, it created a separate limited liability company (LLC).<sup>36</sup> The LLC's board of directors is composed of 20% hospital representation and 80% physician practice group representation.<sup>37</sup> The ACO serves 210,000 patients annually.<sup>38</sup> Fewer than 2% of the physicians practicing there are employed by the ACO; the remaining 98% are affiliated with the ACO.<sup>39</sup> Of the physicians, 61% are primary care physicians and 39% are specialty practitioners.<sup>40</sup> The ACO owns two hospitals and has no prior experience with risk-sharing contracts.<sup>41</sup> Only 8% of the ACO's revenues are

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<sup>25</sup> Larson, *supra* note 7, at 2397-98.

<sup>26</sup> Larson, *supra* note 7, at 2398.

<sup>27</sup> Larson, *supra* note 7, at 2397.

<sup>28</sup> Larson, *supra* note 7, at 2397.

<sup>29</sup> Larson, *supra* note 7, at 2397.

<sup>30</sup> Larson, *supra* note 7, at 2397.

<sup>31</sup> Larson, *supra* note 7, at 2397.

<sup>32</sup> Larson, *supra* note 7, at 2398.

<sup>33</sup> Larson, *supra* note 7, at 2397.

<sup>34</sup> Larson, *supra* note 7, at 2397.

<sup>35</sup> Larson, *supra* note 7, at 2397.

<sup>36</sup> Larson, *supra* note 7, at 2397.

<sup>37</sup> Larson, *supra* note 7, at 2398.

<sup>38</sup> Larson, *supra* note 7, at 2397.

<sup>39</sup> Larson, *supra* note 7, at 2397.

<sup>40</sup> Larson, *supra* note 7, at 2398.

<sup>41</sup> Larson, *supra* note 7, at 2397.

derived from outcomes-based contracts due to the high level of integration and service delivery taking place internally.<sup>42</sup>

An ACO may consist of an integrated delivery network (“IDN”) that owns not only hospitals and physician practices but also health plans. For example, Norton Healthcare in Louisville, KY operates as an integrated delivery network ACO.<sup>43</sup> It serves 444,261 patients annually and is incorporated as a 501(c)(3) not-for-profit organization governed by a board of trustees, of which 18% are physicians.<sup>44</sup> 100% of its physicians are employed by the ACO, which owns a total of five hospitals and has no prior experience with risk-sharing contracts.<sup>45</sup> Of the physicians, 71% are primary care physicians and 29% are specialty practitioners.<sup>46</sup> None of the revenues are derived from outcomes-based contracting, as everything takes place internally and the ACO owns all of its providers.<sup>47</sup>

An ACO may also consist of a joint venture or partnership between physician practices and hospitals to deliver care to patients in a geographic region. The definition of ACO was expanded by HHS in 2011 to include federally funded health care providers such as Rural Health Clinics, Critical Access Hospitals, and Federally Qualified Health Centers.<sup>48</sup> As of 2012, there are an estimated 164 ACOs nationwide, including commercial and CMS-sponsored entities.<sup>49</sup> Of these, 99 are hospital-based systems, 38 are independent physician associations, and 27 are organized under a commercial insurer.<sup>50</sup> Of the ACOs thus far approved by CMS under the MSSP, there are 116 and a majority are physician-led organizations.<sup>51</sup> This, however, is likely to change in the future as hospitals increasingly assume control of both private and CMS-sponsored ACOs.<sup>52</sup>

ACOs organized as medical groups may often be affiliated with a nearby hospital.<sup>53</sup> Groups are typically well-situated to coordinate service delivery and share information in an ACO structure.<sup>54</sup> This is because often the entities already employ many physicians in the group and coordinate through intra-group computerized medical records.<sup>55</sup> In integrated delivery networks, providers, insurers, and patients

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<sup>42</sup> Larson, *supra* note 7, at 2397, 2399.

<sup>43</sup> Larson, *supra* note 7, at 2397.

<sup>44</sup> Larson, *supra* note 7, at 2397.

<sup>45</sup> Larson, *supra* note 7, at 2397.

<sup>46</sup> Larson, *supra* note 7, at 2397.

<sup>47</sup> Larson, *supra* note 7, at 2397.

<sup>48</sup> See Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67,802, 67806, 961 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 425).

<sup>49</sup> FURROW, *supra* note 2, at 253.

<sup>50</sup> FURROW, *supra* note 2, at 253.

<sup>51</sup> FURROW, *supra* note 2, at 253.

<sup>52</sup> FURROW, *supra* note 2, at 253.

<sup>53</sup> See Furrow, *supra* note 2.

<sup>54</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 3.

<sup>55</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 3.

are likewise well-connected through streamlined electronic health records.<sup>56</sup> This structure may create even greater incentives for ACO participants to work together because payors have buy-in and input in designing and implementing cost reduction measures and strategies for meeting quality benchmarks.<sup>57</sup>

Hospital-centric ACO models might have a more difficult time bearing the risk of failing to meet performance objectives given their traditional Medicare fee-for-service reimbursement under Part A.<sup>58</sup> Fee-for-service payment, even if capped for episodes of care, does not encourage hospitals to share risk for meeting cost or quality objectives or otherwise limit services per patient. Hospital-based models may include medical staff organizations, where physicians are affiliated with hospital facilities and resources, or physician/hospital organizations, a collaborative hospital/physician system that includes physicians outside the medical staff.<sup>59</sup> Physician-centric models, on the other hand, may find this transition to be less difficult given that many are currently paid capitated amounts per patient under managed care contracts.<sup>60</sup> Because they are used to controlling costs in this fashion, a fee-for-service-plus-bonus structure under ACOs would likely be easier to comply with.

For tax-exempt entities such as many hospitals participating in ACOs, their contribution of facilities, infrastructure, or services to the ACO at less than fair market value might run afoul of private inurement doctrine under the federal tax laws.<sup>61</sup> This doctrine regulates not-for-profit entities going beyond statutory tax-exempt purposes to pursue private ends—in this case, receiving bonuses from CMS for its cost reductions.<sup>62</sup> The risk of ACOs falling within inurement doctrine's ambit can be mitigated through satisfying a number of criteria, including memorializing the arrangement in a written agreement and sharing benefits and losses proportionate to an ACO participant's interest in the ACO.<sup>63</sup>

Some ACOs fully employ all participating physicians whereas others employ only a few physicians and maintain loose affiliations with several others.<sup>64</sup> Many ACOs include private insurers as members, who collaborate with providers and contribute valuable infrastructure such as EHR.<sup>65</sup> Some ACOs are comprised of a high proportion of specialist physicians, whereas others contain no or very few specialists.<sup>66</sup> ACOs may be owned or governed by a committee consisting of

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<sup>56</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 3.

<sup>57</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 3.

<sup>58</sup> These observations are based on a study of early ACO models implemented under the Brookings-Dartmouth Pilot Series. See Larson, *supra* note 7, at 2399.

<sup>59</sup> See FURROW, *supra* note 2, at 253.

<sup>60</sup> See FURROW, *supra* note 2, at 254.

<sup>61</sup> See FURROW, *supra* note 2, at 257-58.

<sup>62</sup> See FURROW, *supra* note 2, at 257-58.

<sup>63</sup> See FURROW, *supra* note 2, at 257-58.

<sup>64</sup> See Larson, *supra* note 7, at 2399.

<sup>65</sup> See Larson, *supra* note 7, at 2397.

<sup>66</sup> See Larson, *supra* note 7, at 2395, 2398.



exclusively physicians or an appointed board of directors comprised of mainly non-physicians.<sup>67</sup> The ACA statute does require that ACO participants, including providers, control at least 75% of the entity's governance.<sup>68</sup>

The proportion of an ACO's total revenue derived from health outcomes-based contracts can vary from ACO to ACO, with some generating all of it from these contracts and others generating none.<sup>69</sup> This variation occurs because some ACOs employ all their providers such that contracting is unnecessary whereas others contract with nearby physician practices to deliver designated services.<sup>70</sup> Most ACOs currently starting up are in regions without existing integrated delivery networks with experience coordinating care.<sup>71</sup> As a result, these entities are more likely to rely on outcomes-based contracting rather than complex health care integration to connect disparate providers.<sup>72</sup>

Every ACO is governed by a Participation Agreement that is signed by all ACO participants.<sup>73</sup> Key elements of the Participation Agreement are: duration of participation; agreed-upon performance measures; general model of provider payment (e.g., two-sided v. one-sided); and patient assignment system of allocating certain patients (e.g., at-risk beneficiaries) to specific providers.<sup>74</sup> Other provisions might include maintenance of and access to electronic health records, certification of accuracy of medical information transmitted to CMS, and assurance of compliance with all applicable health laws and regulations, including the federal Stark Law.<sup>75</sup>

ACOs may choose between "one-sided" or "two-sided" payment models for providers for the initial three-year agreement period.<sup>76</sup> According to researchers, one-sided models were more popular among a sample of ACOs formed and operated as part of the early ACO demonstration projects.<sup>77</sup> In a "one-sided" model, ACOs bear no financial risk for failing to meet program requirements in years one and two but stand to benefit from any savings realized.<sup>78</sup> The ACO assumes greater risk in

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<sup>67</sup> See Larson, *supra* note 7, at 2398.

<sup>68</sup> FURROW, *supra* note 2, at 252.

<sup>69</sup> This is based on a recent study of early ACO pilot demonstrations implemented and not actual MSSP ACOs being implemented in 2012. See Larson, *supra* note 7, at 2395-2404.

<sup>70</sup> FURROW, *supra* note 2, at 253.

<sup>71</sup> FURROW, *supra* note 2, at 253.

<sup>72</sup> FURROW, *supra* note 2, at 253.

<sup>73</sup> See Final Waivers in Connection With the Shared Savings Program, Ctrs. for Medicare & Medicaid Servs., 76 Fed. Reg. 67992, 67997 (Nov. 2, 2011) (to be codified at 42 C.F.R. ch. IV & 42 C.F.R. ch. V).

<sup>74</sup> See *id.*

<sup>75</sup> See *id.*

<sup>76</sup> FURROW, *supra* note 2, at 214.

<sup>77</sup> See Larson, *supra* note 7, at 2397, 2399.

