

# No VIP Treatment: ACOs Should Not Get Waiver Protection from the Prohibition on Beneficiary Inducement

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## INTRODUCTION

Virgil is known for saying “the greatest wealth is health.”<sup>1</sup> Based on the astronomical amount spent on healthcare, the United States has taken his idea literally—spending more “wealth” will lead to greater “health.” In 2006, the United States spent over seven thousand dollars per person annually on healthcare.<sup>2</sup> While that number may not seem very high to spend on an individual level, the total amounted to approximately 2.1 trillion dollars in 2006.<sup>3</sup> In 2014, that number hit three trillion, or seventeen percent of the country’s Gross Domestic Product (“GDP”).<sup>4</sup> One justification for spending nearly one-fifth of the United States GDP on healthcare<sup>5</sup> is that high quality health outcomes will result.<sup>6</sup> However, this causal leap depends on the assumption that spending more money on healthcare automatically leads to high quality, which is simply not the case.<sup>7</sup>

The traditional payment model in the United States for healthcare services is a fee-for-service model, where physicians and other healthcare providers are reimbursed based on the quantity of healthcare services delivered.<sup>8</sup> Physicians are financially rewarded based on high quantity, not high quality, and are incentivized to deliver as many services as possible.<sup>9</sup> As a result, healthcare innovators focused

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1. See *The Greatest Wealth Is Health*, U.N. ENVTL. PROGRAMME, <http://www.unep.org/stories/WorldHealthDay/The-Greatest-Wealth-Health.asp> (last visited Oct. 11, 2016) [<https://perma.cc/8XBF-2KUF>] (attributing the phrase “the greatest wealth is health” to the Roman poet Virgil).

2. Aaron Catlin et al., *National Health Spending in 2006: A Year of Change for Prescription Drugs*, 27 HEALTH AFF. 14, 14 (2008).

3. *Id.*

4. See *National Health Expenditures 2014 Highlights*, CTRS. FOR MEDICARE & MEDICAID SERVS. (2014), <https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/downloads/highlights.pdf> [<https://perma.cc/2VPU-JWF6>] (stating healthcare spending in the United States reached three trillion dollars in 2014).

5. *Id.*; see also *Health Care Costs to Reach Nearly One-Fifth of GDP by 2021*, KAISER HEALTH NEWS: KHN MORNING BRIEFING (June 13, 2012), <http://khn.org/morning-breakout/health-care-costs-4/> [<https://perma.cc/7N5X-MP8H>].

6. See David Auerbach & Arthur Kellermann, *A Decade of Health Care Cost Growth Has Wiped Out Real Income Gains for An Average U.S. Family*, 30 HEALTH AFF. 1630, 1633–34 (2011) (discussing whether rising costs have been accompanied by an increase in the value of healthcare).

7. See Katherine Baicker & Amitabh Chandra, *Medicare Spending, the Physician Workforce, and Beneficiaries’ Quality of Care*, HEALTH AFF. W4-184, W4-184 (Apr. 7, 2004), <http://content.healthaffairs.org/content/early/2004/04/07/hlthaff.w4.184.full.pdf> [<https://perma.cc/M6AV-UAYL>] (finding that “states with higher Medicare spending have lower-quality care”).

8. Steven M. Lieberman & John M. Bertko, *Building Regulatory and Operational Flexibility into Accountable Care Organizations and ‘Shared Savings’*, 30 HEALTH AFF. 23, 24 (2011).

9. See *id.* (arguing that under a fee-for-service model, providers are rewarded for performing a higher quantity of more expensive services).

on creating integrated healthcare delivery systems<sup>10</sup> to align financial incentives with cost containment and improved quality.<sup>11</sup> This Note focuses on Accountable Care Organizations (“ACOs”), specifically Medicare Shared Savings Program (“MSSP”) ACOs,<sup>12</sup> one of the healthcare delivery innovations introduced and endorsed by the Patient Protection and Affordable Care Act (“ACA”) enacted in 2010.<sup>13</sup> The Center for Medicare & Medicaid Services (“CMS”) defines ACOs as “groups of doctors, hospitals, and other healthcare providers, who come together voluntarily to give coordinated high quality care.”<sup>14</sup> An ACO is a legal entity accountable for the management and care coordination of a defined group of patients<sup>15</sup> and for delivering that care in an effective and efficient manner.<sup>16</sup>

Although increasing the efficiency and effectiveness of healthcare is a worthy goal, the design of integrated systems is inherently at odds with the fraud and abuse laws that currently regulate the healthcare industry.<sup>17</sup> In the healthcare context, fraud and

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10. See LEIYU SHI & DOUGLAS A. SINGH, *ESSENTIALS OF THE U.S. HEALTH CARE SYSTEM* 7 (2015) (defining an integrated delivery system as “a network of health care providers and organizations that provides or arranges to provide a coordinated continuum of services to a defined population and is willing to be held clinically and fiscally accountable for the clinical outcomes and health status of the population served”); Michael E. Porter, *What Is Value in Health Care?*, *NEW ENG. J. MED.* (Dec. 23, 2010), <http://www.nejm.org/doi/full/10.1056/NEJMp1011024?viewType=Print> [<https://perma.cc/3DGN-S9BL>] (describing healthcare delivery as “involv[ing] numerous organizational units, ranging from hospitals to physicians’ practices to units providing single services”).

11. See Donald Berwick, *The Triple Aim: Care, Health, and Cost*, 27 *HEALTH AFF.* 759, 761–62 (2008) (giving examples of innovations such as the primary care medical home, “Minute Clinics,” and hospitals using “lean production”).

12. For the purposes of this Note, “ACO” refers only to MSSP ACOs.

13. Patient Protection and Affordable Care Act, 42 U.S.C. § 18001 (2010). For the purposes of this Note, only Medicare ACOs and Medicare beneficiaries enrolled in Medicare Shared Savings Programs will be discussed. Section 3022 of the ACA created the MSSP for ACOs by amending Title XVIII of the Social Security Act, 42 U.S.C. § 1395, to include section 1899, “Shared Savings Program.” Patient Protection and Affordable Care Act, H.R. 3590, 111th Cong. (2009) (enacted).

14. *Accountable Care Organizations (ACO)*, *CTRS. FOR MEDICARE & MEDICAID SERVS.*, <http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/ACO/> (last visited Nov. 17, 2015) [<https://perma.cc/9UGR-VXC4>].

15. For the purposes of this Note, the words “beneficiary” and “patient” will be used interchangeably. By statutory definition, beneficiary “means an individual who is eligible to receive items or services for which payment may be made under a federal health care program but does not include a provider, supplier or practitioner.” 42 U.S.C. § 1320a-7a(i)(5) (2012).

16. Kelly Devers & Robert Berenson, *Can Accountable Care Organizations Improve the Value of Health Care by Solving the Cost and Quality Quandaries?*, *URB. INST.* 1–2 (Oct. 2009), <http://www.urban.org/sites/default/files/alfresco/publication-pdfs/411975-Can-Accountable-Care-Organizations-Improve-the-Value-of-Health-Care-by-Solving-the-Cost-and-Quality-Quandaries-.PDF> [<https://perma.cc/J4QK-YHWR>].

17. See Medicare Program; Final Waivers in Connection with the Shared Savings Program, 80 Fed. Reg. 66726, 66727 (Oct. 29, 2015) (describing initial concerns that the healthcare fraud and abuse regulatory regime in place at the time of the development of ACOs could “impede

abuse laws address referral or business remunerations, self-referrals, false claims, beneficiary inducements, and relevant civil monetary penalty provisions.<sup>18</sup> While these laws prevent abuse under traditional healthcare models, they can also limit efforts to coordinate care, reduce overall costs, and improve efficiencies.

The Centers for Medicare and Medicaid Services have given ACOs certain waivers to the healthcare fraud and abuse laws based on the notion that the structural design of ACOs will not work without violating these laws.<sup>19</sup> Affording this leniency to ACOs at such an early stage, however, may in fact perpetuate new and different kinds of abuse and fraud.<sup>20</sup> While all of these waivers are discussed generally, this Note focuses on the waiver from the prohibition on the inducement of beneficiaries.<sup>21</sup> The waiver broadly expands the scope of permissible inducements, despite the numerous existing exceptions to the prohibition.<sup>22</sup> Broadening this scope puts patients at risk, as they are often unaware of financial incentives motivating their providers.<sup>23</sup> Information asymmetry<sup>24</sup> between providers and patients combined

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development of innovative integrated-care arrangements envisioned by the Shared Savings Program, including shared savings arrangements and care coordination arrangements”).

18. See Robert D. Stone & Kim McWhorter, *Healthcare Fraud and Abuse Laws*, in *GHA HOSPITAL LAW MANUAL 6* (2014), [http://www.alston.com/files/docs/6th\\_rev\\_Healthcare\\_Fraud\\_Abuse.pdf](http://www.alston.com/files/docs/6th_rev_Healthcare_Fraud_Abuse.pdf) [<https://perma.cc/J8TZ-W8WP>] (providing an overview of the fraud and abuse laws that regulate the healthcare industry).

19. See Robert G. Homchick & Sarah Fallows, *ACOs: Fraud & Abuse Waivers and Analysis*, DAVIS WRIGHT TREMAINE, LLP, [https://www.healthlawyers.org/events/programs/materials/documents/hct13/h\\_homchick.pdf](https://www.healthlawyers.org/events/programs/materials/documents/hct13/h_homchick.pdf) (last visited Jan. 6, 2017) [<https://perma.cc/7299-C268>] (portraying the waivers as a means to “facilitate the establishment of ACOs” because ACOs as envisioned could not exist without violating these laws).

20. See Medicare Program; Final Waivers in Connection with the Shared Savings Program, 80 Fed. Reg. at 66739 (noting that during the notice-and-comment period before the Final ACO Waivers were approved, commentators highlighted the fact that the beneficiary inducement waiver may “encourage behaviors viewed as fraudulent and abusive”).

21. See Civil Monetary Penalties Law, 42 U.S.C. § 1320a-7a(a)(5) (2012) (beneficiary inducement CMP); 42 U.S.C. § 1395jjj(f) (2012) (“The Secretary may waive such requirements of sections 1320a-7a and 1320a-7b of this title and this subchapter as may be necessary to carry out the provisions of this section.”).

22. See Medicare Program; Final Waivers in Connection with the Shared Savings Program, 80 Fed. Reg. at 66739 (highlighting one commentator’s advocacy “that ACOs should have the same flexibility to offer inducements that is permitted under current law, which the commentor believes will allow health care professionals not in an ACO to be on a level playing field with those in ACOs”).

23. Information asymmetry is not limited to disparities in medical knowledge. There is widespread lack of knowledge among the general population on how healthcare is paid for and what the existing financial incentives in place for providers are.

24. See Ake Blomqvist, *The Doctor as Double Agent: Information Asymmetry, Health Insurance, and Medical Care*, 10 J. HEALTH ECON. 411, 428–29 (1991) (describing the relationship between providers and patients as characterized by information asymmetry).

with ACO providers' ability to induce enrollees in ways other healthcare organizations cannot is problematic.<sup>25</sup>

This Note examines the rationale for allowing ACOs to have such broad exemptions from fraud and abuse laws, specifically focusing on the waiver of the prohibition on inducing beneficiaries. Part I discusses the tumultuous healthcare space in which ACOs developed and defines ACOs and their basic requirements. Part II examines the traditional healthcare fraud and abuse laws and the underlying rationale for allowing ACOs waivers from these laws, the exceptions to the prohibition on beneficiary inducement for non-ACOs, and the expanded scope of permissible inducements ACOs can employ under the waiver. Part III identifies problems with affording ACOs more freedom to use inducements more broadly. Finally, Part IV recommends that ACOs should no longer have this waiver, and instead, ACOs should implement shared decisionmaking initiatives, reduce information asymmetry between patients and providers, and strategize methods to retain patients and contain patient leakage.<sup>26</sup> This will create stronger patient-provider relationships that are rooted in education, analysis, and true change as opposed to relationships created through inducement and shallow interactions.

## I. WHAT ARE ACOS, AND WHY DO THEY MATTER?

ACOs are a key model in the current phase of healthcare delivery and reform. The drafters of the ACA viewed ACOs as an important experiment in healthcare innovation that could serve as an interim model for future healthcare delivery alternatives.<sup>27</sup> This Part discusses (A) the traditional healthcare system and landscape prior to healthcare reform and the role both providers and patients have in driving up healthcare costs, and (B) the emergence of ACOs as an innovative healthcare delivery system.

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25. 42 U.S.C. 1320a-7a(a)(5).

26. See J. Michael McWilliams et al., *Outpatient Care Patterns and Organizational Accountability in Medicare*, 174 JAMA INTERNAL MED. 938, 939 (2014) (defining "leakage of outpatient care" as "the proportion of office visits for an ACO's assigned patients that occurs outside of the contracting organization").

27. Frank Pasquale, *Accountable Care Organizations in the Affordable Care Act*, 42 SETON HALL L. REV. 1371, 1371 (2012).

