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The Free Transportation Safe Harbor Misses the Boat: Why Social Determinants of Health and Value-Based Payments Should Influence the Anti-Kickback Statute

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I. Introduction

The United States has a lower life expectancy, higher infant mortality, and higher prevalence of chronic disease than most developed countries.[1] One potential reason for these discrepancies is that while the country spends exorbitantly on health care, it allocates minimal resources to social services.[2] Social factors, like socio-economic status, the environment, and employment status account for approximately 1/3 of U.S. deaths.[3] Research has shown that these social determinants of health (SDH)[4], which include factors like access to transportation, need to be addressed through investment in broad population-based approaches in order to drive positive health change.[5] Nations that are members of the Organization for Economic Cooperation and Development spend about $1.70, on average, on social services for every $1 on health services; the U.S. spends only 56 cents.[6] While health care services are essential to positively impacting overall health status,[7] only through addressing the SDH can the U.S. achieve health equity.[8] Currently, efforts to target these activities can be seen within the health care system, as payment reform initiatives increase their focus on the SDH.[9]

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[1] Thomas L. Greaney, *Medicare Advantage, Accountable Care Organizations, and Traditional Medicare: Synchronization or Collision?*, 15 Yale J. of Health Pol'y*, Law, and Ethics* 37, 39 (2015).
[2] *Id.*
[3] Harry J. Heiman & Samantha Artiga, *Beyond Health Care: The Role of Social Determinants in Promoting Health and Health Equity*, The Kaiser Commission on Medicaid and the Uninsured at 8 (Nov. 2015), http://files.kff.org/attachment/issue-brief-beyond-health-care; E.H. Bradley, H. Sipsma & L.A. Taylor, *American Health Care Paradox—High Spending on Health Care and Poor Health*, 110 Q. J. of Med. 62, 69 (2017) (as income goes down, rates of premature death increase).
[4] Bradley, *supra* note 3, at 69.
[5] *Id.* at 62.
[6] Stuart M Butler, Dayna Bowen Matthew, & Marcela Cabello, *Re-balancing medical and social spending to promote health: Increasing state flexibility to improve health through housing*, USC-Brookings Schaeffer on Health Policy (Feb. 15, 2017), http://brook.gs/2lLn7BB.
[7] Heiman, *supra* note 3, at 1.
[8] *Id.*at 3 (health equity is defined as the highest level of health for all people).
[9] *Id.* at 5.

The importance of SDH in driving health care delivery and payment reforms can be seen across the country.[10] One example is the State Innovation Models Initiative (SIM), which is led by the Center for Medicare and Medicaid Innovations.[11] SIM seeks to develop multi-payer models that improve overall health system performance, quality, and costs through the emphasis on establishing linkages between primary care and community-based organizations and social services.[12] The core strategy of SIM is to ensure that health care focuses on the person as a whole, which includes not only health care, but social and environmental factors as well.[13] Similarly, Medicaid has expressed that its delivery and payment reform initiatives will include a focus on linking health care and social needs.[14] In order for population health improvements and cost-reductions to be realized, the U.S. health care system needs to focus on integration and coordination of services across providers and settings, including the means to connect people to social supports.[15]

Unfortunately, laws targeting health care fraud, like the Anti-Kickback Statute (AKS), were developed through a fee-for-service (FFS) lens, which inhibits the ability of providers to embrace modern payment models. Under FFS, providers seek to maximize the volume of their services in order to increase their profits.[16] The AKS was founded on the notion that the payment structure of FFS created incentives for providers to behave in potentially fraudulent ways.[17] Since its inception, the AKS has not undergone any significant transformations to reflect changes in

[10] *See id*.
[11] *Id.*
[12] *Id.* at 5-6.
[13] *Id.* at 6.
[14] *Id.*
[15] *Id.* at 8.
[16] Timothy Stoltzfus Jost & Sharon L. Davies, *The Empire Strikes Back: A Critique of the Backlash Against Fraud and Abuse Enforcement*, 51 Ala. L. Rev. 239, 251 (Fall 1999).
[17] *Id.*at 250.