<sup>78</sup> See FURROW, *supra* note 2, at 214; Jennifer O. Mitchell & Tyler N. Williams, *Final ACO Rule: Retooled Risk and Reward Model – But is it Still Too Risky?*, ABA HEALTH ESOURCE (Dec. 2011), available at [http://www.americanbar.org/newsletter/publications/aba\\_health\\_esource\\_home/aba\\_health\\_law\\_esource\\_1211\\_aco\\_mitchell.html](http://www.americanbar.org/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1211_aco_mitchell.html).

the third year, sharing in up to 5% of losses.<sup>79</sup> In a “two-sided” payment model, by contrast, ACOs are at risk from the outset for spending beyond required thresholds (5% of losses in year one, 7.5% in year two, and 10% in year three) in addition to benefitting from shared savings.<sup>80</sup> All one-sided ACOs will be required to convert into two-sided models following expiration of the initial three-year agreement period.<sup>81</sup>

The maximum share of savings is higher in two-sided payment models (up to 60% depending on outcomes for 33 quality measures) than it is for one-sided payment models (up to 50% depending on outcomes for 33 quality measures).<sup>82</sup> The maximum share is also slightly higher (52.5%) if federally funded health providers such as Federally Qualified Health Centers participate in the ACO.<sup>83</sup> Additionally, there is a difference in the maximum sharing cap for ACO participants.<sup>84</sup> In one-sided ACOs, participants may not receive a total savings distribution exceeding 10% of cost benchmark whereas, in two-sided models, participants may receive up to 15% of benchmark spending levels.<sup>85</sup>

ACO quality benchmarks fall into four basic categories: Patient/Caregiver Experience, Care Coordination/Patient Safety, Preventive Health, and At-Risk Population.<sup>86</sup> Only At-Risk Population is based on actual patient health outcomes such as blood pressure level or hemoglobin control for diabetes.<sup>87</sup> The first three are measured based on, respectively: patient survey responses (e.g., access to care, communication with provider); process measures (e.g., readmission rates, medication reconciliation) as reflected in medical records; and whether various services and screenings (e.g., mammograms, influenza immunization, smoking cessation intervention) are delivered or not as reflected in medical records.<sup>88</sup> These measures are more focused on patient satisfaction and preventing wasteful allocations of health resources than with what health benefits are actually conferred to patients through ACO services delivered.<sup>89</sup>

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<sup>79</sup> See Mitchell & Williams, *supra* note 78.

<sup>80</sup> See Mitchell & Williams, *supra* note 78.

<sup>81</sup> See Mitchell & Williams, *supra* note 78.

<sup>82</sup> See Mitchell & Williams, *supra* note 78.

<sup>83</sup> See Mitchell & Williams, *supra* note 78.

<sup>84</sup> See Mitchell & Williams, *supra* note 78.

<sup>85</sup> See Mitchell & Williams, *supra* note 78.

<sup>86</sup> See Ctrs. for Medicare & Medicaid Servs., *Guide to Quality Performance Standards for Accountable Care Organizations Starting in 2012: Pay for Reporting and Pay for Performance* (Nov. 16, 2012), available at <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO-Guide-Quality-Performance-2012.PDF>.

<sup>87</sup> See *id.*; Mitchell & Williams, *supra* note 78.

<sup>88</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 86.

<sup>89</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 86. This could be a problematic measurement for discerning negative health effects of ACO cost reduction measures on patients with health conditions falling outside the “At-Risk” domain.

Quality benchmarks are based on national averages.<sup>90</sup> There are a total of 33 indicators, 8 of which are outcomes-based and 25 of which are based on patient survey responses, provider compliance with internal process standards, and delivery of certain types of preventive health care.<sup>91</sup> Of the 33 measures, 7 are collected via patient surveys, 3 are calculated via reported Medicare claims, 1 is calculated from EHR Incentive Program data, and 22 are collected from providers via an electronic group reporting interface.<sup>92</sup>

During the first year of operation, an ACO need only completely and accurately report on all 33 measures for year 1 to benefit from shared savings.<sup>93</sup> In later years, the ACO's share depends on how well it performs on quality relative to the benchmark standard.<sup>94</sup> For year 2, the amount of the ACO's shared savings will depend on reported information for 25 of the 33 quality measures.<sup>95</sup> For year 3 and onward, shared savings will depend on reported information for 32 out of 33 quality measures.<sup>96</sup> Of the 33 quality indicators, 23 are assigned a numerical score and the remainder consists of qualitative or binary variables.<sup>97</sup> Of the 33 quality measures used for ACOs, only 5 are based on clinical patient health outcomes.<sup>98</sup>

In addition to defining quality benchmarks, CMS establishes a Minimum Attainment Level ("MAL") as a percentage of the national quality standard, below which ACOs will not share in savings.<sup>99</sup> Performance above the minimum but below the benchmark will translate into shared savings on a sliding scale based on proximity to the benchmark.<sup>100</sup> The minimum level is currently set at the 30th percentile.<sup>101</sup> Once an ACO surpasses the minimum standard, CMS awards points, or increased shares of cost savings, to ACOs on a sliding scale up to the 90th percentile.<sup>102</sup> When performance exceeds this percentile, CMS awards full points, or the maximum allowable share of savings (50% of savings for one-sided and 60% for two-sided), to the ACO.<sup>103</sup>

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<sup>90</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 86.

<sup>91</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 86.

<sup>92</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 86.

<sup>93</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 86.

<sup>94</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 86.

<sup>95</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 86.

<sup>96</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 86.

<sup>97</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 86.

<sup>98</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 86.

<sup>99</sup> FURROW, *supra* note 2, at 214-15.

<sup>100</sup> FURROW, *supra* note 2, at 214-15.

<sup>101</sup> See Ctrs. for Medicare & Medicaid Servs., *Improving Quality of Care for Medicare Patients: Accountable Care Organizations* (Nov. 2012), [http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO\\_Quality\\_Factsheet\\_ICN907407.pdf](http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/Downloads/ACO_Quality_Factsheet_ICN907407.pdf).

<sup>102</sup> See *id.*

<sup>103</sup> See *id.*

The total points in each of the ACO's four quality domains are then aggregated and divided into all possible points for each domain.<sup>104</sup> The ACO's overall performance score is calculated by averaging the scores for each of the ACO's four quality domains.<sup>105</sup> For example, a one-sided ACO score of 90 percentage points would receive 90% of the 50% maximum share of savings generated, or 45% of total savings.<sup>106</sup> A physician-directed committee within each ACO is responsible under MSSP regulations for internally overseeing and implementing the organization's quality improvement program.<sup>107</sup>

The share of savings an ACO receives also depends on its cost saving benchmark set by CMS.<sup>108</sup> ACO participants receive a proportion of the difference between the cost benchmark and actual savings achieved by the ACO.<sup>109</sup> As with quality benchmarks, CMS sets a Minimum Savings Rate ("MSR") as a percentage of the benchmark above which providers must perform in order to receive any shared savings.<sup>110</sup> ACO cost benchmarks are determined based on historical average medical expenditures per beneficiary for a given set of providers and adjusted based on CMS trending analysis of national Medicare expenditure data.<sup>111</sup> Each ACO thus receives its own unique benchmark to meet.<sup>112</sup> The benchmark can be adjusted for addition or removal of ACO participants, commencement of a new agreement term, or annual national growth in health care costs.<sup>113</sup>

### C. Preliminary Cost and Quality Findings

CMS has estimated that new ACOs will generate somewhere between \$170 million and \$960 million in savings over the three-year initial agreement period.<sup>114</sup> Total Medicare expenditures during this period are estimated to be \$1.8 trillion.<sup>115</sup> The ACOs approved by HHS pursuant to the MSSP began implementation in 2012 and data is still being collected to assess effects on quality, cost, and patients.<sup>116</sup> There is no formal reporting, evaluation, or analysis of data based on this wave of implementation.

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<sup>104</sup> See FURROW, *supra* note 2, at 215.

<sup>105</sup> See FURROW, *supra* note 2, at 215.

<sup>106</sup> See FURROW, *supra* note 2, at 215.

<sup>107</sup> See FURROW, *supra* note 2, at 215.

<sup>108</sup> See FURROW, *supra* note 2, at 214.

<sup>109</sup> See FURROW, *supra* note 2, at 214.

<sup>110</sup> See FURROW, *supra* note 2, at 214.

<sup>111</sup> See Mitchell & Williams, *supra* note 78.

<sup>112</sup> See FURROW, *supra* note 2, at 214.

<sup>113</sup> See Mitchell & Williams, *supra* note 78.

<sup>114</sup> See FURROW, *supra* note 2, at 216.

<sup>115</sup> See FURROW, *supra* note 2, at 216.

<sup>116</sup> See Final Waivers in Connection With the Shared Savings Program, Ctrs. for Medicare & Medicaid Servs., 76 Fed. Reg. 67992, 68008 (Nov. 2, 2011) (to be codified at 42 C.F.R. ch. IV & 42 C.F.R. ch. V).

CMS has, however, released a report in 2011 based on results from ten ACO demonstration projects implemented by different types of health care entities from 2005-2010.<sup>117</sup> In this study, the agency found impressive gains in service quality, patient health outcomes, and cost reductions.<sup>118</sup> On average, participating ACOs increased their quality scores overall from baseline to year 5 performance levels.<sup>119</sup> Specifically, ACOs increased quality by 11 percentage points on diabetes measures, 12 points on heart failure indicators, 6 points on coronary artery disease indicators, 9 points on cancer screening indicators, and 4 points on hypertension measures.<sup>120</sup>

In year one, all ten ACOs improved clinical management of diabetes patients by attaining benchmark performance in at least 7 out of 10 clinical quality measures.<sup>121</sup> Two hospital-based ACOs achieved benchmark performance in all 10 measures.<sup>122</sup> Of the two ACOs participating in year 1 shared savings, both multi-specialty physician groups collectively generated a total of \$9.5 million in Medicare savings in year 1.<sup>123</sup> In year 2, all ten ACOs met benchmark for improving quality of care for chronically ill patients in at least 25 out of 27 clinical indicators for diabetes, coronary artery disease, and congestive heart failure.<sup>124</sup> Five ACOs achieved benchmark in all 27 indicators—including two hospital-based entities, two multi-specialty physician groups, and one integrated delivery network.<sup>125</sup> Of the four ACOs participating in year 2 shared savings, including one hospital-based entity and three physician and multi-specialty groups, they collectively generated a total of \$17.4 million in Medicare savings in year 2.<sup>126</sup>

In year 3, all ten ACOs met quality benchmarks for improving quality of care for patients with chronic illness or who require preventive care on at least 28 out of 32 clinical indicators, including hypertension and cancer screening.<sup>127</sup> Two integrated delivery network entity ACOs achieved benchmark on all 32 indicators.<sup>128</sup> Of the five ACOs participating in year 3 shared savings, including two hospital-based entities, one integrated delivery network, and two multi-specialty group physician practices, they collectively generated a total of \$32.3 million in Medicare savings in year 3.<sup>129</sup>

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<sup>117</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 4-6.