*A. Bad Incentives and a Broken System*

Healthcare spending by all payers<sup>28</sup> has risen in part due to the assumption that increased spending on healthcare services produces better care outcomes.<sup>29</sup> However, extensive research and analysis has demonstrated that this is not the case.<sup>30</sup> In many situations, the impact of increased spending on healthcare outcomes has been negligible and can even result in poorer outcomes for patients, such as unnecessary procedures and out-of-pocket expenses.<sup>31</sup> There is no longer a consensus that increased spending on a higher quantity of services will deliver better quality care and outcomes.<sup>32</sup> Evidence of clinical variation for treating the same diseases<sup>33</sup> across geographical regions and even within the same cities has called into question the notion that more services lead to better outcomes.<sup>34</sup> Differences in the course of treatment for the same disease across clinical settings reflect the fact that there is no unitary standard for practicing medicine in the United States.<sup>35</sup> A provider in one locale presented with a set of symptoms may treat a patient in an entirely different manner than a provider in a different locale.<sup>36</sup> Each provider is free to pursue any medically defensible course of treatment with no accountability for the total cost or overall quality, leading to widely different costs and quality outcomes.<sup>37</sup>

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28. The rise in overall systemic healthcare costs reflects increased spending by all payers, which includes the government (Medicare and Medicaid), insurance companies (third-party payers), and individuals (if uninsured). Government and third-party payers reimburse doctors and hospitals on a fee-for-service basis.

29. See Arnold Milstein & Helen Darling, *Better U.S. Health Care at Lower Cost*, 26 ISSUES SCI. & TECH. 31, 31 (2010) (“Unsustainable growth in U.S. health care spending . . . out-paced other industrialized nations by 30% from 2000 to 2006, without evidence of a proportionally higher health dividend.”).

30. See Karen Davis et al., *The Commonwealth Fund, Mirror, Mirror on the Wall, 2014 Update: How the U.S. Health Care System Compares Internationally* (2014), <http://www.commonwealthfund.org/publications/fund-reports/2014/jun/mirror-mirror> [<https://perma.cc/47A9-CZNG>] (finding that the United States consistently spends more than other comparable countries on healthcare and achieves lower quality outcomes).

31. See John E. Wennberg, *Unwarranted Variations in Healthcare Delivery: Implications for Academic Medical Centres*, 325 BRITISH MED. J. 961, 963–64 (2002) (discussing how greater healthcare expenditure results in “no better, or possibly worse, global outcomes”).

32. STEFAN TIMMERMANS & MARC BERG, *THE GOLD STANDARD: THE CHALLENGE OF EVIDENCE-BASED MEDICINE AND STANDARDIZATION IN HEALTH CARE* (2010).

33. Wennberg, *supra* note 31, at 964.

34. See *id.* (suggesting greater healthcare expenditure may actually result in worse outcomes).

35. See *id.* (discussing the “variation in clinical practice”).

36. *Id.*

37. *Id.*

Under the traditional healthcare system, the most common model of reimbursement is fee-for-service. Fee-for-service payments reimburse physicians according to the volume of services rendered, incentivizing physicians to exponentially increase volume.<sup>38</sup> However, the volume of services<sup>39</sup> rendered by physicians and the quality of these services are not aligned in this model.<sup>40</sup> Third-party payers are responsible for physician reimbursement and often deny or limit reimbursement to providers based on the patient's insurance.<sup>41</sup> Thus, payers further incentivize physicians to render as many services as possible because it is not always clear for which services physicians will actually receive payment. For example, if a physician sees a Medicare patient in his or her private practice, it is possible that Medicare will reimburse only a small fraction of payment, if Medicare reimburses at all.<sup>42</sup> This places the provider in a position where he or she must cross-subsidize<sup>43</sup> to break even or make a profit. The pressure to cross-subsidize pushes physicians to provide as many possible tests and services to a patient with high-paying insurance or Medicare, as there is a stronger likelihood of reimbursement with these payers,<sup>44</sup> with no accountability or requirement for a provider to demonstrate a justified connection to the healthcare outcomes of that patient.<sup>45</sup> In short, the traditional system results in overutilization.

Misaligned incentives and overutilization in the healthcare system do not affect only the way providers behave. Imagine a scenario

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38. See Steven A. Schroeder & William Frist, *Phasing Out Fee-For-Service Payment*, 368 NEW ENG. J. MED. 2029, 2029 (2013).

39. *Id.* "Volume of services" refers to any medical service that can be reimbursed by a payer and for the purposes of this Note, by Medicare. Under a fee-for-service model, payers reimburse providers for specific procedures, visits, and surgeries but generally do not reimburse for less tangible services like coordinated care, patient education, preventative efforts, and public health initiatives. Institutions and providers often end up bearing the brunt of the cost of these services and are therefore not financially incentivized to implement these services, despite the fact that they have been shown to reduce cost and improve the quality of care in the long run.

40. See *id.* (recommending "a shift from a payment system based on a fee-for-service model to one based on value").

41. Merrill Matthews, *Doctors Face a Huge Medicare and Medicaid Pay Cut in 2015*, FORBES (Jan. 5, 2015), <http://www.forbes.com/sites/merrillmatthews/2015/01/05/doctors-face-a-huge-medicare-and-medicaid-pay-cut-in-2015/#24a779035c6d> [<https://perma.cc/XT5N-EB7E>].

42. Robert S. Kaplan et al., *Intelligent Redesign of Health Care*, HARV. BUS. REV. (Oct. 14, 2013), <https://hbr.org/2013/10/intelligent-redesign-of-health-care/> [<https://perma.cc/CBB3-RD6N>].

43. *Id.* Cross-subsidization in the healthcare industry refers to the practice of offsetting losses caused by services rendered in a delivery setting that lose money with profit-making services in order to remain competitive in the healthcare marketplace. *Id.*

44. Because most low-paying insurers will not cover expensive services, providers will be minimally reimbursed and may in fact lose money by treating patients with low-paying insurance like Medicaid patients.

45. Kaplan et al., *supra* note 42.

in which a patient has shortness of breath or heart palpitations and goes to the emergency room, the most expensive place to receive care.<sup>46</sup> This patient is covered by Medicare and will want every single test possible.<sup>47</sup> The patient is not responsible for the majority of the payment due to his or her Medicare coverage and will likely not account for the costs of these procedures when demanding multiple tests.<sup>48</sup> Likewise, the provider will be more than happy to oblige because he or she will be able to get a larger reimbursement for more tests.<sup>49</sup> This perpetuates an unsustainable system where patients are positioned to demand as many services as possible, and physicians are incentivized to provide those services without being held accountable for the quality.<sup>50</sup> This, in turn, drives up costs without necessarily improving outcomes or increasing efficiencies.

Patient demand for possibly unnecessary services is directly linked to widespread information asymmetry between providers and patients.<sup>51</sup> Trust and confidence, along with a mutual understanding that providers have more knowledge to make decisions with regard to treatments, referrals, and hospitalizations, have defined the relationship between providers and patients.<sup>52</sup> Patients, too, have been unwilling to consider costs when presented with comparable options, resisting choosing the less expensive, marginally inferior option,<sup>53</sup> and consistently preferring the best care at any cost as opposed to “good enough” care at a less expensive cost.<sup>54</sup> Under the traditional healthcare model, patients were not required to think about the costs associated

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46. See Robin M. Weinick et al., *How Many Emergency Department Visits Could Be Managed at Urgent Care Centers and Retail Clinics*, 29 HEALTH AFF. 1630, 1634 (2010) (“Prior studies have estimated that costs of care at retail clinics and urgent care centers are \$279–\$460 and \$228–\$414 less than emergency department costs, respectively, for similar cases.”).

47. See WILLIAM JACK, *PRINCIPLES OF HEALTH ECONOMICS FOR DEVELOPING COUNTRIES* 56 (1993) (arguing that the existence of insurance allows many healthcare services to be provided at low cost, indicating that demand will likely be infinite, or at a minimum extremely high).

48. *Id.*

49. See Schroeder & Frist, *supra* note 38, at 2029 (acknowledging that the traditional fee-for-service healthcare model “contains incentives for increasing the volume and cost of services (whether appropriate or not)”).

50. *Id.* at 2030; see also Stephen Shmanske, *Information Asymmetries in Health Services: The Market Can Cope*, 1 INDEP. REV. 191, 194 (1994) (“If a third party pays all or part of the cost of additional care, consumers will demand more care than they would otherwise.”).

51. See Blomqvist, *supra* note 24, at 428–29 (asserting that there is “a high degree of information asymmetry between buyers and sellers” in the healthcare industry).

52. Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 951 (1963).

53. See Roseanna Sommers et al., *Focus Groups Highlight that Many Patients Object to Clinicians’ Focusing on Costs*, 32 HEALTH AFF. 338, 339 (2013) (finding “four times as many negative comments as there were positive ones on the theme of willingness to discuss costs”).

54. *Id.* at 340.

with healthcare services and felt little responsibility for unsustainable growth in healthcare spending resulting from expensive and potentially excessive healthcare.<sup>55</sup>

Moreover, a knowledge gap exists not only with regard to medical information, but also with regard to cost information. Patients are unconcerned with containing systemic costs because discussions between patients and providers regarding cost rarely take place under the traditional model.<sup>56</sup> Because many providers are often unaware of the actual prices the hospital may charge, it is possible they do not have these conversations because they do not have the specific knowledge. They may not feel compelled to gain this knowledge either, as patients themselves tend to ignore any cost for which they are not personally responsible.<sup>57</sup> Patients covered by Medicare may not be interested in learning about the costs of various procedures and care, as they are not financially responsible.<sup>58</sup>

### B. *The ABCs of ACOs*

The unsustainable costs of a fragmented healthcare system led to experiments in healthcare innovation and reform by different institutions, the government, and insurance companies.<sup>59</sup> ACOs are an example of an innovative healthcare delivery model that may serve as a possible solution to the problems existing in the healthcare space. Different institutions had made efforts to integrate care and implement value-based reimbursement methods before the introduction of ACOs, and these efforts informed much of what is seen in the design and structure of ACOs.<sup>60</sup>

Before the passing and initial implementation of the ACA in 2010, there was widespread acknowledgment within the healthcare community that improved clinical integration could lead to better, more

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55. *Id.* at 341.

56. *See id.* at 344 (discussing the effort “to educate the public about the overuse of tests and treatments” and the approach “that providers should explicitly discuss the costs of treatments with patients”).

57. James Hardee et al., *Discussing Healthcare Costs with Patients: An Opportunity for Empathic Communication*, 20 J. GEN. INTERNAL MED. 666, 667 (2005).

58. *Id.*

59. *Id.*

60. *See* Vanessa Fuhrmans, *Replicating Cleveland Clinic’s Success Poses Major Challenges*, WALL ST. J., <http://www.wsj.com/articles/SB124831191487074451> (last updated July 23, 2009) [<https://perma.cc/YX9K-HR7B>] (“[President Obama] has held up [the Cleveland Clinic] as a model for delivering high-quality and cost-effective health care. But trying to replicate the clinic’s approach . . . would pose difficult challenges.”).

efficient outcomes.<sup>61</sup> The healthcare community, on both an academic and practical level, began to emphasize aligning financial incentives with quality, intensified pressure to improve care coordination,<sup>62</sup> and generated an impetus to eliminate fragmentation in healthcare service delivery.<sup>63</sup> Despite a widespread understanding by the stakeholders in the healthcare community of the issues, a complete systemic overhaul posed numerous difficulties.<sup>64</sup> For many healthcare institutions, achieving these goals would be extremely difficult due to financial and operational constraints often associated with providing highly integrated care, such as technological barriers and advanced data analytics.<sup>65</sup> However, even before the ACA was enacted, there were examples of integrated healthcare delivery models that achieved success by deviating from the traditional fee-for-service model of reimbursement.<sup>66</sup>

One example that President Obama held up as a model for high quality at a low cost is the Cleveland Clinic in Ohio.<sup>67</sup> Specific structural aspects that make the Clinic distinctive include its “being a closed staff, salaried, group practice” that is “physician-led” and features a “vigorous annual review process for all physicians and leaders.”<sup>68</sup> The Clinic is an extensive regional clinic that is integrated and consists of a tiered care delivery system that “provides patients with the appropriate level of care for each phase of their condition.”<sup>69</sup> It promoted patient-centered

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61. See Ellen Pryga et al., *Clinical Integration: The Key to Reform*, TRUSTEE, June 1, 2010, at 2 (“Clinical integration can improve the quality and efficiency of our current health care system.”).

62. See generally NAT’L ACAD. OF SCIS., COMM. ON DIAGNOSTIC ERROR IN HEALTH CARE, IMPROVING DIAGNOSIS IN HEALTH CARE (Erin P. Balogh et al. eds., 2015).

63. See Thomas Bodenheimer, *Coordinating Care—a Perilous Journey Through the Health Care System*, 358 NEW ENG. J. MED. 1064 (2008) (calling for an end to fragmentation and a move to “care coordination”).

64. See *id.* at 1065–66 (discussing various “barriers to seamless coordination” within the industry).

65. Thomas C. Brown, Jr., et al., *Current Trends in Hospital Mergers and Acquisitions: Healthcare Reform Will Result in More Consolidation and Integration Among Hospitals, Reversing a Recent Trend in Which Hospitals Tended to Stay Away from Such Transactions*, HEALTHCARE FIN. MGMT., Mar. 2012, at 114, 115 (discussing how the “municipal bond market” and the notion that “hospitals are part of the local economy” have both contributed to the failure of hospitals to consolidate).