<sup>118</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 4-6.

<sup>119</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 4-6.

<sup>120</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 5.

<sup>121</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 4.

<sup>122</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 4.

<sup>123</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 4.

<sup>124</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 4.

<sup>125</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 4.

<sup>126</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 4.

<sup>127</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 5.

<sup>128</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 5.

<sup>129</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 5.

In year 4, all ten ACOs achieved benchmark on at least 29 out of 32 quality measures and three ACOs achieved benchmark on all 32 indicators—two integrated delivery networks and one multi-specialty physician group.<sup>130</sup> All ten ACOs achieved benchmark on heart failure and seven of the coronary artery disease measures.<sup>131</sup> Participating ACOs increased their average overall quality scores from baseline to year 4 performance levels.<sup>132</sup> Specifically, ACOs increased quality by 10 percentage points on diabetes measures, 13 percentage points on heart failure indicators, 6 points on coronary artery disease indicators, 9 points on cancer screening indicators, and 3 points on hypertension measures.<sup>133</sup> Total savings in year 4 for the five ACOs participating in shared savings, including two hospital-based entities, one integrated delivery network, and two multi-specialty group physician practices, that year amounted to \$38.7 million.<sup>134</sup>

In year 5, all ten ACOs achieved benchmark performance on 30 out of 32 clinical quality indicators.<sup>135</sup> Seven of these ACOs achieved benchmark performance on all 32 performance measures—four hospital-based entities, two integrated delivery networks, and one physician practice group.<sup>136</sup> All ten achieved benchmark performance on 10 of heart failure, 7 of coronary artery disease, and 2 of preventive care quality measures.<sup>137</sup> In addition to the impressive overall quality improvements from baseline to year 5, the ACOs participating in shared savings in year 5, including two multi-specialty groups, one hospital-based entity, and one integrated delivery network, also generated a total of \$36.2 million in Medicare savings.<sup>138</sup> Incentive payments that year amounted to a provider share of \$29.4 million.<sup>139</sup>

### III. CONFLICT WITH FEDERAL STARK PHYSICIAN SELF-REFERRAL LAW

This section outlines the points of conflict between ACOs and Stark's group practice regulations. It discusses the underlying purpose of Stark and its group practice definitions and the divergence in Stark's and ACOs' approach to cutting costs and improving quality of care.

#### A. Potential Implication of Stark

Experts and CMS note that forming, financing, and operating ACOs will implicate Stark in many instances.<sup>140</sup> In the words of CMS, "when a participating

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<sup>130</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 5.

<sup>131</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 5.

<sup>132</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 5.

<sup>133</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 5.

<sup>134</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 5.

<sup>135</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 5.

<sup>136</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 5.

<sup>137</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 5.

<sup>138</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 6.

<sup>139</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 7, at 6.

<sup>140</sup> Julie E. Kass & John S. Linehan, *Fostering Healthcare Reform Through a Bifurcated Model of Fraud and Abuse Regulation*, 5 J. HEALTH & LIFE SCI. L. 75, 97 (2012); Wasif A.

physician receives a portion of the cost savings attributable to his or her efforts in reducing waste . . . a financial relationship is created between the hospital . . . and the participating physician.”<sup>141</sup> This is because of the internal coordination required to operate an ACO through referrals and sharing of organizational savings and costs.<sup>142</sup> Absent a waiver, physician referrals within an ACO will need to satisfy one of Stark’s exceptions in order to avoid strict liability under the statute.<sup>143</sup> For multi-specialty groups and other physician group practices to meet any of Stark’s exceptions, they must first be properly defined as a “group practice” under the Law and its corresponding regulations.<sup>144</sup> Failing to do so may subject them to, *inter alia*, civil sanctions, mandated refunds, civil monetary penalties, *qui tam* liability under the civil False Claims Act (including treble damages), and/or the ultimate death knell—exclusion from participation in the Medicare program.<sup>145</sup>

Stark’s group practice definition is problematic for multi-specialty groups and other physician group practices seeking immunity under Stark exceptions through its criteria.<sup>146</sup> First, under the Single Legal Entity Test, a group practice may not be owned, in whole or in part, by an entity that is, in itself, an operating medical practice—including a hospital.<sup>147</sup> In Stark rulemaking, CMS indicates that a group practice “does not include a loose confederation of physicians, a substantial purpose

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Khan, *Accountable Care Organizations: A Response to Critical Voices*, 14 DEPAUL J. HEALTH CARE L. 309, 326-27 (2012); Bruce M. Fried et al., *Accountable Care Organizations: Navigating the Legal Landscape of Shared Savings and Coordinated Care*, 4 J. HEALTH & LIFE SCI. L. 88, 98 (2010).

<sup>141</sup> Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009, 73 Fed. Reg. 38502, 38549 (Jul. 7, 2008) (to be codified at 42 C.F.R. Pts 405, 409, 410, 411, 414, 415, 424, 485, and 486).

<sup>142</sup> Khan, *supra* note 140, at 324-5.

<sup>143</sup> Bruce A. Johnson & Sara V. Blass, *Compensating Individual Providers Based on Quality: Practical and Legal Considerations in a Changing Environment*, 5 J. HEALTH & LIFE SCI. L. 1, 9-10, 35-36 (2011); Mike Segal et al., *Understanding Group Practice Compensation Arrangements: How to Drive Yourself ‘Stark’ Raving Mad!* 19 HEALTH L. 6, 6-7 (2007); Kass & Linehan, *supra* note 140, at 89-90.

<sup>144</sup> Segal et al., *supra* note 143, at 1.

<sup>145</sup> Kass & Linehan, *supra* note 140, at 89-90.

<sup>146</sup> Rulemaking has occurred in three phases, with relevant group practice provisions being Medicare and Medicaid Programs: Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Phase I), 66 Fed. Reg. 856 (Jan. 4, 2001) (to be codified at 42 C.F.R. Pts. 411 and 424)(Phase I); Medicare Program: Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Phase II), 69 Fed. Reg. 16054 (Mar. 26, 2004) (to be codified at 42 C.F.R. Pts. 411 and 424), (Phase II); and Medicare Program: Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships (Phase III), 72 Fed. Reg. 51012 (Sept. 5, 2007) (to be codified at 42 C.F.R. Pts. 411 and 424) (Phase III).

<sup>147</sup> 42 C.F.R. § 411.352(a) (2012).

of which is to share profits from referrals . . . or separate group practices under common ownership or control through a . . . hospital or health care system.”<sup>148</sup>

Under many ACO organizational formulations, however, hospitals may have at least some ownership interest in the physician and/or multi-specialty group practices it is affiliated with by virtue of the ACO and Participation Agreement.<sup>149</sup> In this circumstance, it is unclear whether an otherwise independent physician practice meets Stark’s group practice definition. Additionally, under the Test, providers must generally bill under the same Medicare provider number.<sup>150</sup> This is unlikely to be the case for ACOs, particularly those that connect otherwise independent providers that are billing separately. Also, as mentioned *supra*, there are no requirements that ACO participants share a Medicare provider number.<sup>151</sup>

Stark requires physician members within group practices to provide 75% of the group’s aggregate services (“Substantially All Services Test”).<sup>152</sup> Because Stark does not contemplate physician-hospital collaboration beyond hospital ownership of physician practices, it does not consider a hospital or other entity within an ACO to be a “member” of the group practice for purposes of Stark.<sup>153</sup> As a result, even full-time independent physicians in a jointly operated ACO will face serious difficulty meeting the service provision requirement.<sup>154</sup> This might discourage provider interest in forming or operating ACOs.<sup>155</sup> It also might necessitate hospital employment of physicians that would otherwise be exposed to Stark liability, perhaps discouraging some independent physicians from participating.<sup>156</sup>

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<sup>148</sup> Physicians’ Referrals to Health Care Entities With Which They Have Financial Relationships, 66 Fed. Reg. 856, 897 (Jan. 1, 2001) (to be codified at 42 C.F.R. Pts. 411 and 424).

<sup>149</sup> Doriann Cain, *Accountable Care Organizations: Providing Quality Healthcare in an Integrated System*, 20 ANNAL HEALTH L. 1, 4 (2010); Khan, *supra* note 140, at 317-23.

<sup>150</sup> Segal et al., *supra* note 143, at 6-7.

<sup>151</sup> Medicare Program; Medicare Shared Savings Program: Accountable Care Organizations, 76 Fed. Reg. 67802, 67814 (Nov. 2, 2011) (to be codified at 42 C.F.R. Pt. 425).

<sup>152</sup> *See generally* 42 C.F.R. 411.352 (2012).

<sup>153</sup> 42 U.S.C. § 1395nn(h)(4)(A) (West 2012); 42 C.F.R. 411.351 (2012); Kass & Linehan, *supra* note 140, at 99-100. For a broader discussion of Stark’s encouragement of physician-only ventures without collaboration with hospitals, *see* Robin L. Nagele, *Hospital-Physician Relationships After National Health Reform: Moving from Competition to Collaboration*, 82 PENN. B. ASS’N Q. 1, 4 (2011).

<sup>154</sup> For a discussion of this problem with respect to part-time physicians and independent contractors, *see* Segal et al., *supra* note 143, at 6-7.

<sup>155</sup> Douglas A. Hastings et. al., *Waivers Under the Medicare Shared Savings Program: An Outline of the Options*, AM. HEALTH LAWYERS ASS’N: PUB. INTEREST COMM., at 3, [www.ftc.gov/os/comments/aco/101028ahla.pdf](http://www.ftc.gov/os/comments/aco/101028ahla.pdf) (accessed through Federal Trade Commission’s website).

<sup>156</sup> For a discussion of the role of interdependent and independent physicians in ACOs, *see* Khan, *supra* note 140, at 322-23. For a discussion of the risks to hospital/physician ownership under the Stark law, *see* Kass & Linehan, *supra* note 140, at 100-01.



Stark's group practice definition likewise requires that 75% of patient encounters be handled by physicians practicing within the group and on its behalf ("Patient Encounters Test").<sup>157</sup> Many existing ACO arrangements between physicians and hospitals will therefore implicate Stark because hospital entities will not be considered "member[s] of the group" handling patient encounters.<sup>158</sup> Physicians alone in the ACO may be unable to meet the 75% of patient encounters requirement, in which case they could be subject to civil liability for ACO referrals.

Another conflict between the Stark group practice definition and ACOs is the Compensation Test under the self-referral statute's provisions.<sup>159</sup> Under these provisions, physician members may not receive any share or bonus that is directly related to the value or volume of referrals to an entity with which it has a financial relationship.<sup>160</sup> However, certain types of productivity bonuses and profit shares indirectly related to referrals may be allowed for all or subsets of the group.<sup>161</sup> This is only allowed, however, if services are personally performed by physicians or "incident to" personal performance and calculated using indirect methodologies based on, e.g., years of experience, patient visits, and percentage of services referred that do not qualify as designated health services ("DHS") under Stark.<sup>162</sup>

Because financial success of an ACO is linked to its referral patterns, the financial bonuses it receives for cost savings may conflict with the Stark compensation rules for group practices.<sup>163</sup> Because ACO providers must collectively reduce costs while meeting patient health benchmarks,<sup>164</sup> there is an incentive to refer within the ACO to monitor and manage patients' care and its associated costs.<sup>165</sup> ACOs depend on using fewer in-ACO referrals to generate more savings.<sup>166</sup> As a result, they will distribute shares of profits among providers that directly correlate to the value and/or volume of referrals they collectively provided, which could violate the Compensation Test.

### B. Purpose of Stark

The purpose of Stark generally is to assure that higher quality and medically appropriate services are delivered to patients through an "indirect, structural" approach.<sup>167</sup> Fraud and abuse are prominent drivers of rising health care system

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<sup>157</sup> 42 C.F.R. 411.352(h) (2012).

<sup>158</sup> 42 U.S.C. § 1395nn(h)(4)(A) (2012); 42 C.F.R. 411.351 (2012).

<sup>159</sup> See 42 C.F.R. 411.352 (2012).

<sup>160</sup> *Id.*

<sup>161</sup> 42 C.F.R. 411.352(g) (2012).

<sup>162</sup> *Id.*; see also Segal et al., *supra* note 143, at 9-10.

<sup>163</sup> Segal et al., *supra* note 143, at 9-10.

<sup>164</sup> See Ctrs. for Medicare & Medicaid Servs., *supra* note 86.

<sup>165</sup> Khan, *supra* note 140, at 326-27.

<sup>166</sup> See Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009, 73 Fed. Reg. 38502 (Jul. 7, 2008) (to be codified at 42 C.F.R. pts. 42 C.F.R. Parts 405, 409, 410, 411, 414, 415, 424, 485, and 486).

<sup>167</sup> See Kristin Madison, *Rethinking Fraud Regulation by Rethinking the Health Care System*, 32 HAMLINE J. PUB. L. & POL'Y 411, 419 (2011).

costs.<sup>168</sup> The financial incentives available to physicians (e.g., fee-for-service reimbursement, ownership interest in ancillary services) supply them with the motive to abuse the system.<sup>169</sup> The decentralized and administratively complex health care system, which obscures fraud and abuse through its layers of organization and responsible parties, provides them the opportunity.<sup>170</sup> Recognizing this, the Stark law targets organizational structures and arrangements conducive to abusive practices via deterring potential violators rather than ferreting out abuse itself.<sup>171</sup>

Stark's purpose, according to CMS, is to "protect patients and the Federal health care programs from fraud, improper referral payments, [and] unnecessary utilization."<sup>172</sup> Some have described its aims as fostering patient choice, quality, and appropriate utilization through removing financial considerations from medical decision-making.<sup>173</sup> Others define it as reconciling the ethical conflict-of-interest facing physicians seeking to capitalize on investments in providers to which they refer patients while maintaining professional ethical responsibility.<sup>174</sup> Self-referral has the potential to restrict physicians' disclosures to patients and, as a result, compromise patients' rights to exercise informed consent and choice.<sup>175</sup> It may increase the chance of misdiagnoses, which can harm patients in a myriad of ways, because financial incentives are motivating physician treatment and non-treatment rather than sound medical judgment.<sup>176</sup> Self-referral may adversely restrict competition among providers to which patients may be referred.<sup>177</sup>

All these purposes and risks, however, assume a fee-for-service reimbursement system that facilitates over-provision of care (and higher-than-necessary billing) rather than under-provision through rewards for cost saving as with ACOs.<sup>178</sup> Experts note the oddity of applying the federal Stark Law, "premised on limiting the influence of financial incentives on physicians' referral patterns," to an ACO model "expressly intended by Congress to incentivize physicians to reduce the cost of care."<sup>179</sup> This is an incomplete interpretation of the conflict, however. Although both Stark and ACOs do, to some degree, seek to reduce utilization of medical services,

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<sup>168</sup> Kass & Linehan, *supra* note 140, at 83.

<sup>169</sup> Madison, *supra* note 167, at 418.

<sup>170</sup> Madison, *supra* note 167, at 418.

<sup>171</sup> Madison, *supra* note 167, at 419.

<sup>172</sup> See Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67,992, 67,993 (Nov. 2, 2011) (to be codified at 42 C.F.R. ch. IV & 42 C.F.R. ch. V).

<sup>173</sup> Kass & Linehan, *supra* note 140, at 82.

<sup>174</sup> Greg Radinsky, *Defining A Group Practice: An Analysis of the Stark I Final Rule*, 41 ST. LOUIS U. L.J. 1119, 1122 (1997).

<sup>175</sup> *Id.*; Kass & Linehan, *supra* note 140, at 82.

<sup>176</sup> Radinsky, *supra* note 174, at 1123.

<sup>177</sup> Kass & Linehan, *supra* note 140, at 82.

<sup>178</sup> Kass & Linehan, *supra* note 140, at 82.

<sup>179</sup> Hastings et. al., *supra* note 155, at 9.

the unique structures of each (e.g., strict liability deterrence versus quality reporting and measurement) go about doing this in vastly different ways.

The fundamental conflict is one of means and not ends. The legislative objective of Stark, to prohibit physician referrals to entities with which they have financial relationships, is the very mechanism by which ACOs reduce aggregate medical expenditures and improve Medicare patient health.<sup>180</sup> ACO providers must self-refer within the ACO to monitor and manage patients' care and its associated costs.<sup>181</sup> It is noteworthy, however, that the MSSP does not in fact alter fee-for-service reimbursement, or its overarching incentives for over-utilization, but simply allows bonuses derived from cost savings to discourage provision of unnecessary services.<sup>182</sup> This could allow ACOs to circumvent the general payment scheme to discourage over-utilization by foregoing shared savings to benefit from anti-abuse, fraud, and kickback immunity.<sup>183</sup>

There are various reasons for the existing group practice definition under Stark. These include, *inter alia*, that more than 40% of practicing physicians practice in a group setting and that Congress did not want to encumber these popular and presumably effective delivery arrangements.<sup>184</sup> Group practices also constitute a strong lobbying arm at the federal level.<sup>185</sup> There are practical efficiencies to be realized in a group setting, including the fact that physicians communicate more easily and patients can more quickly be seen upon referral within a group.<sup>186</sup> Finally, under a managed care capitated payment system, payment to specialists will be more cost-effective if specialists are actually integrated with primary care providers who self-refer to them rather than operating as stand-alone providers receiving per-patient compensation for services they are unlikely to deliver to most patients.<sup>187</sup>

### C. Stark and ACO Approaches to Achieving Shared Goals

Until this point, physicians have not coordinated with hospitals to manage and deliver care to patients beyond assuming medical staffing positions and hospitals have done little to coordinate with physicians beyond acquiring ownership of practices.<sup>188</sup> In the words of CMS, physicians have perverse incentives to over-utilize as hospital practitioners because they are "not financially at risk for items and services that they use and prescribe, and therefore, do not have a financial stake in

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<sup>180</sup> Federal Stark Physician Self-Referral Statute, 42 U.S.C. § 1395nn(a)(1)(A) (West 2012) (establishing prohibitions for physicians); *see also* Medicare Shared Savings Program, 42 U.S.C. § 1395jjj (2012) (outlining statutory goals for providers).

<sup>181</sup> Khan, *supra* note 141, at 326-27.

<sup>182</sup> 42 U.S.C. § 1395jjj (West 2012).

<sup>183</sup> This is an unlikely outcome given rigorous ACO program integrity requirements, data reporting and performance evaluation, and external auditing. There is also no independent evidence that it has occurred or is occurring.

<sup>184</sup> Radinsky, *supra* note 174, at 1129-30.

<sup>185</sup> Radinsky, *supra* note 174, at 1129-30.

<sup>186</sup> Radinsky, *supra* note 174, at 1130-31.

<sup>187</sup> Radinsky, *supra* note 174, at 1131-33.