66. *Id.*

67. See Obama, Romney Agree: ‘No Debate’ that Cleveland Clinic is Great, ADVISORY BOARD (Oct. 8, 2012), <https://www.advisory.com/Daily-Briefing/2012/10/08/Obama-Romney-agree-no-debate-Cleveland-Clinic-is-great> [<https://perma.cc/NV2N-GHMX>] (highlighting the fact that Cleveland Clinic was recognized as one of the nation’s top health systems across party lines).

68. James K. Stoller, *The Cleveland Clinic: A Distinctive Model of American Medicine*, 2 ANNALS TRANSLATIONAL MED. 33, 33 (2014).

69. Delos M. Cosgrove, *A Healthcare Model for the 21st Century: Patient-Centered, Integrated Delivery Systems*, 80 GROUP PRAC. J. 11, 12 (2011).

care by consolidating clinical services into patient-centered institutes,<sup>70</sup> created the role of the Patient Experience Officer,<sup>71</sup> and implemented a Patient Advisory Council for patients to “share ideas on improving the patient experience.”<sup>72</sup> The Clinic has universal data sharing and requires patient outcomes and procedure costs to be published, shared, and used to achieve new efficiencies.<sup>73</sup> The Clinic is a group practice with physician leadership, but with no financial incentives in place for salaried physicians.<sup>74</sup> Because physicians receive only one-year contracts, the annual performance reviews are used to renew contracts and ensure the quality of the institution is maintained.<sup>75</sup> The design of the institute structure promotes collaboration and teamwork to solve complicated problems efficiently.<sup>76</sup>

The Cleveland Clinic, and other models like it, provides an example of a highly coordinated system that achieves great success in delivering high quality care without waivers from healthcare antifraud laws.<sup>77</sup> Unlike traditional healthcare models, the Clinic demonstrates that focusing on patient-centered care within one integrated network, performing annual reviews, and removing any connection between

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70. See *Patient-Centered Medical Home*, CLEVELAND CLINIC (2016), <http://my.clevelandclinic.org/services/medicine-institute/patient-centered-medical-home> [<https://perma.cc/3VZE-5CVJ>]. Cleveland Clinic has instituted patient-centered medical homes where patients have a direct relationship with a team designed to coordinate their care, manage their medications, take collective responsibility for the totality of care for the patient, and perform follow-up care in the case of hospitalization.

71. See *Office of Patient Experience*, CLEVELAND CLINIC (2017), <http://my.clevelandclinic.org/patients-visitors/patient-experience> [<https://perma.cc/3HYR-BFPD>] (describing the role of the Chief Experience Officer as the head of the Office of Patient Experience and initiatives to improve the patient experience across the Cleveland Clinic Health System). Specific examples of these initiatives include same-day access for patients, patient-tracking GPS, integrated Intensive Care Units and physicians, critical care transport, bed management, and direct, standardized communication with patients. See *Creating a Patient-Centered Healthcare System*, CLEVELAND CLINIC, <http://my.clevelandclinic.org/ccf/media/files/redefining-healthcare/patient-centered.pdf> (last visited Jan. 7, 2017) [<https://perma.cc/JJ5X-K4JY>].

72. *A Model for Healthcare of the Future*, CLEVELAND CLINIC, <https://my.clevelandclinic.org/ccf/media/Files/redefining-healthcare/healthcare-future.pdf?la=en> (last visited Feb. 27, 2016) [<https://perma.cc/5H57-NNDA>] (focusing the Cleveland Clinic’s resources on promoting healing and enhancing the experiences of patients and employees).

73. See *Cleveland Clinic CEO: Four Ingredients in Our ‘Secret Sauce,’* ADVISORY BOARD (Dec. 10, 2012), <https://www.advisory.com/daily-briefing/2012/12/10/cleveland-clinic-ceo-four-ingredients-in-our-secret-sauce> [<https://perma.cc/B2EN-QCEA>] (sharing an example where analyzing cost variability of prostatectomies at different hospitals led to improved efficiencies and a reduction in procedure costs by twenty-five percent).

74. *Id.*

75. Cosgrove, *supra* note 69, at 14.

76. *Id.*

77. See *id.* (stating that “[t]he Mayo Clinic and Cleveland Clinic, which share the same model of healthcare delivery, were the two leaders in low-cost chronic care”).

financial reimbursement and the quantity of services performed can lead to greater efficiencies and improvement in care.<sup>78</sup>

Models like the Cleveland Clinic, however, cannot be feasibly implemented everywhere across the country for a number of reasons. First, there are significant cultural barriers that cannot be easily changed.<sup>79</sup> For example, many providers are independent and highly value their autonomy to make decisions regarding the treatment of their patients and how best to practice medicine.<sup>80</sup> Second, because of the Clinic's unique reputation and numerous international locations,<sup>81</sup> it stays profitable by receiving payments from private insurers and foreign patients who can afford to pay entirely out of pocket, which generally is not the case for many institutions.<sup>82</sup> Third, there are significant financial and technological barriers for smaller hospitals to replicate the level of integration and care of the Clinic.<sup>83</sup>

In order to address these barriers, many institutions, practices, and physicians began consolidating to better deliver integrated, high-quality care at a lower cost.<sup>84</sup> These entities viewed consolidation as the only way to survive financially and keep up with changing technology.<sup>85</sup> ACOs and the idea of "virtual" organizations as the locus for integration and accountability developed as an alternative to consolidation and as a means to replicate many of the methods employed by institutions like the Cleveland Clinic.<sup>86</sup>

ACOs aspire to contain costs, deliver higher quality care to patients, improve access, and correctly align financial incentives for

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78. *Id.*

79. Fuhrmans, *supra* note 60.

80. *See id.* (quoting Dr. John Kastor, a medical professor at the University of Maryland, stating "[p]hysicians don't like others to tell them what to do").

81. *See Locations & Directions*, CLEVELAND CLINIC (2017), [http://my.clevelandclinic.org/locations\\_directions](http://my.clevelandclinic.org/locations_directions) [<https://perma.cc/9GYF-7NZN>] (listing the various domestic and international locations where the Cleveland Clinic model has been implemented).

82. *Id.*

83. Fuhrmans, *supra* note 60.

84. *Id.*

85. *See* Bob Herman, *Consolidation Could Be Next for Academic Medical Centers*, MODERN HEALTHCARE (July 5, 2014), <http://www.modernhealthcare.com/article/20140705/MAGAZINE/307059964> [<https://perma.cc/YU2P-6UCP>] (arguing that supporting infrastructure changes and surviving in a cost-cutting environment is difficult to do without consolidation or access to capital).

86. *See* Elliott Fisher et al., *Creating Accountable Care Organizations: The Extended Hospital Medical Staff*, 26 HEALTH AFF. w44, w45–w46 (2007), <http://content.healthaffairs.org/content/26/1/w44.full.pdf> [<https://perma.cc/T28K-R4DM>] (exploring an approach that fosters "the development of accountable care organizations comprising local hospitals and the physicians who work within and around them"). ACOs, unlike models like the Cleveland Clinic, are not necessarily found in a specific, physical location and can consist of a virtual organization of providers in different locations forming one ACO. *Id.*

physicians.<sup>87</sup> Providers operating in an ACO must “work together to coordinate care for the Medicare Fee-For-Service beneficiaries they serve.”<sup>88</sup> Three essential characteristics of ACOs include (1) managing and providing a continuum of care for patients across different institutional settings; (2) prospectively planning budget and resource needs; and (3) supporting valid, reliable, and comprehensive performance measurement.<sup>89</sup>

ACOs operate under the premise that coordinated care with an emphasis on preventative medicine helps ensure that patients receive the “right care at the right time.”<sup>90</sup> By focusing attention on preventative medicine and the totality of care, proponents of ACOs believe that medical errors can be significantly reduced and that high cost treatments can potentially be avoided, saving money for the system and improving overall health outcomes.<sup>91</sup> The MSSP helps currently existing Medicare fee-for-service program providers become ACOs.<sup>92</sup> It was created to coordinate providers and facilitate cooperation to reward ACOs that lower healthcare costs while simultaneously meeting performance standards.<sup>93</sup>

ACOs agree to be accountable for health outcomes and the total experience of care received by patients enrolled in the ACO.<sup>94</sup> To qualify as an ACO under the MSSP, providers must have a patient population of at least five thousand primary care Medicare beneficiaries to whom they are responsible for at least three years.<sup>95</sup> Shared savings are then rewarded to the ACO members based on annual quality metric outcomes of the specific population.<sup>96</sup> ACOs do not necessarily abandon

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87. Mark McClellan et al., *A National Strategy to Put Accountable Care into Practice*, 29 HEALTH AFF., 982, 982–83 (2010).

88. *Summary of Final Rule Provisions for Accountable Care Organizations Under the Medicare Shared Savings Program*, CTRS. FOR MEDICARE & MEDICAID SERVS. 3 (Mar. 2016), [https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharesavingsprogram/Downloads/ACO\\_Summary\\_Factsheet\\_ICN907404.pdf](https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/sharesavingsprogram/Downloads/ACO_Summary_Factsheet_ICN907404.pdf) [https://perma.cc/WTS8-CZRR] [hereinafter ACO Fact Sheet].

89. Devers & Berenson, *supra* note 16, at 2.

90. ACO Fact Sheet, *supra* note 88, at 2.

91. *Id.*

92. *Id.*

93. *Medicare Shared Savings Program and Rural Providers*, CTRS. FOR MEDICARE & MEDICAID SERVS. 1 (Mar. 2016), [https://www.cms.gov/medicare/medicare-fee-for-service-payment/sharesavingsprogram/downloads/aco\\_rural\\_factsheet\\_icn907408.pdf](https://www.cms.gov/medicare/medicare-fee-for-service-payment/sharesavingsprogram/downloads/aco_rural_factsheet_icn907408.pdf) [https://perma.cc/A8GB-25VU].

94. *Id.*

95. Erin Bradley, *Accountable Care Organizations Antitrust Guidelines Will Not Save Rural Providers*, 34 J. LEGAL MED. 295, 301 (2013).

96. ACO Fact Sheet, *supra* note 88, at 3.

the traditional fee-for-service model under Medicare.<sup>97</sup> Instead, they enter risk-sharing agreements with CMS and receive a portion of any shared savings obtained by reductions in costs<sup>98</sup> associated with the enrolled population of the particular ACO,<sup>99</sup> as long as they meet the required quality benchmarks.<sup>100</sup> These risk-sharing agreements can be one-sided,<sup>101</sup> where an ACO will be rewarded for spending below projected costs, or two-sided,<sup>102</sup> where an ACO can also be penalized for spending above projections.<sup>103</sup> Under the MSSP, ACOs can choose how to structure the risk of monetary loss. If an ACO wants a larger part of shared savings at the end of the year, it can assume a larger portion of the risk of potentially losing more money, or it can enter a program with no risk of penalty but will receive a smaller portion of savings.<sup>104</sup>

ACOs are also required to establish and maintain a governing body that must include meaningful representation by not just the ACO participants, but by ACO beneficiaries as well.<sup>105</sup> In order to meet CMS-defined quality and improvement goals, the ACO governing body must ensure compliance with evidence-based clinical guidelines.<sup>106</sup> Examples of other requirements include the implementation of an information technology infrastructure, a physician-directed quality improvement program, and a written plan for achieving and distributing shared savings.<sup>107</sup>

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97. *Id.* at 5.

98. *Id.* at 6.

99. See 42 C.F.R. § 425.20 (2011) (defining an enrolled beneficiary as a Medicare beneficiary who receives at least one primary care service with a date of service during a specified twelve-month assignment window from a Medicare-enrolled physician who is a primary physician or has an enumerated specialty designation).

100. Charles B. Oppenheim et al., *Accountable Care Organization Final Regulations: Analysis and Implications*, HOOPER, LUNDY & BOOKMAN, P.C. 1 (2011), [http://www.health-law.com/media/news/48\\_HLB\\_ACO\\_White\\_Paper\\_-\\_Final\\_Rule.pdf](http://www.health-law.com/media/news/48_HLB_ACO_White_Paper_-_Final_Rule.pdf) [<https://perma.cc/VTL6-Q6DD>]; see also 42 C.F.R. § 425.500 (2011) (listing the minimum quality standards an ACO needs to meet in order to obtain shared savings).

101. 42 C.F.R. § 425.604 (2011).

102. 42 C.F.R. § 425.610 (2011).

103. Oppenheim et al., *supra* note 100, at 25.

104. Jenny Gold, *Accountable Care Organizations, Explained*, KAISER HEALTH NEWS (Sept. 14, 2015), <http://khn.org/news/aco-accountable-care-organization-faq/> [<https://perma.cc/72GL-5GB6>].

105. See 42 C.F.R. § 425.106 (2011) (stating that an ACO governing body must include a Medicare beneficiary who is (1) served by the ACO, (2) is not an ACO provider or supplier, (3) does not have a conflict of interest with the ACO, and (4) does not have an immediate family member who has a conflict of interest with the ACO).