<sup>188</sup> Cain, *supra* note 149, at 7.

controlling the hospital's patient care costs."<sup>189</sup> Stark's approach to physician/hospital collaboration, and the frequent changes and complexity in its exceptions and group practice definitions, have further discouraged provider collaboration.<sup>190</sup>

CMS has issued fraud alerts indicating that physician collaboration with hospitals is a vehicle through which hospitals indirectly compensate physicians for self-referral through a guaranteed, continuous stream of revenue.<sup>191</sup> This runs counter to critics' assertions that it reflects a partnership to raise capital and create needed efficiencies in health care delivery.<sup>192</sup> Additionally, CMS has imposed retroactive modifications in rulemaking for physicians operating "under arrangements" with hospitals to discourage physician billing through hospitals.<sup>193</sup> In taking these measures, CMS has encouraged more fee-for-service, physician-only ventures, arguably more predisposed to over-utilization, and discouraged joint hospital/physician arrangements, in which hospitals might help to curb costs.<sup>194</sup>

Stark is both under and over-inclusive because it regulates incentives within the referral process in a fee-for-service system rather than directly seeking to control costs or assure value of care.<sup>195</sup> As such, it can chill arrangements that ultimately promote cost and quality objectives because of their financially-motivated referral patterns while also failing to detect abusive arrangements because of highly technical and sometimes arbitrary guidelines as to what is and is not excepted from prohibition under the statute.<sup>196</sup> If insurers could instantly determine quality and appropriateness of care, there would be no need for fraud and abuse laws such as Stark.<sup>197</sup> Medicare would never admit patients for certain services in the first place because they would already know they are unnecessary or delivered by low-quality providers.<sup>198</sup>

The problem of implementing this, however, is that it is extremely difficult for regulators to determine quality and appropriateness of care for patients and nearly impossible to evaluate it real-time to achieve specified outcomes.<sup>199</sup> Often information available on quality measures is supplied directly by physicians, who are financially interested in the result, or patients, poorly positioned to assess the care they are receiving.<sup>200</sup> This is precisely why Stark seeks to deter abusive incentive

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<sup>189</sup> Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009, 73 Fed. Reg. 38502, 38549 (Jul. 7, 2008) (to be codified at 42 C.F.R. pts. 42 C.F.R. Parts 405, 409, 410, 411, 414, 415, 424, 485, and 486).

<sup>190</sup> Kass & Linehan, *supra* note 140, at 97; Nagele, *supra* note 153, at 4.

<sup>191</sup> Nagele, *supra* note 153, at 4.

<sup>192</sup> Nagele, *supra* note 153, at 4.

<sup>193</sup> Kass & Linehan, *supra* note 140, at 99-100.

<sup>194</sup> Nagele, *supra* note 153, at 4.

<sup>195</sup> Madison, *supra* note 167, at 419-20.

<sup>196</sup> Madison, *supra* note 167, at 419-20.

<sup>197</sup> Madison, *supra* note 167, at 418-19.

<sup>198</sup> See Madison, *supra* note 167, at 418-19.

<sup>199</sup> See Madison, *supra* note 167, at 418-19.

<sup>200</sup> See Madison, *supra* note 167, at 418-19.

structures within care processes rather than attempting to regulate decisions physicians make or their actual effects on patients.<sup>201</sup>

The MSSP, however, adopts a more direct, outcome-based approach through requiring providers to improve electronic health records (“EHR”) tracking and sharing,<sup>202</sup> coordinate more on implementing care management systems, and execute best practices as collaborative medical partners.<sup>203</sup> These are all new tools through which ACO providers may reduce medical expenditures while maintaining specified patient quality thresholds.<sup>204</sup> It also, however, injects financial incentives into the service delivery process through requiring the inverse of the Stark law—that physicians have a financial interest in the referral and treatment decisions of their patients—as a way to deter provision of low-quality, high-cost services.<sup>205</sup> Other reforms such as payment bundling and incentives for EHR adoption by non-ACO providers, buttress this provider-controlled, outcome-based approach of the ACA statute to deliver care in a more centralized delivery and payment system.<sup>206</sup>

The potential benefits of ACOs have led some to propose a bifurcated system of fraud and abuse enforcement that distinguishes between integrated systems implicating Stark and traditional fee-for-service systems (e.g., Medicare Part A) with better-understood incentives and risks for physician abuse.<sup>207</sup> Under this approach, Stark requirements would be substantially relaxed or eliminated altogether for integrated systems because of extant internal safeguards, auditing, and pay-for-performance standards.<sup>208</sup> As some argue, current ACOs are already highly-regulated, “risk-bearing” entities with substantial “self-correcting” safeguards and mechanisms to prevent abuse such as site visits, public disclosure, data accessibility, governance controls, and program integrity compliance.<sup>209</sup> This view, however, discounts *any* value to Stark’s presence in the fee-for-service-plus-bonus delivery and payment system of ACOs.

Some fear that ACOs may be entered into and operated by providers and suppliers not primarily to improve patient care and reduce costs, but to increase prices for consumers. This would be accomplished by consolidating and reorganizing otherwise competitive providers into centralized profit centers.<sup>210</sup> Relatedly, ACO providers may enter into these agreements to receive a generous waiver from all fraud and abuse laws even if they increase over-utilization and

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<sup>201</sup> See Madison, *supra* note 167, at 418-19.

<sup>202</sup> Notably, the Stark exception for EHR infrastructure is set to expire in 2013.

<sup>203</sup> *Shared Savings Program*, CTRS. FOR MEDICARE & MEDICAID SERVS. <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharedsavingsprogram/index.html?redirect=/sharedsavingsprogram/> (last visited March 19, 2013).

<sup>204</sup> *Id.*

<sup>205</sup> Khan, *supra* note 140, at 326-27.

<sup>206</sup> Madison, *supra* note 167, at 420.

<sup>207</sup> Kass & Linehan, *supra* note 140, at 124.

<sup>208</sup> Kass & Linehan, *supra* note 140, at 124.

<sup>209</sup> Kass & Linehan, *supra* note 140, at 80, 115-16, 128.

<sup>210</sup> Khan, *supra* note 140, at 326.

forego receiving savings distributions,<sup>211</sup> depending on penalties for doing so.<sup>212</sup> Scholars also fear that, because small or isolated physicians and hospitals will be at a financial disadvantage in joining or forming ACOs because of high capital and infrastructure costs, they may be crowded out or become extinct because of ACO implementation.<sup>213</sup>

MSSP also allows EHR donations and capital contributions by hospitals that would otherwise be prohibited under Stark's EHR exception, expiring in 2013,<sup>214</sup> as well as payments to reduce amount of care, utilize lower-cost supplies, or influence referral trends within the ACO.<sup>215</sup> The MSSP does not require arrangements to be in writing, signed by the parties, provided at fair market value, or be based on value or volume of referrals—as do many of Stark's exceptions.<sup>216</sup> This lack of restriction diminishes the accountability ordinarily expected from self-referring providers who stand to gain from participating in various ACO compensation arrangements.<sup>217</sup> The absence of these restrictions, however, is anything but an accident. It was largely a response to complaints from providers during the initial public comment period citing fair market value and pre-determined payment requirements of Stark exceptions as specific barriers to ACO implementation.<sup>218</sup>

CMS issued a proposed rule in 2008, never finalized, that created an affirmative Stark exception for shared savings distribution programs.<sup>219</sup> It required that cost savings measures be supported by “objective, independent medical evidence” suggesting they would not adversely affect or represent a diminution in patient care.<sup>220</sup> Likewise, all performance measures would be required to “use an objective methodology, be verifiable, be supported by credible medical evidence, and be individually tracked.”<sup>221</sup> Such measures would also need to “reasonably relate” to hospital practices and its patient population.<sup>222</sup> The program would need to conduct

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<sup>211</sup> Cf. Khan, *supra* note 140, at 326.

<sup>212</sup> See Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992, 67994 (Nov. 2, 2011) (to be codified at 42 C.F.R. ch. IV & 42 C.F.R. ch. V).

<sup>213</sup> *Id.*

<sup>214</sup> Khan, *supra* note 140, at 337.

<sup>215</sup> Khan, *supra* note 140, at 337.

<sup>216</sup> Khan, *supra* note 140, at 337.

<sup>217</sup> Khan, *supra* note 140, at 337.

<sup>218</sup> See Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992, 67996 (Nov. 2, 2011) (to be codified at 42 C.F.R. ch. IV & 42 C.F.R. ch. V).

<sup>219</sup> See Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009, 73 Fed. Reg. 38502, 38549 (Jul. 7, 2008) (to be codified at 42 C.F.R. pts. 405, 409, 410, 411, 414, 415, 424, 485, and 486) (this has since been replaced by an MSSP waiver for fraud and abuse laws.)

<sup>220</sup> *Id.* at 38553; see also Johnson & Blass, *supra* note 143, at 38.

<sup>221</sup> Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009, 73 Fed. Reg. 38502, at 38553 (July 7, 2008) (to be codified at 42 C.F.R. pts. 405, 409, 410, 411, 414, 415, 424, 485, and 486).

<sup>222</sup> *Id.*

pre-program and annual reviews to determine the effect of cost-savings practices on patients.<sup>223</sup> Furthermore, CMS would have limited participating physicians entitled to bonuses to members of the hospital's medical staff at the outset of ACO implementation and constrained timing and amount of savings distributions attributable to a single cost saving measure implemented through "re-basing" and "scaled" limitations.<sup>224</sup>

The proposed rule would constrain the possibilities for ACOs' organizational and operational structures.<sup>225</sup> Generally, the rule contemplates applying a stricter scrutiny to providers' chosen methods of cost reduction and more closely evaluating whether decision-making is based on patient health or financial gain.<sup>226</sup> In its justification for the rule, the agency notes that "[t]he variety and complexity of these programs make them potential vehicles for the unscrupulous to disguise payments for referrals or compromise quality in the interest of maximizing revenues."<sup>227</sup>

The government's identified risks of abuse resulting from shared savings programs include concerns of physicians limiting use of costly, but health-improving, treatments ("stinting"), electing to treat only healthier patients ("cherry picking"), avoiding sick patients during rounds at the hospital ("steering"), and discharging patients earlier than would be clinically desirable ("quicker-sicker" discharge).<sup>228</sup> More broadly, CMS was concerned that physicians would drive hospitals to "game the arrangement" by manipulating hospital accounts to generate "phantom savings" or engage in "unfair competition" toward non-ACO physicians.<sup>229</sup>

CMS has continued to express reservations that ACOs may be "misused for fraudulent or abusive purposes that harm patients of Federal health care programs" despite its present waiver policy.<sup>230</sup> It is currently monitoring ACO performance to automatically narrow waivers "unless information gathered . . . suggests that the waivers . . . are adequately protecting the Medicare program and beneficiaries."<sup>231</sup> In this case, fraud and abuse controls will become more stringent.<sup>232</sup> Unsurprisingly,

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<sup>223</sup> *Id.*

<sup>224</sup> Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009, 73 Fed. Reg. 38502, 38554, 38555-56 (Jul. 7, 2008) (to be codified at 42 C.F.R. pts. 405, 409, 410, 411, 414, 415, 424, 485, and 486).

<sup>225</sup> Cain, *supra* note 149, at 4-5; Khan, *supra* note 140, at 317-23.

<sup>226</sup> Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009, 73 Fed. Reg. 38502, 38550 (Jul. 7, 2008) (to be codified at 42 C.F.R. pts. 405, 409, 410, 411, 414, 415, 424, 485, and 486).

<sup>227</sup> *Id.* at 38547.

<sup>228</sup> *Id.* at 38550.

<sup>229</sup> *Id.*

<sup>230</sup> See Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992, 67993 (Nov. 2, 2011) (to be codified at 42 C.F.R. pt. 400 & 42 C.F.R. pt. 1000); Kass & Linehan, *supra* note 140, at 110.

<sup>231</sup> See Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992, 68008 (Nov. 2, 2011) (to be codified at 42 C.F.R. Chapter IV & 42 C.F.R. Chapter V).

<sup>232</sup> *Id.*

ACO stakeholders have commented unfavorably on the negative framing of the question of waiver modification.<sup>233</sup> It would appear to trigger narrowing of waivers even in the presence of ambiguous or non-existent evidence of actual fraud or abuse caused by ACOs.<sup>234</sup>

#### IV. CMS' WAIVER APPROACH AND ALTERNATIVES

This section details the current waiver approach adopted by CMS in its Interim Final Rule (“IFR”). It discusses stakeholder reactions to the IFR in public comments and alternatives to the current CMS approach of addressing Stark-ACO conflict.

##### A. Current Waiver

The statutory language of the MSSP delegates to the Secretary of Health and Human Services the power to “waive such requirements of [fraud and abuse laws] as may be necessary to carry out the provisions” of the program.<sup>235</sup> On November 2, 2011, CMS issued an IFR on “Final Waivers in Connection With the Shared Savings Program,” effective notwithstanding subsequent public comments, after reviewing stakeholder comments on its more stringent proposed waiver rule (“Waiver Designs Notice”), issued on April 7, 2011.<sup>236</sup> The interim final rule creates multiple ACO waivers for multiple purposes and functions within MSSP, as per concerns raised in public comments relating to the need for greater flexibility in waiver conditions to accommodate a “broader array of ACO activities,” including start-up, compensation, operations, and disposition of the entity.<sup>237</sup>

In pertinent part, these waivers include an ACO pre-participation waiver, ACO participation waiver, and shared savings distributions waiver with respect to Stark and other fraud and abuse laws (e.g., the Anti-Kickback Statute).<sup>238</sup> Though the rule segments waiver qualifications for different phases of ACO activities, it makes clear that “[a]n arrangement need only fit in one waiver to be protected.”<sup>239</sup> Designed to facilitate flexibility and certainty for providers, the multitude of waivers does complicate the regulatory analysis somewhat as compared to a singular standard.<sup>240</sup> Nonetheless, it avoids the dreaded and costly “transaction-by-transaction” analysis for ACO implementers whereby they would determine legality of individual

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<sup>233</sup> Letter from Am. Hosp. Ass'n to Marilyn Tavenner, Acting Administrator, Ctrs. for Medicare & Medicaid Servs. & Daniel R. Levison, Inspector General, Dep't of Health & Human Servs. (Jan. 3, 2012), *available at* [www.aha.org/advocacy-issues/letter/.../120103-cl-cms-1439-ifc.pdf](http://www.aha.org/advocacy-issues/letter/.../120103-cl-cms-1439-ifc.pdf).

<sup>234</sup> *Id.*

<sup>235</sup> 42 U.S.C. § 1395jjj(f) (2012).

<sup>236</sup> *See* Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992, 67993 (Nov. 2, 2011) (to be codified at 42 C.F.R. Chapter IV & 42 C.F.R. Chapter V).

<sup>237</sup> *See id.* at 67993-94.

<sup>238</sup> *See id.* at 67993.

<sup>239</sup> *See id.* at 67994.

<sup>240</sup> *See id.* at 67996-97.



transactions based on facts and circumstances rather than ensuring compliance for arrangements generally.<sup>241</sup>

One of the most significant modifications to CMS' initial proposed rule reflected in the interim final rule is a legal standard, "reasonably related to," that all three MSSP waivers share. It concerns the nature and extent of the relationship required between the proposed ACO arrangement and statutory goals of the MSSP. Under CMS' initial rule, an arrangement was exempt so long as it was "necessary for and directly related to" the statutory goals.<sup>242</sup> Citing overwhelming criticism received from commenters that this standard was overly restrictive; CMS relaxed its standard considerably to give certainty to providers forming ACOs.<sup>243</sup> ACO activities in the previous waiver rule did not cover or include expenses related to ACO formation and investment, including "start-up, training, hiring, and infrastructure."<sup>244</sup> There were also concerns that the "compartmentalized" approach of CMS' initial waiver, which did not include financial arrangements outside of savings distributions, was not conducive to the variety of activities ACOs must pursue with multiple actors (e.g., insurers, manufacturers) at different phases of operation (e.g., start-up, wind-down) to succeed.<sup>245</sup>

CMS' standard under the IFR for relationship between any proposed ACO arrangement under a waiver and the MSSP's statutory goals is that such arrangement be "reasonably related to" the purposes of the program.<sup>246</sup> The pre-participation and participation waivers entrust this determination to the ACO's governing body, whereas the shared savings distributions waiver leaves the question open-ended, requiring generally that distributions correspond to activities "reasonably related" to MSSP purposes.<sup>247</sup> CMS' explanation of the "reasonably related" provision of the waiver indicates that an ACO entity need only relate a given arrangement to any "one enumerated purpose" of the MSSP and that it "articulate clearly the nexus" between an arrangement and the respective statutory goal.<sup>248</sup> The boundaries of what constitutes a sufficient nexus or satisfactory explanation are unclear, though CMS does provide in regulations a non-exhaustive, but nonetheless extensive, list of covered "start-up" activities.<sup>249</sup> CMS defines "start-up activities" quite broadly as

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<sup>241</sup> See *id.* at 67996; see Letter from Am. Hosp. Ass'n, *supra* note 233; see Letter from Am. Med. Ass'n, Comment on Final Waivers in Connection with the Shared Savings Program, CMS – 1439 – IFC, at 1 (Jan. 3, 2012), available at <http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/html/2011-27460.htm>.

<sup>242</sup> See Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992, 67996 (Nov. 2, 2011) (to be codified at 42 C.F.R. Chapter IV & 42 C.F.R. Chapter V).

<sup>243</sup> See *id.*

<sup>244</sup> Kass & Linehan, *supra* note 140, at 110-11.

<sup>245</sup> Kass & Linehan, *supra* note 140, at 112.

<sup>246</sup> See Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992, 68002 (Nov. 2, 2011) (to be codified at 42 C.F.R. Chapter IV & 42 C.F.R. Chapter V).

<sup>247</sup> See *id.* at 68001.

<sup>248</sup> See *id.* at 68002.

<sup>249</sup> See *id.* at 68003.

“items services facilities, or goods . . . used to create or develop an ACO.”<sup>250</sup> These include network development, capital investment, infrastructure creation, clinical management systems, legal fees, hiring, and IT resources.<sup>251</sup>

This broad language affords ACO arrangements considerable flexibility for financial transactions and contributions as compared to traditional Stark exceptions or previous CMS waivers for shared savings.<sup>252</sup> There is no guarantee, however, that, in ensuring cost reduction measures are related to the goals of the MSSP, such measures will not nevertheless create abusive referrals or under-utilization. For instance, hospitals are now allowed under this rule to directly make compensation payments to ACO physicians for reducing patient duration of stay, readmission, and contracting with low-cost suppliers.<sup>253</sup> Regulations do indicate that ACO participants should “exercise diligence” in ensuring arrangements comply with this standard and that governing bodies specifically indicate their “bases for determinations” of reasonable relatedness.<sup>254</sup> The AMA indicated in final rule comments that it does not wish for CMS to add to this list or further delineate specific practices that are acceptable,<sup>255</sup> reflecting a desire to maximize providers’ discretionary control over how ACOs are structured.

The requirements for the pre-participation, participation, and shared savings distributions waivers for ACOs are distinct, though consistent in many respects. Pre-participation waivers are designed to facilitate proposed ACOs attracting necessary capital, investment, and contributions of infrastructure that might be otherwise prohibited.<sup>256</sup> They require, *inter alia*, that parties enter into the arrangement with “good faith intent” to form an ACO, include at least one party of the type eligible to form an ACO, take “diligent steps” to develop an eligible ACO, and provide “contemporaneous documentation” of all phases of formation and execution of an ACO arrangement to create an “audit trail.”<sup>257</sup> Requirements for the participation waiver are quite similar, except that they obligate ACO participants to be in “good standing” under the MSSP such that governance, leadership and management

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<sup>250</sup> *See id.*

<sup>251</sup> *See id.*

<sup>252</sup> *See* Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009, 73 Fed. Reg. 38502, 38549, 38553 (Jul. 7, 2008) (to be codified at 42 C.F.R. pts. 405, 409, 410, 411, 414, 415, 424, 485, and 486); *see* Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009, 73 Fed. Reg. 38502, at 38553 (July 7, 2008) (to be codified at 42 C.F.R. pts. 405, 409, 410, 411, 414, 415, 424, 485, and 486); *see* Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009, 73 Fed. Reg. 38502, 38554, 38555-56 (Jul. 7, 2008) (to be codified at 42 C.F.R. pts. 405, 409, 410, 411, 414, 415, 424, 485, and 486); *see also* Johnson & Blass, *supra* note 143, at 38.

<sup>253</sup> Khan, *supra* note 140, at 337-38.

<sup>254</sup> *See* Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992, 68004 (Nov. 2, 2011) (to be codified at 42 C.F.R. Chapter IV & 42 C.F.R. Chapter V).

<sup>255</sup> Letter from Am. Med. Ass’n., *supra* note 241, at 3.

<sup>256</sup> *See* Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992, 68003 (Nov. 2, 2011) (to be codified at 42 C.F.R. Chapter IV & 42 C.F.R. Chapter V).

<sup>257</sup> *See id.* at 68000, 68004.

structures satisfy all MSSP requirements.<sup>258</sup> The shared savings distributions waiver is also similar, except that it requires savings to be earned during the term of the participation agreement and distributed only to entities who were ACO participants or providers during the years in which the savings were actually earned.<sup>259</sup>

*B. Public Comments Received on CMS' Interim Final Waiver Rule*

There were numerous comments received in response to the IFR on MSSP Waivers issued by CMS. The following includes highlights from public comment on the current waivers for ACOs and concerns raised by prominent commenters about effects of ACOs on patients and the appropriate scope of waivers for Stark and other fraud and abuse laws.