106. See 42 C.F.R. § 425.502 (2011). There are currently thirty-three quality performance measures across four quality domains: (1) patient/caregiver experience, (2) care coordination/patient safety, (3) preventive health, and (4) at-risk populations. *Id.*

107. 42 C.F.R. § 425.112 (2011).

In order to preserve patient autonomy, patients have the freedom to choose any provider they wish and are not limited to seeking care only from providers within the ACO they are assigned to.<sup>108</sup> This presents problems for ACOs concerned with controlling costs and promoting efficient utilization of services when beneficiaries choose to seek care from a provider outside of the ACO. ACOs are interested in retaining the same beneficiaries assigned to their ACO because monitoring and coordinating care over longer periods of time positions ACOs to provide better care and reduce costs.<sup>109</sup> Further, ACOs are accountable for the entire beneficiary population assigned to them.<sup>110</sup> When beneficiaries seek care outside of the ACO network, that care will still be reflected in the quality measures to which ACO shared savings are tied.<sup>111</sup> Negative quality outcomes or excessive spending on unnecessary tests will affect the total amount of shared savings split among ACO providers.<sup>112</sup> Providers are therefore incentivized to keep beneficiaries within the network because it can affect their bottom line and the dollar amount reimbursed by CMS.

## II. ANTIFRAUD LAWS AND ACOS

This Part analyzes the relationship between existing healthcare fraud and abuse laws with ACOs. Specifically, it discusses (A) the types of fraud and abuse that occur in the healthcare industry and the laws enacted to prevent fraud and abuse from occurring, (B) the Beneficiary Inducement Prohibition and its enumerated exceptions, and (C) the expansion of permissible inducements ACOs may use under the protection of the waiver.

### *A. Fraud and Abuse in the Traditional Healthcare Model*

Following the introduction of Medicare<sup>113</sup> and Medicaid<sup>114</sup> as large governmental payers, poorly aligned incentives resulted in numerous opportunities for providers and institutions to commit fraud and abuse. After the implementation of Medicare and Medicaid, the

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108. 42 C.F.R. § 425.304(c) (2011).

109. *Id.*

110. *Id.* at 4.

111. *Id.* at 13.

112. *Id.*

113. 42 U.S.C. §§ 1395–1395hhh (2012).

114. 42 U.S.C. §§ 1396–1396v (2012).

government greatly increased spending on healthcare.<sup>115</sup> For providers, obtaining referrals from colleagues became a way to increase the volume of services rendered and consequently the amount of reimbursement, which led to providers paying other providers kickbacks in exchange for referrals.<sup>116</sup> In order to prevent this from occurring, Congress enacted what is commonly known as the Anti-Kickback Statute.<sup>117</sup> The Anti-Kickback Statute was enacted in order to prevent individuals from “knowingly offering and receiving any kind of payment or gift” that induces or influences the generation of healthcare services or business that can be paid for in whole or part by the federal government.<sup>118</sup> This statute has been interpreted to cover any arrangement in which “one purpose” of the remuneration was to obtain money for the referral of services or to induce further referrals.<sup>119</sup>

As healthcare costs continued to rise in the 1970s and 1980s, physicians began investing in ancillary services and referring patients to treatment at facilities in which they had financial interests.<sup>120</sup> Studies have also shown that when physicians had ownership interests in another facility, they were much more likely to refer their patients to that facility.<sup>121</sup> In response, Congress passed what is commonly known as the Stark Law.<sup>122</sup> Subject to limited exceptions, the Stark Law prevents physicians from referring Medicare patients for certain designated healthcare services to an entity with whom the physician or

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115. Corbin Santo, *Walking a Tightrope: Regulating Medicare Fraud and Abuse and the Transition to Value-Based Payment*, 64 CASE W. RES. L. REV. 1377, 1379 (2014).

116. *Id.*

117. Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(1)–(2) (2012); *see also* Santo, *supra* note 115 (recognizing Congress realized the detrimental effects kickback payment arrangements could have on the long-term solvency of Medicare and Medicaid programs).

118. 42 U.S.C. § 1320a-7b(b)(1)–(2).

119. *See, e.g.*, *United States v. Borrasi*, 639 F.3d 774, 781–82 (7th Cir. 2011) (“We join our sister circuits in holding that if part of the payment compensated past referrals or induced future referrals, that portion of the payment violates 42 U.S.C. § 1320a-7b(b)(1).”); *United States v. McClatchey*, 217 F.3d 823, 834–35 (10th Cir. 2000) (“This court . . . holds that a person who offers or pays remuneration to another person violates the [Anti-Kickback Statute] so long as one purpose of the offer or payment is to induce Medicare or Medicaid patient referrals.”); *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998) (same); *United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985) (same).

120. *See* Santo, *supra* note 115, at 1379–80 (arguing that physicians offset reimbursement reductions caused by cost containment measures by investing in laboratory services, diagnostic imaging centers, medical equipment companies, and outpatient surgery centers and then referring patients to these entities).

121. *See generally* Patrick A. Sutton, *The Stark Law in Retrospect*, 20 ANNALS OF HEALTH LAW 15, 16–18 (2011).

122. *See* Santo, *supra* note 115, at 1380 (stating that Representative Fortney Stark sponsored the legislation and that the statute presumes all existing referrals made to entities with physician ownership interests or compensation arrangements were illegal unless the arrangement satisfied an existing enumerated exception or an exception later promulgated by CMS).

his or her immediate family member has a financial relationship.<sup>123</sup> If an entity receives a prohibited referral, it may not bill the Medicare program for the resulting items and services.<sup>124</sup> In addition to these two major pieces of legislation, the Civil Monetary Penalties (“CMP”) provisions of the Social Security Act<sup>125</sup> and the False Claims Act<sup>126</sup> provided a structural framework to regulate relationships in the healthcare sector.<sup>127</sup> The CMP provisions include the gainsharing CMP<sup>128</sup> and the beneficiary inducement CMP.<sup>129</sup>

These statutes were designed to prevent providers and suppliers from overusing government healthcare resources, to constrain the exorbitant spending on healthcare, and to ensure that patients’ care is not influenced by doctors’ desires to make a larger profit.<sup>130</sup> However, as lawmakers began to recognize that these laws stifled innovation in the healthcare delivery space, exceptions to these laws became more pervasive.<sup>131</sup> Safe harbor regulations were introduced in order to protect specific business practices that would not be deemed unlawful or contrary to the statutory intent of the healthcare fraud laws but that could easily be textually interpreted to be in violation of these laws.<sup>132</sup>

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123. Limitation on Certain Physician Referrals (Stark Law), 42 U.S.C. § 1395nn (2012).

124. *Id.*

125. 42 U.S.C. § 1320a-7a (2012).

126. False Claims Act, 42 U.S.C. § 1320a-7b(a) (2012). For the purposes of this Note, the False Claims Act will not be discussed, as ACOs do not receive waivers from the False Claims Act.

127. Santo, *supra* note 115, at 1380.

128. 42 U.S.C. § 1320a-7a(b) (gainsharing CMP). This provision will not be addressed in this Note. ACOs initially received a waiver. However, the final rule issued in October 2015 deviated from the interim final rule by no longer waiving the gainsharing CMP. Medicare Program; Final Waivers in Connection with the Shared Savings Program, 80 Fed. Reg. 66726 (Oct. 29, 2015). At the time the interim final rule was published, hospitals were prohibited from knowingly paying providers or inducing providers to reduce or limit services, including medically unnecessary services. *Id.* However, the statute has been amended to only prohibiting hospitals from paying physicians to reduce or limit medically necessary services. *Id.* at 66726–27. Thus, according to CMS, ACOs no longer require a waiver from this provision, as the amendment no longer interferes with the goal of limiting medically *unnecessary* services. *Id.*

129. 42 U.S.C. § 1320a-7a(a)(5) (2012) (beneficiary inducement CMP).

130. *See* Santo, *supra* note 115, at 1394 (describing the motivations behind these statutes).

131. Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88368, 88368 (Dec. 7, 2016).

132. *See* Stone & McWhorter, *supra* note 18, at 14 (“To ensure that certain acts or arrangements will not be subject to prosecution under the AKS, the OIG has adopted safe harbor regulations.”). Criteria used by the Secretary of Health and Human Services in considering whether a specified payment practice should lead to the creation of a safe harbor regulation include (1) an increase or decrease in access to health care services; (2) an increase or decrease in the quality of health care services; (3) an increase or decrease in patient freedom of choice among health care providers; (4) an increase or decrease in competition among health care providers; (5) an increase or decrease in the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations; (6) an increase or decrease in the cost

If an act or arrangement complies with one of the safe harbor regulations promulgated by the Office of the Inspector General (“OIG”), those involved in the act or arrangement will generally “not be prosecuted or sanctioned.”<sup>133</sup> Safe harbors and advisory opinions issued by the OIG assess the risk of various arrangements that would otherwise violate existing fraud and abuse laws and give guidance on more specific situations.<sup>134</sup>

### *B. The Beneficiary Inducement Prohibition*

The beneficiary inducement prohibition, included in the CMP provisions of the Social Security Act, prevents healthcare service providers from offering or transferring remunerations they “know or should know” will likely influence a beneficiary’s decision to order or receive services from a particular provider, practitioner, or supplier.<sup>135</sup> In order for the statute to be implicated, a person must either act in “deliberate ignorance” or “reckless disregard” of the truth or falsity of information and there must be proof of a specific intent to defraud.<sup>136</sup> The requirement that an inducement be related to a specific provider differentiates the beneficiary inducement CMP from the Anti-Kickback Law, which requires only a “remuneration to induce beneficiaries to order an item or service” for the law to be implicated.<sup>137</sup>

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to federal health care programs; (7) an increase or decrease in the potential overutilization of health care services; (8) the existence or nonexistence of any potential financial benefit to a health care professional or provider, in which the benefit may vary depending on whether the health care professional or provider decides to order a health care item or service or arrange for a referral of health care items or services to a particular practitioner or provider; and (9) any other factors the Secretary deems appropriate in the interest of preventing fraud and abuse in federal health care programs. 42 U.S.C. § 1320a-7d (2012).

133. Santo, *supra* note 115, at 1394.

134. *Beneficiary Inducements in an Evolving Market: Assessing the Risks, Understanding the Benefits, and Drawing the Lines*, AM. HEALTH LAWYERS ASS’N 5, <https://www.healthlawyers.org/hlresources/PI/ConvenerSessions/Documents/Beneficiary%20Inducements%20White%20Paper.pdf> (last visited Oct. 5, 2016) [<https://perma.cc/5TMR-5ANU>].

135. 42 U.S.C. § 1320a-7a(a)(5) (2012). This provision only prohibits inducements to Medicare and state health care program beneficiaries. Medicare and State Health Care Programs: Fraud And Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88368 (Dec. 7, 2016).

136. *See* 42 U.S.C. § 1320a-7a(i)(7) (defining the term “should know” for the purposes of the beneficiary inducement CMP).

137. *See* Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. at 88390 (stating that the beneficiary inducement CMP would not be triggered “if a hospital were to offer a beneficiary remuneration post-discharge to follow up with a physician (without regard to who that physician might be, and without recommending a particular physician or group)”).

In December 2016, the OIG issued a Final Rule expanding the scope of statutory exceptions to the beneficiary inducement CMP by amending the definition of “remuneration.”<sup>138</sup> Remunerations for all healthcare providers now include “waiver[s] of coinsurance and deductible amounts” and “transfers of items or services for free or for other than fair market value.”<sup>139</sup> These exceptions are established by their explicit exclusion from the definition of remuneration.<sup>140</sup> The amended definition includes an exception protecting “any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal Health care programs.”<sup>141</sup> The OIG narrowly construes this exception to protect only behaviors promoting access to care and does not protect inducements “rewarding patients for accessing care.”<sup>142</sup> However, some incentives that encourage patients to actively seek care may be protected under a different exception—the exception protecting inducements promoting preventive care.<sup>143</sup> Depending on the set of circumstances, the same remuneration can either trigger the beneficiary inducement prohibition CMP or completely avoid any implication.<sup>144</sup> In practice, this expansion of exceptions broadens the tools all providers can use to encourage patients to take ownership of their own care.

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138. *Id.* at 88369. These enumerated exceptions relate to copayment reductions for outpatient department services; remunerations that promote access to care and pose a low risk of harm to beneficiaries; remunerations for certain eligible retailer rewards programs; certain remunerations to financially needy individuals; and copayment waivers for the first fill of generic drugs. *Id.* at 88370.

139. 42 U.S.C. § 1320a-7a(i)(6).

140. 42 U.S.C. § 1320a-7a(i)(6)(A-H).

141. 42 U.S.C. § 1320a-7a(i)(6)(F). “Care,” in the context of “access to care,” refers to “access to items and services that are payable by Medicare or a State health care program for the beneficiaries who receive them.” Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. at 88391. In order for a remuneration to be considered “low risk,” the remuneration must (1) be unlikely to interfere with, or skew, clinical decisionmaking; (2) be unlikely to increase costs to federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (3) not raise patient-safety or quality-of-care concerns. *Id.* at 88396.

142. Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. at 88393.

143. 42 U.S.C. § 1320a-7a(i)(6)(D).

144. Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. at 88391–92.

*C. ACOs: Why Do They Get To Cut in Line?*

The restrictive nature of the existing healthcare regulatory framework posed numerous obstacles for introducing value-based reimbursement initiatives and other alternative delivery options. The rigid healthcare regulatory framework, developed to prevent fraud from occurring in the traditional system, allowed only integrated organizations to operate under scrutiny from regulatory bodies or within the confines of a safe harbor. This framework was not designed to complement value-based, collaborative, risk-sharing delivery systems like ACOs, but to curb the kind of abuse that ACOs have arguably been designed to avoid entirely.<sup>145</sup> The fraud and abuse laws were designed to protect government healthcare programs and beneficiaries; however, these laws can “act as barriers to incentivizing the kind of performance and behavior that CMS is trying to get out of ACOs.”<sup>146</sup> Recognizing this, the antitrust agencies, the Department of Health and Human Services (“HHS”), and the OIG allowed ACOs that met certain criteria to be granted waivers from these laws.<sup>147</sup> Shared savings and other incentives considered critical to the success of ACOs violate these laws, so the HHS Secretary therefore found it necessary to waive certain fraud and abuse laws in order for the goals of the MSSP to be carried out.<sup>148</sup>

For example, providers within an ACO are financially integrated as a result of their contract with CMS and are able to make referrals to each other, despite this financial relationship.<sup>149</sup> Financial integration and collective responsibility for a defined group of patients are the basic building blocks of ACOs. Thus, an ACO violates the Stark Law by simply existing.<sup>150</sup> Because of this inherent violation, CMS and the OIG

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145. *See supra* Section II.A.

146. Lisa Schencker, *HHS Extends Stark, Anti-kickback Waiver for ACOs*, MODERN HEALTHCARE (Oct. 17, 2014), <http://www.modernhealthcare.com/article/20141017/NEWS/310179934> [<https://perma.cc/6E7L-FC6R>] (discussing the “underlying tension” between ACOs and the fraud and abuse statutes).

147. *See* Medicare Program; Waiver Designs in Connection with the Medicare Shared Savings Program and the Innovation Center, 76 Fed. Reg. 19655 (proposed Apr. 7, 2011) (seeking public comment on proposed waivers to ACOs). The Federal Trade Commission (“FTC”) and the Department of Justice (“DOJ”) have issued specific antitrust guidelines regarding ACOs because of their unique nature, but ACOs do not have an exemption from antitrust law. Statement of Antitrust Enforcement Policy Regarding Accountable Care Organizations Participating in the Medicare Shared Savings Program, 76 Fed. Reg. 67026 (Oct. 28, 2011) [hereinafter ACO Antitrust Policy]; *see also supra* Part I.

148. Medicare Program; Final Waivers in Connection with the Shared Savings Program, 80 Fed. Reg. 66726, 66726 (Oct. 29, 2015).

149. *Id.*

150. *See supra* Section II.A.

allow waivers because they believe the structural design and statutory requirements of ACOs mitigate the risks financial integration pose.<sup>151</sup>

CMS and the OIG recognized that ACOs and their constituent parts needed flexibility to “pursue a wide array of activities, including start up and operating activities that further the purposes of the Shared Savings Program.”<sup>152</sup> Without these waivers, ACOs are subject to the same safe harbors and enumerated exceptions as any other healthcare organization. The waivers are intended to protect arrangements that do not fall under a safe harbor or exception, minimizing situations where ACOs must undergo the case-by-case review process often undertaken when arrangements are questionable.<sup>153</sup>

ACOs participating in the Medicare Shared Savings Program currently have waivers<sup>154</sup> from the Stark Law,<sup>155</sup> the Anti-Kickback Statute,<sup>156</sup> and some provisions of the civil money penalty law, including the gainsharing CMP<sup>157</sup> and the prohibition on inducements to beneficiaries.<sup>158</sup> The ACA offers additional authority for the HHS Secretary to waive various fraud and abuse laws for pilot and demonstration programs, with CMS and OIG responsible for administering and regulating such waivers.<sup>159</sup> These waivers have been fine-tuned since the first proposed rule in November 2011, and the most recent final rule has been in effect since October 29, 2015.<sup>160</sup> The final existing waivers as of the most recently issued Final Rule are (1) “ACO

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151. Medicare Program; Final Waivers in Connection with the Shared Savings Program, 80 Fed. Reg. at 66726. CMS and the OIG viewed them as necessary because “providers must integrate in ways that potentially implicate fraud and abuse laws addressing financial arrangements between sources of federal healthcare program referrals and those seeking such referrals. *Id.*

152. *See id.* at 66726–28 (noting the concerns of stakeholders that the fraud and abuse laws inhibit incentives necessary for innovative care coordination models to be successful, such as the provision of EHR systems, IT services, or free care management personnel). It should also be noted that these waivers only apply to ACOs participating or seeking to participate in the MSSP. Homchick & Fallows, *supra* note 19, at 2.

153. Final Waivers in Connection with the Shared Savings Program, 80 Fed. Reg. at 66739.

154. The authority to promulgate these waivers comes from section 1899(f) of the Social Security Act. *See* 42 U.S.C. § 1395jjj(f) (2012) (“The Secretary may waive such requirements of sections 1320a-7a and 1320a-7b of this title and this subchapter as may be necessary to carry out the provisions of this section.”).

155. 42 U.S.C. § 1395nn (2012).

156. 42 U.S.C. § 1320a-7b(b)(1)–(2) (2012).

157. 42 U.S.C. § 1320a-7a(b).

158. 42 U.S.C. § 1320a-7a(a)(5).

159. *See* Medicare Program; Final Waivers in Connection with the Shared Savings Program, 80 Fed. Reg. 66726, 66727 (Oct. 29, 2015) (“The [ACA] includes separate authority for the Secretary to waive certain laws, including certain fraud and abuse laws, for some other demonstrations and pilot programs.”).

160. *See id.* at 66726 (describing the dates associated with the waivers).

pre-participation” waiver;<sup>161</sup> (2) “ACO participation” waiver;<sup>162</sup> (3) “shared savings distributions” waiver;<sup>163</sup> (4) “compliance with the physician self-referral law” waiver;<sup>164</sup> and (5) “patient incentive” or prohibition on beneficiary inducement waiver.<sup>165</sup>

The existing safeguard limiting these waivers is that the “arrangement in question or the use of certain funds be reasonably related to the purposes of the Shared Savings Program.”<sup>166</sup> An ACO’s governance body is responsible for making determinations as to whether an arrangement is “reasonably related” to the purposes of the MSSP.<sup>167</sup> CMS and the OIG expect that the governing body formed by the ACO will engage in a “thoughtful, deliberative process” when determining whether an arrangement is reasonably related to “truly furthering the interests of the ACO as a whole and meeting the objectives of the Shared Savings Program.”<sup>168</sup> If an arrangement is formed and timely review does not follow, this may indicate that the ACO was “acting for other purposes” and did not make a bona fide determination.<sup>169</sup> It becomes the responsibility of the ACO governing body to ensure that the arrangements formed are for the purposes of improving quality outcomes and reducing cost and not to further

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161. *See id.* at 66727–28 (defining “ACO pre-participation” waiver as a waiver of the physician self-referral law and the federal anti-kickback statute that applies to ACO-related start-up arrangements in anticipation of participating in the MSSP, subject to limitations that include the duration of the waiver and the types of parties covered).

162. *See id.* at 66728 (defining “ACO participation” waiver as a waiver of the physician self-referral law and the federal anti-kickback statute that applies broadly to ACO-related arrangements during the term of the ACO’s participation agreement under the Shared Savings Program and for a specified time thereafter).

163. *See id.* (defining “shared savings distributions” waiver as a waiver of the physician self-referral law and the federal anti-kickback statute that applies to distributions and uses of shared savings payments under the MSSP).

164. *See id.* (defining “compliance with the physician self-referral law” waiver as a waiver of the physician self-referral law and the federal anti-kickback statute for ACO arrangements that implicate the physician self-referral law and satisfy the requirements of an existing exception).

165. *See id.* (defining “patient incentive” waiver as a waiver of the beneficiary inducements CMP and the federal anti-kickback statute for medically related incentives offered by ACOs, ACO participants, or ACO providers/suppliers under the MSSP to beneficiaries to encourage preventive care and compliance with treatment regimes). For the purposes of this Note, “patient incentive waiver” is used interchangeably with “beneficiary inducement waiver.”

166. *See id.* at 66730; Robert Belfort, *A New Fraud and Abuse Paradigm for ACOs: Blurring the Distinction Between Providers and Payers*, 15 *Health Care Fraud Rep.* (BNA) No. 6, at 274 (Mar. 23, 2011).

167. Medicare Program; Final Waivers in Connection with the Shared Savings Program, 80 *Fed. Reg.* at 66734.

168. *Id.*

169. *Id.*

“individual financial or business interests” of ACO participants, providers, or suppliers.<sup>170</sup>

One of the reasons CMS and the OIG waived the beneficiary inducement was to prevent patients from seeking care outside the ACO and to “foster patient engagement in improving quality and lowering costs.”<sup>171</sup> Supporters emphasize that this waiver is necessary to achieve better health and better care for Medicare patients.<sup>172</sup> As a result, Congress authorized the regulatory agencies to waive the prohibition on beneficiary inducement for ACOs as “ne[cessary] to promote greater preventive care, to incentivize patients to follow treatments or follow-up care regimes, and to increase participation in ACOs.”<sup>173</sup>

In order to receive protection under the waiver, ACOs must enter into an ACO participation agreement and be in good standing.<sup>174</sup> As with the other healthcare fraud waivers, the item or service being offered to a beneficiary must have a reasonable connection to the medical care of the beneficiary.<sup>175</sup> The items or services must be in-kind and must either be a preventive care item or service or advance adherence to a treatment regime, drug regime, follow-up care plan, or management of a chronic disease condition.<sup>176</sup> ACOs, however, are expressly prohibited from using inducements to reward beneficiaries for receiving care or remaining in an ACO.<sup>177</sup>

Unlike healthcare providers who do not have a waiver of the beneficiary inducement CMP, ACOs are permitted to use incentives designed to encourage and reward beneficiaries who seek care.<sup>178</sup> For example, a reward for simply adhering to a treatment plan is permissible for ACOs who have a patient inducement waiver. In contrast, this would not be a protected inducement under the “promotes access to care” statutory exception, unless the remuneration removes obstacles preventing adherence to a plan or somehow assists the beneficiary with compliance.<sup>179</sup>

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170. *Id.*

171. *Id.* at 66739.

172. *Id.* at 66729.

173. *Id.*

174. *Id.* at 66743.

175. *Id.*

176. *Id.*

177. *Id.* at 66739.

178. Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88368, 88394 (Dec. 7, 2016).

179. *Id.*

### III. PROBLEMS WITH GIVING ACOs A BENEFICIARY INDUCEMENT WAIVER

By offering “giveaways,” providers can distort patient decisionmaking and can result in inappropriate medical choices and increased costs.<sup>180</sup> Expanding the range of allowable inducements for ACOs alone can potentially harm competing providers and suppliers who cannot afford to compete in this manner.<sup>181</sup> The corresponding risk to patients increases as well.<sup>182</sup>

#### *A. ACOs Are Financially Incentivized to Retain Patients*

The Stark Law prevents physicians from referring Medicare patients to an entity “with which the physician or an immediate family member has a financial relationship.”<sup>183</sup> The Secretary for HHS waived this rule for ACOs because ACO providers make referrals to each other, despite being in the same risk pool and sharing in the same cost savings annually.<sup>184</sup> However, in order to avoid the pitfalls associated with the managed care movement,<sup>185</sup> ACOs are required to give patients the ability to seek providers outside the ACO network, preserving patient choice.<sup>186</sup> Limiting patients to providers within a specific network can be restrictive and can lead to frustrated patients who are unsatisfied with the care they are receiving.<sup>187</sup>

Allowing patients to pursue provider options outside the ACO network gives patients more freedom but poses problems for ACOs interested in reducing patient turnover. Patient leakage occurs when patients enrolled in an ACO seek care from providers outside of the

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180. Publication of OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, 67 Fed. Reg. 55855, 55856 (Aug. 30, 2002).

181. *See id.* (“The use of giveaways to attract business also favors large providers with greater financial resources for such activities, disadvantaging smaller providers and businesses.”).

182. *See id.* (“Providers may have an economic incentive to offset the additional costs attributable to the giveaway by . . . substituting cheaper or lower quality services.”).

183. Limitation on Certain Physician Referrals (Stark Law), 42 U.S.C. § 1395nn (2012).

184. Medicare Program; Final Waivers in Connection with the Shared Savings Program, 80 Fed. Reg. 66726, 66737 (Oct. 29, 2015).

185. Ctrs. for Medicare & Medicaid Servs., *Accountable Care Organizations & You: Frequently Asked Questions for People with Medicare*, DEP’T OF HEALTH & HUM. SERVS. (2015), <https://www.medicare.gov/Pubs/pdf/11588.pdf> [<https://perma.cc/32XL-WHG7>]; *see also* Lawton R. Burns & Mark V. Pauly, *Accountable Care Organizations May Have Difficulty Avoiding the Failure of Integrated Delivery Networks of the 1990s*, 31 HEALTH AFF. 2407, 2413 (2012).