The American Hospital Association (“AHA”) was pleased with the waivers and the “reasonably related” requirement and recommended finalizing them as-is.<sup>260</sup> AHA did complain, however, that the rule’s request for comments to narrow the waiver and provide more definition or specificity frustrated the “certainty” and “latitude” the IFR intended to afford ACO participants.<sup>261</sup> Certainty is required, according to AHA, to “develop the infrastructure necessary” for ACOs and encourage “beneficial innovation” in service delivery.<sup>262</sup> AHA opposed the rule’s presumption of automatically narrowing waivers without a notice and comment period absent evidence that fraud and abuse is not occurring.<sup>263</sup> AHA argued this imposes too exacting a standard on CMS if it desires to maintain waivers as it requires it to “prove a negative.”<sup>264</sup> AHA asserts the structure of ACOs and their quality and financial reporting will safeguard against abuse by medical providers so long as they comport with current waiver requirements.<sup>265</sup> AHA suggested that CMS use monitoring tools to take corrective action against individual ACOs that are abusive rather than base its entire policy on such risks.<sup>266</sup>

The American Medical Association (“AMA”) argued that “it is important to codify” the existing waivers in the IFR rather than permit them to be again changed in the near term to “assure prospective participants of their permanence.”<sup>267</sup> The AMA voiced concern about CMS’ indication in the IFR that shared savings distribution waivers would not extend to private ACOs not authorized under the MSSP and offered to help CMS “identify comparable private payer arrangements.”<sup>268</sup> It also asked CMS to extend the EHR exception under Stark

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<sup>258</sup> See *id.* at 28000-01.

<sup>259</sup> See *id.* at 28001.

<sup>260</sup> Letter from Am. Hosp. Ass’n, *supra* note 233, at 3.

<sup>261</sup> Letter from Am. Hosp. Ass’n, *supra* note 233, at 1.

<sup>262</sup> Letter from Am. Hosp. Ass’n, *supra* note 233, at 1.

<sup>263</sup> Letter from Am. Hosp. Ass’n, *supra* note 233, at 3.

<sup>264</sup> Letter from Am. Hosp. Ass’n, *supra* note 233, at 3.

<sup>265</sup> Letter from Am. Hosp. Ass’n, *supra* note 233, at 4.

<sup>266</sup> Letter from Am. Hosp. Ass’n, *supra* note 233, at 4.

<sup>267</sup> Letter from Am. Med. Ass’n, *supra* note 241, at 1.

<sup>268</sup> Letter from Am. Med. Ass’n, *supra* note 241, at 3.

beyond the 2013 expiration currently set by statute for purposes of ACOs and EHR adoption generally.<sup>269</sup>

The American Physical Therapy Association (“APTA”) submitted two separate comments to the IFR, one from the entire Association and another from its Private Practice Section.<sup>270</sup> The Association starts by arguing that the existing In-Office Ancillary Services exception to Stark results in “abusive financial arrangements” whereby physicians steer patients to in-house physical therapy services to increase practice profits.<sup>271</sup> The Association contends these arrangements are created “solely for profit” and without regard to the “best interest of the Medicare beneficiary.”<sup>272</sup> It is concerned that waivers associated with ACO implementation will only exacerbate this behavior and harm independent physical therapist practitioners in the process.<sup>273</sup> APTA argues that quality metrics used by MSSP to evaluate ACOs “do not contain the adequate measures to ensure that arrangements . . . truly result in improved quality of care” and, therefore, cannot substitute for Stark in protecting patients (and physical therapists) from abusive referrals.<sup>274</sup>

APTA argues that the waivers’ “reasonably related” standard is broad enough to cover most any arrangement and delivery of items or services within an ACO.<sup>275</sup> It recommends CMS narrow the language and articulate the nexus required for an activity to sufficiently further ACO objectives.<sup>276</sup> At a minimum, APTA argues the waiver protection should only be extended to activities for beneficiaries attributed to the ACO.<sup>277</sup> Immunity for non-ACO business will only create, according to APTA, new avenues for abuse and confer to ACOs an unfair market advantage over non-ACO providers.<sup>278</sup> Finally, APTA recommends, in lieu of the current approach, that CMS establish “bright line safeguards” that balance the need for flexibility in ACO implementation with protection from abuses associated with physician ownership of DHS.<sup>279</sup>

The Private Practice Sections’ comment is considerably more vocal about the potential for physician abuses within ACOs.<sup>280</sup> The Section focuses specifically on

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<sup>269</sup> Letter from Am. Med. Ass’n, *supra* note 241, at 5.

<sup>270</sup> Letter from APTA, Comment on Final Waivers in Connection with the Shared Savings Program, CMS – 1439 – IFC, at 1 (Jan. 3, 2012), *available at* <http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/html/2011-27460.htm>.

<sup>271</sup> *See id.*

<sup>272</sup> *See id.*

<sup>273</sup> *See id.*

<sup>274</sup> *See id.*

<sup>275</sup> *See id.*

<sup>276</sup> *See id.*

<sup>277</sup> *See id.*

<sup>278</sup> *See id.*

<sup>279</sup> *See id.*

<sup>280</sup> Letter from APTA Private Practice Section, Comment on Final Waivers in Connection with the Shared Savings Program, CMS – 1439 – IFC, at 1 (Jan. 3, 2012), *available at* <http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/html/2011-27460.htm>.

ACOs causing “underutilization, stinting of care, [and] lapses in quality” that will benefit physicians at the expense of patients.<sup>281</sup> The Section took issue with the “reasonably related” standard, noting that it was “vague and ambigu[ous]” and “broad and loose.”<sup>282</sup> This, according to the Section, is over-inclusive because it covers any kind of ACO inducement and will prompt physician abuse because of the lenient standard and lack of safeguards.<sup>283</sup> The Section anecdotally cited “creative business arrangements” designed to avoid the self-referral prohibition as evidence that physicians should not receive leeway in ACO implementation.<sup>284</sup> Moreover, it noted that, if the penalty or shared savings received by participants in ACOs are not greater than the gain from self-referral, they may nonetheless use ACOs to increase utilization and profits under the fee-for-service payment system.<sup>285</sup>

The Section was concerned about CMS’ “broad, permissive” pre-participation waivers granted for start-up arrangements.<sup>286</sup> Because the waiver currently allows a hospital or insurance company to donate a “complete [EHR] system as well as training and ongoing technical support” free of charge, the Section believes the inducement will corrupt ACO physicians’ decision-making to the benefit of the donor.<sup>287</sup> It further recommended requiring specific arrangements and their descriptions to be disclosed to patients and the general public and memorialized in signed writings.<sup>288</sup> The Section was also concerned about CMS allowing ACO participants to use savings distributions to later transact with “downstream” private insurers not involved with the ACO.<sup>289</sup> The Section noted that these payments increased the risk of physician abuse and were more likely to be sensitive to volume or value of referrals even if “reasonably related” to ACO objectives.<sup>290</sup>

The Section recommends incorporating prohibitions against exclusivity and commercial reasonableness/fair market value requirements into waiver eligibility.<sup>291</sup> It proposed to require ACO participants not to use shared savings to transact with outside parties as this would delegate care provision to “workers not recognized by Medicare.”<sup>292</sup> Finally, it recommended a return to the initial proposed rule’s standard that arrangements be “necessary for and directly related to” ACO objectives in order

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<sup>281</sup> *Id.*

<sup>282</sup> *Id.*

<sup>283</sup> *Id.*

<sup>284</sup> *Id.*

<sup>285</sup> *Id.*

<sup>286</sup> *Id.*

<sup>287</sup> *Id.*

<sup>288</sup> *Id.*

<sup>289</sup> *Id.*

<sup>290</sup> *Id.*

<sup>291</sup> *Id.*

<sup>292</sup> *Id.* at 8.

to qualify for waiver from Stark and other fraud and abuse laws to screen out abusive practices with little benefit.<sup>293</sup>

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) were generally pleased with the IFR.<sup>294</sup> Specifically, they appreciated anti-kickback immunity afforded by pre-participation and participation waivers to arrangements between ACOs and drug manufacturers.<sup>295</sup> They did, however, discuss previous OIG advisory opinions regarding gain-sharing arrangements of cost savings between hospitals and physicians and incentive payments in the 2009 Medicare fee schedule.<sup>296</sup> While the features and requirements of these arrangements are not identical to ACOs, the incentives created by and principles underlying shared savings are similar.<sup>297</sup> Risks for patient harm identified by OIG included providers cherry-picking patients, stinting patient services, and receiving payments to self-refer or reduce services.<sup>298</sup>

PhRMA recommends that CMS adopt the safeguards recommended by OIG in these advisory opinions, including: ACO assurance that physicians can use and prescribe pre-ACO items and services; heightened public transparency of arrangements and accountability for individual physicians; written disclosures of specific arrangements to patients; and greater limitation on duration and amount of financial rewards to be realized by ACOs.<sup>299</sup> PhRMA also, similarly to the APTA, notes the limitations of the existing set of quality measures used by the MSSP in evaluating ACOs, observing that the categories “do not encompass many diseases or conditions that frequently affect Medicare beneficiaries.”<sup>300</sup>

### C. Alternative Approaches

There are a number of alternative approaches to the current waiver structure adopted by CMS.<sup>301</sup> One is for CMS to conduct an individualized review of applications for waiver and grant or deny requests based on the circumstances and risks involved in each particular case.<sup>302</sup> This would preserve the existing Stark framework in scenarios where it is needed and allow CMS more flexibility and input into when the tradeoff between cost savings and risk for abuse favors enforcement. This option could, however, be costly for applicants and CMS to administer and

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<sup>293</sup> *Id.*

<sup>294</sup> Letter from PhRMA, Comment on Final Waivers in Connection with the Shared Savings Program, CMS – 1439 – IFC, at 1 (Jan. 3, 2012), *available at* <http://www.gpo.gov/fdsys/pkg/FR-2011-11-02/html/2011-27460.htm>.