186. Oppenheim et al., *supra* note 100, at 10.

187. *See* Burns & Pauly, *supra* note 185, at 2413 (noting that providers in ACOs cannot control whether patients use out-of-network providers and must rely on persuasion instead).

ACO.<sup>188</sup> This diminishes an ACO's ability to achieve successful care coordination at a lower cost for the enrolled population.<sup>189</sup> While only limited research has been performed, early findings suggest that a substantial number of ACO beneficiaries do not stay attributed to the same ACO, and leakage is an extensive problem.<sup>190</sup> ACOs are motivated to do everything possible to keep patients from "leaking" outside of the ACO as they are still responsible for all outcomes of patients attributed to the ACO, with those outcomes affecting the ultimate financial reward providers receive.<sup>191</sup> ACOs are also responsible for all associated expenses when an ACO patient receives care outside the ACO.<sup>192</sup> Additionally, if a patient receives the majority of primary care services from a non-ACO physician, it is possible he or she will no longer be attributed to the ACO, which can affect an ACO's ability to remain qualified under the MSSP.<sup>193</sup>

### *B. Information Asymmetry Leaves Beneficiaries Exposed*

The financial motivations tied to preventing patient attrition are exacerbated by the information asymmetry that exists between physicians and patients. Physicians, by nature of their professional medical training, possess information that patients cannot access and cannot understand.<sup>194</sup> This information is not limited to medical knowledge—it extends to knowledge of incentives built into the traditional model along with incentives built into the ACO model. Patients have no guarantees that physicians will not use "their informational advantage for personal gain."<sup>195</sup> It is unlikely that patients will question the amount of tests a provider orders for them, just as it is unlikely that a patient will question why they are being offered an inducement.<sup>196</sup> Personal motivations may lead a physician to

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188. Kip Sullivan, *Patient Turnover in ACOS Destroys Accountability*, PHYSICIANS FOR A NAT'L HEALTH PROGRAM (June 23, 2015), <http://pnhp.org/blog/2015/06/23/patient-turnover-in-acos-destroys-accountability/> [<https://perma.cc/U4ZD-XUSX>].

189. McWilliams et al., *supra* note 26, at 939.

190. *See id.* at 941 (finding that over one-third of beneficiaries attributed to an ACO in 2010 or 2011 were not assigned to the same ACO in both years).

191. *Id.* at 943.

192. Lindsay Blazej, *Help, My ACO Is Leaking Patients!*, LAUNCHMED (July 11, 2014), <http://www.launch-med.com/resources/blog/help-my-aco-is-leaking-patients.html> [<https://perma.cc/A7BQ-5NZX>].

193. *Id.*

194. Stephen Shmanske, *Information Asymmetries in Health Services: The Market Can Cope*, 1 INDEP. REV. 191, 197 (1996).

195. *Id.* at 198.

196. *Id.*

order more tests to receive higher reimbursement, and unless this leads to higher out-of-pocket costs, patients would have neither the incentive nor the knowledge to challenge such decisions.<sup>197</sup> Similarly, ACO providers may take advantage of the relaxed limitations on inducements and use inducements to keep patients from seeking care elsewhere.

In order to improve transparency, ACOs are required to publish data that include general information regarding the ACO, organizational information, information regarding shared savings or losses, and the results of patient experience of care surveys and other claims-based measures.<sup>198</sup> CMS also requires ACO providers to inform patients that the provider may receive an additional financial reward based on quality and cost outcomes.<sup>199</sup> This disclosure, however, is reported on the ACO website, and the only other requirement is notifying beneficiaries of participation in an ACO at the point of care.<sup>200</sup> Patients are often unaware they are even enrolled in an ACO, and many do not have access to this disclosure or may not understand this disclosure.<sup>201</sup>

Publicly providing these details is an important step towards improving transparency, but falls short of providing patients with relevant, understandable guidance on how ACOs are structured and the potential financial incentives that may affect ACO provider behavior. Numerous barriers still exist for patients. Many patients, especially elderly patients, are impaired by minimal health literacy.<sup>202</sup> Patients with low levels of health literacy and literacy in general are often unable to understand disseminated health material that is produced at a much higher reading level than the estimated average reading level of the public.<sup>203</sup> Some patients also have limited access to the internet,<sup>204</sup> where ACO reporting requirements are published.<sup>205</sup> Many ACO beneficiaries are unaware that they have even been attributed to

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197. *Id.*

198. Oppenheim et al., *supra* note 100, at 17.

199. ACO Fact Sheet, *supra* note 88, at 3.

200. Oppenheim et al., *supra* note 100, at 17.

201. *See supra* Section III.A (discussing how physicians naturally have information that patients can neither access nor understand).

202. Blazej, *supra* note 192.

203. A.S. Vivian & E.J. Robertson, *Readability of Patient Education Materials*, 3 CLINICAL THERAPEUTICS 129, 129 (1980); *see also* Atul Gawande, *Overkill*, NEW YORKER (May 11, 2015), <http://www.newyorker.com/magazine/2015/05/11/overkill-atul-gawande> [<https://perma.cc/V8ZF-AYX2>].

204. Gunther Eysenbach & Alejandro Jadad, *Evidence-Based Patient Choice and Consumer Health Informatics in the Internet Age*, 3 J. MED. INTERNET RES. 19, 19 (2001).

205. Oppenheim et al., *supra* note 100, at 18.

an ACO and, even worse, some enrolled beneficiaries do not even know what an ACO is, how it works, or the potential benefits that it can offer.<sup>206</sup> The beneficiary notification requirements for ACOs are minimal, requiring only notice at the point of care.<sup>207</sup> A simple sign in the waiting room is sufficient to fulfill this requirement, despite how insufficient that sign may be at adequately informing patients about ACOs.<sup>208</sup>

Inadequate information dissemination may also be affected by how closely CMS regulates any marketing materials and activities performed by ACOs to reach out to patients.<sup>209</sup> The definition of what constitutes “marketing materials and activities” is broad and includes almost any document used to “educate, solicit, notify, or contact” beneficiaries or providers about the ACO.<sup>210</sup> All materials and activities that fall under this category must be submitted to CMS for approval before an initial five-day review period beginning on the date of submission expires.<sup>211</sup> ACOs must stop using or disseminating any marketing material of which CMS does not approve.<sup>212</sup> The intent behind this extensive oversight was to protect beneficiaries from misleading marketing materials.<sup>213</sup> However, these strict regulations on the kinds of materials and activities ACOs can use may prevent providers from conducting meaningful outreach and from being more candid with patients about existing financial motivations to keep them assigned to a particular ACO.<sup>214</sup> If ACOs need approval from CMS for every kind of material they want to disseminate, it follows that less information will be disseminated to patients as a result of such heavy oversight and control, creating a barrier to meaningful and candid communication.<sup>215</sup>

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206. Valerie A. Lewis et al., *Attributing Patients to Accountable Care Organizations: Performance Year Approach Aligns Stakeholders’ Interests*, 32 HEALTH AFF. 587, 588 (2013).

207. 42 C.F.R. § 425.312 (2011).

208. *Id.*

209. Oppenheim et al., *supra* note 100, at 18.

210. *Id.*

211. *Id.*

212. *Id.*

213. 42 C.F.R. § 425.310 (2011).

214. Robert Schwartz et al., *ACO—Marketing*, ABA HEALTH ESOURCE (Aug. 2011) [https://www.americanbar.org/content/newsletter/publications/aba\\_health\\_esource\\_home/aba\\_health\\_law\\_esource\\_1108\\_aco\\_schwartz.html](https://www.americanbar.org/content/newsletter/publications/aba_health_esource_home/aba_health_law_esource_1108_aco_schwartz.html) [<https://perma.cc/V4BU-43D9>].

215. See Steven Lieberman, *Proposed CMS Regulation Kills ACOs Softly*, HEALTH AFF. BLOG (Apr. 6, 2011), <http://healthaffairs.org/blog/2011/04/06/proposed-cms-regulation-kills-acos-softly/> [<https://perma.cc/LH4Q-N2F2>].

*C. The Underlying Risks Are Not Mitigated by ACO Design*

Despite the recent expansion of the universally applicable enumerated exceptions to the beneficiary inducement prohibition, ACOs still have much more flexibility to utilize a larger range of inducements compared to non-ACO providers.<sup>216</sup> Allowing ACOs, and only ACOs, a waiver from the prohibition on inducing beneficiaries can create a very unfair situation for providers that compete with ACOs.<sup>217</sup> For example, in a rural area where there is an ACO as well as a small group of providers, it would be almost impossible for the small group of providers to compete with an ACO that has more resources and the ability to offer inducements and gifts to patients to keep them within the ACO network.<sup>218</sup> As ACOs grow in scale and capture larger portions of geographic market share, they are positioned to disadvantage smaller providers and businesses by having more leeway to use “giveaways to attract business.”<sup>219</sup>

Allowing an ACO to induce beneficiaries to prevent “patient leakage” places non-ACO providers in a difficult situation because non-ACO providers cannot compete with offerings such as “gym memberships, personal training sessions, massages or skin creams.”<sup>220</sup> In order for an inducement to be permissible, it need only be “reasonably related”<sup>221</sup> to the broad goals of an ACO—however, CMS does not specifically define this term in the Final Rule and leaves it broad in scope, creating an uneven playing field for non-ACO providers.<sup>222</sup>

Waiving the beneficiary inducement prohibition further amplifies information asymmetry between providers and patients. The risks of using inducements to distort patient decisionmaking are just as present in an ACO as they are in other models, even if these risks

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216. See *supra* Sections II.B, II.C.3 (explaining what is permissible under the statutory exceptions with what is permissible for ACOs who meet the requirements for the patient inducement waiver).

217. *Id.*

218. Publication of OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, 67 Fed. Reg. 55855, 55855 (Aug. 30, 2002); see also Erin Bradley, *Accountable Care Organizations Antitrust Guidelines Will Not Save Rural Providers*, 34 J. LEGAL MED. 295, 301–02 (2013).

219. Publication of OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, 67 Fed. Reg. at 55855.

220. Medicare Program; Final Waivers in Connection with the Shared Savings Program, 80 Fed. Reg. 66726, 66739 (Oct. 29, 2015).

221. *Id.* at 66730.

222. See *id.* at 66739 (commenting that ACOs should not be given more flexibility beyond what is currently legally permissible as this “will allow health care professionals not in an ACO to be on a level playing field with those in ACOs”).

present themselves in another form.<sup>223</sup> An ACO provider is financially motivated to induce patients to be seen by another provider within the ACO because that generates more business for the ACO and allows the ACO to retain control over the patient's outcomes.<sup>224</sup> Overall patient outcomes are directly related to the amount of shared savings an ACO receives from CMS and can affect the financial bottom line of ACO providers. Despite the express prohibition of using items or services to induce patients to receive care or remain in an ACO, ACOs are financially incentivized to reduce patient leakage. ACOs can make use of the much more expansive incentives at their disposal to keep patients within the network, even if this is not the expressed purpose. While the Medicare ACO Final Rule states: “[t]he strategies employed by an ACO to optimize care coordination should not impede the ability of a beneficiary to seek care from providers that are not participating in the ACO,” providers are incentivized to do exactly that.<sup>225</sup> The patient inducement waiver gives ACO providers an additional set of tools to discourage patients from seeking care elsewhere.

The rationale behind waiving the beneficiary inducement is that it is required to “promote greater preventive care, to incentivize patients to follow treatment or follow-up care regimes, and to increase participation in ACOs.”<sup>226</sup> Without this waiver, ACOs would be prevented from using “appropriate incentives to help achieve better health and better care for their Medicare patients.”<sup>227</sup> The OIG and CMS view beneficiary compliance with ACO care management programs as an essential component of the strategy of ACOs to improve long-term outcomes and focus on preventative care to avoid exorbitant costs down the line.<sup>228</sup>

However, this stands in direct contrast with how the OIG has viewed offering gifts to beneficiaries in the past.<sup>229</sup> In the past, financial status and severity of condition did not provide a meaningful enough

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223. *See supra* Sections III.A, III.B.

224. Medicare Program; Final Waivers in Connection with the Shared Savings Program, 80 Fed. Reg. at 66730.

225. Heather Punke, *Reducing ACO Patient Leakage Begins with Education*, BECKER'S HOSP. REV. (Sept. 26, 2013), <http://www.beckershospitalreview.com/accountable-care-organizations/reducing-aco-patient-leakage-begins-with-education.html> [<https://perma.cc/BPB3-WRSJ>].

226. Medicare Program; Final Waivers in Connection with the Shared Savings Program, 80 Fed. Reg. at 66729.

227. *See id.* (using the example that providing a blood pressure cuff for a hypertensive patient participating in an ACO's chronic disease management program may, depending on the circumstances, implicate the Beneficiary Inducements CMP).

228. *Id.* at 66739.

229. Publication of OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, 67 Fed. Reg. 55855, 55855–56 (Aug. 30, 2002).

basis to allow gifts of value to be given.<sup>230</sup> It is not difficult to understand how inducements can be valuable to beneficiaries with specific chronic conditions.<sup>231</sup> The recent expansion and clarification of the statutory exceptions to the inducement prohibition reflect CMS and the OIG's recognition that there are certain circumstances where inducements should be permissible.<sup>232</sup> Many Medicare beneficiaries suffer from chronic conditions, and the government is responsible for paying the medical bills of the elderly who are often chronically ill.<sup>233</sup> Often, these beneficiaries do not have the financial means to receive additional services that providers are positioned to offer to make their care easier. Inducements can promote community and individual awareness of health risks and resources, promote access to care, improve patient adherence to treatment regimes, potentially reduce the cost of care, improve care coordination, engage at-risk populations, and provide beneficiary education.<sup>234</sup> The patient inducement waiver for ACOs, however, expands the scope of permitted inducements too far.

In the current healthcare marketplace, the risks of allowing inducements outweigh the benefits. ACOs are designed to reduce overutilization of medical services and unnecessary spending in healthcare. But offering inducements to patients can in fact have opposite effects.<sup>235</sup> One risk of the patient inducement waiver is that it can improperly influence patient treatment decisions by offering items or services of value.<sup>236</sup> Using inducements to keep patients within the ACO network can distort a patient's selection of a provider by "shifting focus to the value of the inducement rather than to the value or quality of the healthcare services."<sup>237</sup> Limiting beneficiary inducements protects patients from selfish decisionmaking. There is a conflict of

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230. *Id.* at 5.

231. *Id.* at 2–3.

232. Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88368, 88370 (Dec. 7, 2016).

233. See Kimberly A. Lochner, *Prevalence of Multiple Chronic Conditions Among Medicare Beneficiaries, United States, 2010*, CTRS. FOR DISEASE CONTROL & PREVENTION (Apr. 25, 2013), [http://www.cdc.gov/pcd/issues/2013/pdf/12\\_0137.pdf](http://www.cdc.gov/pcd/issues/2013/pdf/12_0137.pdf) [<https://perma.cc/MX8M-JH2K>] (finding 68.4 percent of Medicare beneficiaries had two or more chronic conditions and 36.4 percent had four or more chronic conditions).

234. Publication of OIG Special Advisory Bulletin on Offering Gifts and Other Inducements to Beneficiaries, 67 Fed. Reg. at 55858.

235. *Id.*

236. Am. Health Lawyers Ass'n Pub. Interest Comm., *Beneficiary Inducements in an Evolving Market: Assessing the Risks, Understanding the Benefits and Drawing the Lines*, AM. HEALTH LAW. ASS'N 4 (Oct. 2013), <https://www.healthlawyers.org/hlresources/PI/ConvenerSessions/Documents/Beneficiary%20Inducements%20White%20Paper.pdf> [<https://perma.cc/MKB9-9SQ5>].

237. *Id.*

interest, as individuals associated with ACOs who have clear financial motivations are responsible for determining whether an arrangement or inducement is reasonably related to the purpose of the ACO.<sup>238</sup> While they are required to report the basis on which the determination was made, it is counterintuitive to have individuals with a financial interest make this determination.

Giving ACOs the opportunity to induce beneficiaries in ways that other healthcare competitors cannot gives ACOs an unfair advantage.<sup>239</sup> Other healthcare providers that do not have the benefit of being part of an ACO cannot induce beneficiaries in the same way, and it does not seem equitable that ACOs should have this competitive advantage in the marketplace. While inducements can be helpful, they are not the only means by which an ACO can improve care coordination for patients with chronic illness.<sup>240</sup> Improving patient engagement, introducing health coaches, and developing self-management programs are examples of strategies that have reliably improved the quality of care delivered to patients in the absence of inducements or perks.<sup>241</sup>

#### IV. SOLUTIONS TO PROMOTING ACO SUCCESS

This Part proposes alternative solutions to the beneficiary inducement waiver that can achieve the benefits CMS and OIG desire. Specifically, this Part will discuss (A) why ACOs should not have a waiver from the beneficiary inducement prohibition, (B) implementing shared decisionmaking to help patients better understand their options while simultaneously strengthening disease-management programs, (C) reducing information asymmetry between ACO providers and ACO beneficiaries, and (D) strategizing ways to reduce patient leakage through meaningful use and analysis of data already collected by the ACO.

##### *A. Achieving Success Within the Existing Exceptions*

ACOs should be required to adhere to the same standards and safeguards governing other existing integrated healthcare delivery models with regard to the prohibition on inducing beneficiaries. Congress, in its recent expansion of exceptions to the beneficiary inducement CMP with the amendment of the definition of

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238. *See supra* Section I.B.1.

239. *See supra* Section III.C.

240. *See supra* Section III.C.

241. *See supra* Section I.B.1.

“remuneration,” intended to give healthcare providers more flexibility to “provide efficient, well-coordinated, patient-centered care with protections against fraud and abuse risks.”<sup>242</sup> Arguably, the waiver may have been needed to some extent prior to this expansion, as the existing exceptions at the time the waivers were developed for ACOs did not allow as much protection.<sup>243</sup> In light of the recent change, however, the OIG should no longer afford this waiver to ACOs. In the time between the Initial and Final Rules for ACO waivers from fraud and abuse laws, the gainsharing CMP was amended in such a way to render the waiver unnecessary, and therefore no waiver was finalized.<sup>244</sup> Similarly, the beneficiary inducement CMP, as amended, gives ACOs more flexibility to pursue the intended purposes of the Shared Savings Program. The new exception for activities that are low-risk and promote access to care can be used alongside other alternative strategies to “promote greater preventive care, incentivize patients to follow treatments or follow-up care regimes, and to increase participation in ACOs,” without the increased risks to patients the waiver introduces.<sup>245</sup>

It is in the best interest of the healthcare system to minimize the risk of patients choosing providers or staying within a network because of a perk.<sup>246</sup> While ACOs are given leeway because of their design and because of their proven success,<sup>247</sup> it is possible for ACOs to achieve the same success without this waiver. Inducements may initially benefit patients but they will not lead to the sustainable change and long-term improvements in healthcare delivery sought by CMS and the OIG. Instead, ACOs should rely on meaningful patient engagement and self-management programs, focused education and decisionmaking initiatives, and data analysis to improve patient retention over inducing patients with gifts.

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242. Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88368, 88370 (Dec. 7, 2016).

243. *See id.* (describing exceptions as mechanisms to address the “evolution of healthcare business arrangements under the fraud and abuse laws”).

244. *See* Medicare Program; Final Waivers in Connection with the Shared Savings Program, 80 Fed. Reg. 66726, 66737 (Oct. 29, 2015) (describing the gainsharing CMP as recently amended to “prohibit a hospital from knowingly making payments to physicians to reduce or limit medically necessary services,” rendering it unnecessary to carry out the purposes of the Shared Savings program).

245. *See supra* Section III.C.

246. *See supra* Section III.B.

247. *See supra* Section III.C.

*B. Promoting Patient Ownership of Their Own Care*

ACOs aim to improve the information gap between patients and providers and create a care setting where patients can take more control and be more involved in their own healthcare decisions.<sup>248</sup> One means of accomplishing this is shared decisionmaking (“SDM”). Under the traditional model, providers typically determine a course of treatment without consulting patients.<sup>249</sup> SDM deviates from this by providing an approach where patients and providers review the existing evidence together before a treatment decision is made and support is provided for patients to consider all of their options, as opposed to accepting whatever option their provider gives them.<sup>250</sup> ACOs are already required to incorporate shared decisionmaking principles into the design of their programs, but the language is very vague and does not actually require the ACO to engage in SDM practices.<sup>251</sup> Requiring, or at least encouraging, all ACOs to implement SDM practices can improve patient adherence to treatment plans and minimize the information gap between providers and patients.<sup>252</sup> For example, ACOs can regularly employ decision aids. Decision aids are materials that offer a more detailed and explicit explanation of the specific healthcare choice a patient faces.<sup>253</sup>

In addition to improving outcomes and containing costs, this approach effectively aligns with enhancing the overall patient

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248. See Judith H. Hibbard et al., *Patients with Lower Activation Associated with Higher Costs; Delivery Systems Should Know Their Patients’ Scores*, 32 HEALTH AFF. 216, 216 (2013) (defining patient activation as “understanding one’s own role in the care process and having the knowledge, skills, and confidence to take on that role” and noting that patient activation and patient engagement are interchangeable terms); Julia James, *Patient Engagement: People Actively Involved in Their Health and Health Care Tend to Have Better Outcomes—and, Some Evidence Suggests, Lower Costs*, HEALTH AFFAIRS: HEALTH POLICY BRIEF 5 (Feb. 14, 2013) [http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief\\_id=86](http://www.healthaffairs.org/healthpolicybriefs/brief.php?brief_id=86) [https://perma.cc/6K5Q-LS8F] (asserting that patient activation, an interchangeable term with patient engagement, can be directly linked to improved outcomes and can be used as a measure of patient engagement for ACOs);

249. See Glyn Elwyn et al., *Shared Decision Making: A Model for Clinical Practice*, 5 J. GEN. INTERNAL MED. 1361, 1362 (2012) (giving reasons providers hesitate to involve patients in decisionmaking, including that “patients don’t *want* to be involved in decisions, lack the capacity or ability, might make ‘bad’ decisions, or worry that SDM is just not practical, given constraints such as time pressure”).

250. *Id.* at 1361.

251. See 42 C.F.R. § 425.112(b)(2)(v) (2011) (requiring that an ACO engage in “[b]eneficiary engagement and shared decision-making that takes into account the beneficiaries’ unique needs, preferences, values, and priorities”).

252. ADI SHAFIR & JILL ROSENTHAL, SHARED DECISION MAKING: ADVANCING PATIENT-CENTERED CARE THROUGH STATE AND FEDERAL IMPLEMENTATION 4–6 (2012).

253. *Id.* at 5.

experience. While the existing evidence is limited, SDM has shown promise in enabling patients to take ownership of their own healthcare.<sup>254</sup> The Institute of Medicine's report, *Crossing the Quality Chasm*, recommends that SDM principles be included in the redesign of healthcare delivery moving forward.<sup>255</sup> Numerous states have implemented SDM as part of various policy initiatives and have been successful.<sup>256</sup> For example, as far back as 2007, the state of Washington enacted legislation promoting SDM as a means to improve the existing informed consent doctrine.<sup>257</sup> In Massachusetts, ACOs must include SDM in order to be certified by the state.<sup>258</sup> SDM processes can be easily integrated into the ACO structure, providing more opportunities for patients and providers to collaborate.<sup>259</sup> Healthcare continues to remain very expensive and, for many before the implementation of ACA, unattainable. Improving patient engagement, through mechanisms like SDM, has been associated with reducing costs and improving health outcomes.<sup>260</sup>

Chronic diseases remain the most expensive drivers of healthcare costs and the most difficult to manage, which explains the emphasis regulatory agencies have placed on improving the management of chronic conditions like diabetes and heart disease.<sup>261</sup> Proper prevention and management of chronic diseases has the potential to save millions of dollars and substantially reduce incidence of these diseases.<sup>262</sup> Problems with disease-management result from noncompliance with treatment plans and critical misunderstandings between patients and providers on the appropriate ways to manage and

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254. *Id.*

255. *Id.* at 6.

256. *Id.* at 9–17.

257. James, *supra* note 248.

258. *Id.*

259. SHAFIR & ROSENTHAL, *supra* note 252, at 22 (recommending that SDM be incorporated in healthcare delivery system redesign, specifically in ACO requirements, to “reduce the burden of independent implementation and help integrate the change into the overall change providers are facing in the healthcare system”).

260. Hibbard et al., *supra* note 248.

261. See Elizabeth Pendo, *Working Sick: Lessons of Chronic Illness for Health Care Reform*, YALE J. HEALTH POL'Y, L., & ETHICS, 453, 453 (2009) (asserting chronic illness imposes significant costs on the overall economy, accounting for three-quarters of all healthcare expenditures).