<sup>295</sup> *Id.*

<sup>296</sup> *Id.*

<sup>297</sup> *Id.*

<sup>298</sup> *Id.*

<sup>299</sup> *Id.*

<sup>300</sup> *Id.*

<sup>301</sup> Hastings et al., *supra* note 179, at 4-5, 8-11.

<sup>302</sup> Hastings et al., *supra* note 179, at 4.

might discourage prospective ACOs from forming because of the additional review time and uncertainty of approval compared to self-implementing waivers.<sup>303</sup>

Another option would be for CMS to issue a waiver that prevents shared savings or care management fees from triggering a “financial relationship” within the meaning of Stark, at least so long as providers adhere to ACO safeguards relating to transparency, program integrity, and performance management.<sup>304</sup> Alternately, the Stark waiver could be conditioned upon ACO providers meeting additional fraud and abuse-oriented safeguards such as “quality of care process or outcome standards”<sup>305</sup> (e.g., give patients more options for referrals, track referral outcomes through EHR). This would ensure that patient health, satisfaction, and choice are not compromised as a result of cost reduction reforms in ACO delivery. Its success will depend on the extent to which MSSP safeguards and reporting/quality standards prevent abuse.<sup>306</sup> As noted by Madison, there is a plethora of concerns and complications to the effectiveness of quality data collection and reporting in terms of achieving various outcomes for patients.<sup>307</sup>

Another approach would be a waiver of Stark constraining the level of remuneration paid to ACO providers through savings distributions.<sup>308</sup> This option would be more restrictive than existing waivers because it limits rewards to savings distributions and excludes financial arrangements with outside investors or partners.<sup>309</sup> An advantage of this, however, is that it limits the scope of the waiver to necessary and agreed-upon functions in ACO operation.<sup>310</sup> Conversely, as ACO stakeholders point out in CMS waiver rulemaking, it reduces ACO participants’ flexibility by constraining their participation in EHR or care management donations, start-up funding and investment, and inducements to attract stakeholders.<sup>311</sup> Critics, by contrast, note the potential for the overbroad “latitude” currently afforded to providers to engage in any financial arrangement “reasonably related” to ACO purposes to foster abuse by providers at the expense of patients.<sup>312</sup>

## V. RECOMMENDATION

CMS’ current policy is to “wait and see” if and to what extent ACOs pose any fraud and abuse harm to patients and the Medicare program.<sup>313</sup> The benefits of “wait

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<sup>303</sup> Hastings et al., *supra* note 179, at 5-6.

<sup>304</sup> Hastings et al., *supra* note 179, at 7.

<sup>305</sup> Hastings et al., *supra* note 179, at 7.

<sup>306</sup> See Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992, 68008 (Nov. 2, 2011) (to be codified at 42 C.F.R. chapter IV and 42 C.F.R. chapter V).

<sup>307</sup> See Madison, *supra* note 167.

<sup>308</sup> Cf. Hastings, *supra* note 179, at 12.

<sup>309</sup> Hastings, *supra* note 179, at 12.

<sup>310</sup> Hastings, *supra* note 179, at 12.

<sup>311</sup> See Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992, 67997-98 (Nov. 2, 2011) (to be codified at 42 C.F.R. chapter IV and 42 C.F.R. chapter V).

<sup>312</sup> *Id.*; Khan, *supra* note 140, at 336-39.

<sup>313</sup> Khan, *supra* note 140, at 337-38.

and see” are readily apparent. Assuming CMS can accurately identify when and where fraud and abuse is occurring,<sup>314</sup> it will be able to better understand its causes and nature than one who is relying on theoretical predictions without observation. This will enable the agency to craft more tailored, effective, and appropriate long-term solutions to the problems actually occurring in the system. It would not incorporate, however, those effects from abuse that are unobserved or unobservable and, thus, not reflected in the data. Another benefit to a “wait and see” approach is that it pacifies ACO implementers in the short-term, ensuring that the delivery model has a chance to launch and begin generating results. It buys CMS more time to devise a sustainable strategy for addressing the difficult question of how to reconcile the fraud and abuse laws and the MSSP. It also grants CMS additional time to win support from the industry after its strong negative reaction to the initial proposed waiver that substantially restricted protections afforded to ACO operations from Stark and other fraud and abuse laws.

Experts and previous experience suggest that ACO providers will behave in predictable ways to maximize revenues and reduce their costs.<sup>315</sup> This suggests that deregulating ACO provider activity through looser standards than previously allowed under Stark will, at least in some circumstances, harm patients and the Medicare program without a Stark-like method to discourage abuse.<sup>316</sup> For example, the pre-participation waiver currently exempts any activity that can be considered “reasonably related” to “encouraging investment in infrastructure” and the participation waiver covers activity “reasonably related” to ACO efforts to “promot[e] accountability for the . . . cost” of care delivered to Medicare beneficiaries.<sup>317</sup> This creates a vacuum of regulation that will be filled with ACO activity that is legitimate and abusive, necessary and unnecessary, and beneficial and harmful.<sup>318</sup> Without a mechanism to balance these risks and concerns or otherwise distinguish between activities that are legitimate and those that are not, CMS is entrusting patients’ and Medicare’s protection from fraud and abuse laws to private self-regulation without much incentive to guard against abuse concerns beyond the MSSP program requirements.

Fashioning an *ex ante* solution has its costs as well. It runs the risk of inaccurately pre-determining the fraud and abuse problems of ACOs before they can be diagnosed. This could unnecessarily restrict beneficial activities of ACO providers and participants and hamper innovation in service delivery.<sup>319</sup> The task of

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<sup>314</sup> *But cf.* Madison, *supra* note 167, at 418-20.

<sup>315</sup> Madison, *supra* note 167, at 417-18; Letter from APTA, *supra* note 270, at 8-10.

<sup>316</sup> Revisions to Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009, 73 Fed. Reg. 38502, 38550 (Jul. 7, 2008) (to be codified at 42 C.F.R. pts. 405, 409, 410, 411, 414, 415, 424, 485, and 486).

<sup>317</sup> *See* Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992, 68001-03 (Nov. 2, 2011) (to be codified at 42 C.F.R. chapter IV and 42 C.F.R. Chapter V).

<sup>318</sup> *See* Khan, *supra* note 140, at 336.

<sup>319</sup> *See* Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992, 67999 (Nov. 2, 2011) (to be codified at 42 C.F.R. chapter IV and 42 C.F.R. Chapter V) (explaining aim of provider flexibility for CMS’ Interim Final Rule approach); Madison, *supra* note 167, at 420.



actually measuring and understanding the harmful effects of ACO operations on patients and Medicare, however, is likely much more daunting than suggested by CMS' rulemaking.<sup>320</sup> There are limits to existing data collection and statistical techniques, interpreting information that is self-reported and evaluated, and assessing medical judgments of practitioners afforded discretion in determining what treatments are best for patients.<sup>321</sup> All present numerous challenges to regulators attempting to visualize all the costs and benefits of ACOs.

Another potential drawback to reconciling Stark and the MSSP at this juncture is that—at least to some degree—the two may be irreconcilable. As noted earlier, the mechanism by which ACOs reduce expenditures, in-ACO referrals to providers that will limit or provide cheaper services in return for a share of savings to the referring physician, runs directly afoul of Stark's prohibition against self-referral.<sup>322</sup> Given the interrelatedness and complexity of existing Stark exceptions, however, it might be difficult to fashion an appropriate modification at this time for ACOs through statutory or regulatory change to Stark.

Based on the evidence discussed *supra* regarding the positive results of ACOs for patients both in terms of improving quality and reducing overall costs, CMS adopting a “wait and see” approach through an interim waiver is probably the best approach at this juncture. It gives physicians and hospitals a chance to implement ACOs in good faith without undue interference from fraud and abuse laws crafted on an entirely different payment and delivery model. It also minimizes cost of error for CMS because it can review 2012 empirical results from the Medicare ACOs currently being implemented, about which there is no data presently, rather than resort to conjecture based on previous integration attempts. Finally, it will give CMS the greatest possible flexibility to make changes later as opposed to finalizing a regulatory structure now that is undoubtedly going to change as ACOs permeate the national delivery system and generate unknown future results for patients and providers.

It would, however, be beneficial for ACO providers to adopt some additional modest safeguards to ensure that implementation does not veer too far from MSSP policies. This could include CMS requiring more direct disclosures to patients about the arrangements in which physicians are participating and financial relationships created. Without these, signage and automatic attribution of patients to ACO networks will fail to give adequate notice to beneficiaries of changes in their Medicare services. Additionally, CMS should require that arrangements be in writing and contain certain specific terms of the agreement. This would guard against any overt circumvention of CMS' requirements for ACOs by increasing transparency and documentation available to regulators and the public. Finally, using existing MSSP channels of oversight such as site visits and auditing during this initial implementation phase will be instructive to CMS monitoring efforts. It will also ensure that ACOs are working toward their promised objectives of cost reduction and improving patient health outcomes.

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<sup>320</sup> See Madison, *supra* note 167, at 418-20.

<sup>321</sup> See Madison, *supra* note 167, at 418-20.

<sup>322</sup> See Federal Stark Physician Self-Referral Statute, 42 U.S.C. § 1395nn(a)(1)(A) (West 2012) (establishing prohibitions for physicians); see also Medicare Shared Savings Program, 42 U.S.C. § 1395jjj (2012) (outlining statutory goals for providers).

## VI. CONCLUSION

Based on the unique payment and delivery structure of ACOs and early empirical evidence of their positive effects on patients, this Article recommends retaining existing waivers along with some modest safeguards.<sup>323</sup> Based on comments received during waiver rulemaking, it is clear that ACO participants require extensive latitude and flexibility to carry out their arrangements and meet target benchmarks for cost and quality performance.<sup>324</sup> Though there are strong arguments on both sides for less or more fraud and abuse protection in the ACO context, there is insufficient data right now to determine whether either side's contentions are realized in the market.<sup>325</sup> Until then, a broad and flexible waiver from CMS will provide regulators and industry participants alike the information they need to make more informed decisions about how to operate and regulate ACOs.

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<sup>323</sup> See *supra* Part IV.

<sup>324</sup> See Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67992, 67996-97 (Nov. 2, 2011) (to be codified at 42 C.F.R. chapter IV and 42 C.F.R. Chapter V).

<sup>325</sup> See Madison, *supra* note 167, at 419-25.