262. Ross DeVol & Armen Bedroussian, *An Unhealthy America: The Economic Burden of Chronic Disease—Charting a New Course to Save Lives and Increase Productivity and Economic Growth*, MILKEN INST. (Oct. 1, 2007), [http://assets1b.milkeninstitute.org/assets/Publication/ResearchReport/PDF/chronic\\_disease\\_report.pdf](http://assets1b.milkeninstitute.org/assets/Publication/ResearchReport/PDF/chronic_disease_report.pdf) [<https://perma.cc/LB4H-TXFG>]. The Milken Institute has projected that even reasonable improvements in chronic disease management and prevention can potentially “avert some 40 million U.S. cases over the next twenty years” and could translate into savings of “more than \$1.1 billion in 2023.” *Id.*

control chronic illness.<sup>263</sup> The patient inducement waiver was intended to give ACOs more ways to address these issues, specifically by allowing ACOs to reward patients for seeking or obtaining care, which they would otherwise be unable to do.<sup>264</sup> The exception for inducements that promote access to care, however, still gives ACOs extensive flexibility to use inducements to remove barriers to access for beneficiaries.<sup>265</sup>

While it may be easier to rely on rewards to push patients to seek treatment or care, patients with truly dangerous chronic illness need explanation, education, and support.<sup>266</sup> Getting a patient to show up to a doctor's appointment is an important part of the equation, but quality disease-management comes from understanding the barriers preventing patients from successfully managing their illnesses.<sup>267</sup> This simply will not occur without directly communicating with patients and implementing a support system for that patient.<sup>268</sup> Carefully developed disease-management programs ("DMPs") are one way to accomplish this. DMPs are designed for specific groups of patients suffering from the same chronic illness.<sup>269</sup> They are rooted in evidence-based, coordinated recommendations, which aim to improve the quality of life for patients, reduce hospitalizations and readmission rates, and ultimately contain costs.<sup>270</sup> ACOs can also provide remunerations that promote access to non-payable care without implicating the beneficiary

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263. See Gawande, *supra* note 203. Dr. Gawande describes an example of a diabetic patient who underwent a series of expensive tests after a diabetic crisis that confirmed what the medical staff treating him already knew—that the patient had dangerously uncontrolled diabetes. However, this did nothing to solve the “core medical problem” of his mismanaged disease. The treating physician spent forty-five minutes with the patient explaining his condition and how to treat it and discovered the patient seriously misunderstood when his insulin was required. The patient was then turned over to a certified diabetes educator who created a personalized plan with the patient. *Id.*

264. See Medicare Program; Final Waivers in Connection with the Shared Savings Program, 80 Fed. Reg. 66726 (Oct. 29, 2015).

265. Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88368, 88370 (Dec. 7, 2016).

266. Gawande, *supra* note 203.

267. *Id.*

268. *Id.*

269. See Stefan Brandt et al., *How to Design a Successful Disease-Management Program*, MCKINSEY & COMPANY (Oct. 2010) <http://www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/how-to-design-a-successful-disease-management-program> [<https://perma.cc/3Z6M-HP6X>].

270. *Id.*

inducement CMP, such as rewards for accessing food pantries or other community resources.<sup>271</sup>

### *C. Reducing Information Asymmetry*

Often times when confronted with healthcare decisions, providers give patients more than they can understand.<sup>272</sup> CMS's strict regulation of patient outreach materials exacerbates these barriers.<sup>273</sup> If the legislative intent behind the MSSP is truly to achieve goals of cost containment and quality improvement,<sup>274</sup> transparency is necessary and information should be delivered in a way that patients can understand.<sup>275</sup> Currently, ACOs can potentially avoid transparency and still remain in compliance with the requirements of the MSSP if they report information in a manner that a layperson cannot interpret.<sup>276</sup> ACOs should be required to give accessible and understandable information regarding specific providers. For example, explaining to patients the specific benefits of seeing multiple providers within the ACO rather than seeking care outside of the ACO can reduce reliance on the use of inducements, while still improving patient retention. An improved understanding of how an uninterrupted continuum of care can improve outcomes and the overall patient experience can not only educate patients but also has the potential to motivate patients to seek all care within the ACO. If patients have a more comprehensive understanding of what they can expect from specific providers within the ACO, they will be in a position to make more informed decisions.<sup>277</sup>

Patient engagement is critical to the success of ACOs and is an important component in the effort to improve care and reduce cost.<sup>278</sup>

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271. Medicare and State Health Care Programs: Fraud and Abuse; Revisions to the Safe Harbors Under the Anti-Kickback Statute and Civil Monetary Penalty Rules Regarding Beneficiary Inducements, 81 Fed. Reg. 88368, 88391 (Dec. 7, 2016).

272. See Eysenbach & Jadad, *supra* note 204; see also *supra* Part II.

273. See *supra* Section III.A.

274. See *supra* Part I.

275. See Pauline W. Chen, *The Missing Ingredient in Accountable Care*, N.Y. TIMES (Jan. 27, 2011), <http://www.nytimes.com/2011/01/27/health/views/27chen.html> [<https://perma.cc/VB94-XDGJ>] (promoting the idea of providing patients with more information on the quality and benefits of ACOs using less jargon).

276. See *id.* (quoting Dr. Meredith Rosenthal, "We aren't using plain English").

277. See Annette O'Connor et al., *Toward the 'Tipping Point': Decision Aids and Informed Patient Choice*, 26 HEALTH AFF. 716, 718 (2007) (suggesting that decision aids to help patients participate in decisionmaking leads to more patient involvement and informed choices "consistent with [patient] values").

278. Cortney Nicolato, *Supporting ACO Success with Meaningful Patient Engagement*, BECKER'S HOSP. REV. (Aug. 1, 2013), <http://www.beckershospitalreview.com/accountable-care-organizations/supporting-aco-success-with-meaningful-patient-engagement.html> [<https://perma>

One possible strategy is to introduce health coaches to motivate behavior change and help patients create actionable lists that are personalized and directly related to health goals of patients.<sup>279</sup> It is also crucial to ensure that patients are aware that they are enrolled in an ACO and how being enrolled in an ACO can benefit them.<sup>280</sup> This can be accomplished by strengthening the beneficiary notice requirement.<sup>281</sup> A potential solution to improve transparency between patients and ACOs is to require a conversation the first time a beneficiary is seen after being assigned to an ACO that discusses the way an ACO is structured, the existing financial motivations of ACO providers to refer within the ACO network, and the added value to the patient of staying within the ACO network to prevent fragmented care.<sup>282</sup> Additionally, ACO providers should candidly inform patients that they have unrestricted freedom in choosing a provider. Similar to requiring informed consent before a surgery, requiring a patient to sign a form after such a conversation can improve transparency and allow the ACO governing body to monitor disclosure to patients.

Another patient engagement strategy that can be used is developing focused educational initiatives. Educating ACO enrollees through explicit discussions about the cost of treatments with patients and the dangers of excessive testing and treatment could help enrollees understand the true impetus behind cost-containment measures and the potential long-term benefits of choosing marginally inferior, less expensive care options.<sup>283</sup> Meaningful patient engagement is associated with positive changes and care coordination, and it can be successful without relying on the inducement of patients, as the Cleveland Clinic model demonstrated.<sup>284</sup> Improving patient engagement through

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.cc/97UC-XADS]; Ross White et al., *Why Patient Engagement Is Key to Improving Health, Reducing Costs*, BROOKINGS INST. (Nov. 13, 2014), <http://www.brookings.edu/blogs/up-front/posts/2014/11/10-patient-engagement-accountable-care> [<https://perma.cc/EEN6-ATX7>].

279. White et al., *supra* note 278.

280. *See id.* (recognizing that many patients are unaware they have been assigned to an ACO and may seek care elsewhere because not enough attention has been placed on educating the patient regarding ACO enrollment).

281. O'Connor et al., *supra* note 277.

282. *See* Punke, *supra* note 225 (quoting Dr. Llerena, an ACO provider, stating “[if] we really truly feel we offer the best care for those services, then we need to explain to the patient why it makes sense”).

283. *See* Christine Cassel & James Guest, *Choosing Wisely: Helping Physicians and Patients Make Smart Decisions About Their Care*, 307 JAMA 1801, 1801 (2012) (describing the “Choosing Wisely” campaign that promotes physician and patient conversations about making wise choices about treatments to reduce unnecessary care and improve the quality of communication between patients and providers).

284. *See* Nicolato, *supra* note 278 (describing a report performed by the Bipartisan Policy Center that linked patient engagement to fewer referrals, increased adherence to prescribed

education and outreach can potentially benefit from more relaxed oversight with regard to the marketing materials ACOs can disseminate. As discussed, ACOs have significant latitude compared to other integrated care organizations.<sup>285</sup> Giving ACOs less oversight with regard to what educational materials can be disseminated to beneficiaries can serve as a means of reducing information asymmetry when it comes to knowledge about the ACO itself.<sup>286</sup>

#### *D. Improving ACO Patient Retention Strategies*

Increasing patient involvement in the management of care and reducing the information gap between providers and patients are alternative ways to address the concerns CMS and the OIG intended to correct with the patient inducement waiver. However, ACOs already have many tools at their disposal by virtue of the program requirements already in place.<sup>287</sup> ACOs can use the information collected to satisfy these requirements to strategize ways to achieve the same intended goals the beneficiary inducement waiver was meant to address.

An ACO is responsible for “routine self-assessment, monitoring, and reporting of the care it delivers.”<sup>288</sup> Monitoring includes “analyzing claims and specific financial and quality data” as well as regularly aggregated reports, site visits, and surveys.<sup>289</sup> ACOs can use these data to analyze factors surrounding patient leakage.<sup>290</sup> ACOs also collect quality and claims data for all assigned beneficiaries, including claims data of beneficiaries who received care from an outside provider, all of which are used as part of the annual shared savings calculus.<sup>291</sup> In order to analyze these data in a way that satisfies the contractual obligations imposed by CMS, ACOs must implement healthcare technology

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medical treatments, increased functional status, faster recovery, and higher levels of satisfaction, health literacy, and positive health-related behavior changes).

285. *See supra* Section II.C.

286. Jennifer Bresnick, *Three Outreach Strategies to Raise ACO Patient Engagement*, HEALTH IT ANALYTICS (June 15, 2015), <http://healthitanalytics.com/news/three-outreach-strategies-to-raise-aco-patient-engagement> [<https://perma.cc/UD2K-TR4C>] (suggesting that ACO leaders leverage social media and other online resources to obtain feedback and to provide beneficiaries with more accessible information about ACOs themselves).

287. *See supra* Section I.B.

288. ACO Fact Sheet, *supra* note 88, at 2.

289. *Id.*

290. *See* Tricia M. Barrett et al., *10 Things You Need to Know About Accountable Care*, INST. FOR HEALTH TECH. TRANSFORMATION 20 (describing the expectation of HHS that an ACO have the requisite technology to collect and evaluate data to “provide feedback across the entire organization, including providing information to influence care at the point of care, feedback from patient experience, and other quality and utilization assessments”).

291. *Id.*

infrastructures capable of performing high-level data analytics.<sup>292</sup> Consequently, ACOs are well positioned to examine trends related to patient leakage. Upon analysis, an ACO may find that patients in a certain zip code are seeking non-ACO providers due to geographic proximity. Rather than relying on inducements to retain those patients, the ACO can potentially reach out to those specific non-ACO providers and contract with them. Alternatively, an ACO may find that patients seeing a specific primary care physician tend to seek specialist care outside the ACO network. The ACO can work with that primary care physician to understand why his or her patients are leaving and to work with the physician to retain those patients through patient engagement and other quality improvement initiatives.

Analysis of patient leakage will not be difficult for ACOs as they already collect that data and have the requisite technological infrastructure to interpret the data.<sup>293</sup> Monitoring provider referrals, however, is a slightly more difficult task. As violations of the Stark Law have shown, providers have attempted to get away with abuse of referral laws in order to gain financial benefits.<sup>294</sup> However, in order to form an ACO, the Stark Law and Anti-Kickback statutes must be waived, unlike the beneficiary inducement prohibition.<sup>295</sup> ACOs cannot function without waivers of the former but can function successfully without the patient inducement waiver. In an attempt to curb patient leakage rates and retain control over quality outcomes of assigned beneficiaries, it is in the provider's singular interest and the ACO's general interest to keep enrolled beneficiaries in the network. With that said, however, the regulatory bodies have determined that the financial incentive of shared savings is mitigated by the design of the ACO and the quality requirements to which payments are tied.<sup>296</sup> In contrast, the patient inducement waiver is not mitigated by the design of the ACO. Rather, the inherent risks of using this waiver for inappropriate purposes contrary to the intention of the shared savings program and healthcare reform are increased.<sup>297</sup>

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292. Oppenheim et al., *supra* note 100, at 16–18.

293. *Id.*

294. See Ayla Ellison, *10 Largest False Claims, Stark Law and Anti-Kickback Settlements of 2014*, BECKER'S HOSP. REV. (Aug. 20, 2014), <http://www.beckershospitalreview.com/legal-regulatory-issues/10-largest-false-claims-stark-law-and-anti-kickback-settlements-of-2014.html> [<https://perma.cc/VF8E-T6G3>] (describing the ten largest cases of 2014 that involved violations of healthcare fraud laws in the United States).

295. See *supra* Section III.C.2.

296. See *supra* Section II.B.3.

297. See *supra* Section III.C.2.

## CONCLUSION

There are many uncertainties regarding the future of the healthcare system in the United States. Accountable Care Organizations are one example of a healthcare delivery model that shifts focus to cost containment and improving the quality of care delivered to patients. However, it is not a perfect model and is by no means a model that solves every large issue in healthcare. ACOs should not be exempt from the prohibition on beneficiary inducements. Rather, ACOs should focus on improving information asymmetry and increasing transparency between the ACO and assigned beneficiaries. Coordinating care in a manner that reduces cost and improves quality should not rely on inducements—it should result from patient engagement, transparency, and patient-centered education. Patients should be making decisions that reflect the best possible medical care available to them. ACOs are in a position to improve population health by focusing on creating a patient-centered environment that retains patients by using meaningful analytics and by educating patients on why it is in their best medical interest to receive coordinated care. A patient's decision should be made for medical reasons. While this may seem like common sense, allowing inducements distorts a patient's decisionmaking and often results in the patient choosing a provider for reasons other than the care itself. ACOs are positioned to achieve the same desired result of improving care coordination and retaining assigned patients without relying on inducements.

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