health care payment structure.[18] Innovation therefore has been stifled, particularly in the realm of SDH. One potential solution is to afford providers more leeway in business practices that target SDH through appropriate AKS safe harbors.[19]

The Health and Human Services (HHS) Office of Inspector General (OIG) recognizes that AKS enforcement may require more liberal discretion to meet the demands of the dynamic U.S. Health Care System, in particular through the implementation of safe harbors to protect beneficial programs or services from prosecution.[20] By expanding its scope beyond the limitations of FFS and into the realm of alternative health payment models that target the SDH, OIG will be able to improve health care access and generate widespread health improvements across at-risk populations. In addition, the move to value-based systems allows for services that target SDH to be implemented without increasing incidents of fraud and abuse, as the dangers inherent in FFS[21] are not present when payments are based on quality of care, not quantity.

This paper employs the Free Transportation Safe Harbor as an analytical vehicle to demonstrate that Federal Health Care Programs would actually benefit by allowing broader experimentation by providers to enable access to care. Part II presents a brief case study to frame the issue between SDH, the AKS, and the Patient Protection and Affordable Care Act (ACA). The case study is followed by an overview of the health care payment system in the United States, with specific emphasis on the move from predominantly fee-for-service into a value based system, the recognition that social barriers can interfere with healthcare access, and the ramifications of

[18] *See* Rebecca C. Martin & Tony Maida, *Affordable Care Act Repeal and Impact on False Claims Act Liability and Defenses*, AHLA Weekly (Dec. 9, 2016) (the ACA amended the AKS to allow False Claims Act actions to be brought through the AKS, and amended the scienter requirement, but did not change AKS' response to payment structures).

[19] Safe harbors are provisions in an agreement, law, or regulation that afford protection from liability or penalty under specified circumstances or if certain conditions are met. Safe Harbor, Business Dictionary, http://www.businessdictionary.com/definition/safe-harbor.html.

[20] 81 Fed. Reg. 88,368, 88,370.

[21] One risk in FFS is increased rates of unnecessary procedures or services.

attempts to update the healthcare and reimbursement systems for AKS enforcement. Part III examines the prevalence of fraud and abuse in the United States and how the AKS acts to police violators, while still attempting to allow "valuable" practices to escape enforcement. Part IV focuses on the development of the Free Transportation Safe Harbor, and juxtaposes the original intent of the AKS with the new policy recommendations of the Affordable Care Act. Part V provides potential solutions to the tension between the ACA and AKS via modifications to the existing Free Transportation Safe Harbor. A brief conclusion follows.

II. Changes in Health Care Payment Theory

A. A Case Study

Jane Smith is a 23-year-old woman who is homeless but staying with a friend in a low-income area of one of the largest urban cities in the northeast. She works for minimum wage at a fast food restaurant a few blocks from where she resides, trying to save enough money to move into her own place. Her employer does not provide health insurance, but she is enrolled in Medicaid. Nonetheless, Jane rarely accesses a physician due to transportation barriers. Recently Jane found out she was pregnant and her friends advised her to go to a clinic, but she is not sure where to turn. One day on her walk to work, Jane saw a flyer from a local health care system advertising that it provided transportation to its clinic for those in need. Jane called the number to schedule her first prenatal visit. The clinic sent a standard passenger van to pick up Jane for her appointment. During her visit with the physician Jane learned that a social service agency across town helps place indigent persons in affordable housing. The clinic offered her transport to the facility. As a result of the intervention, Jane was able to make all of her necessary prenatal visits and secure modest housing. Her little girl was born healthy and happy.

Unfortunately, under the AKS, the above scenario could never happen as it violates numerous aspects of the statute.[22] Two specific factors illustrate the problem. First, the health care system is not allowed to use advertisement or marketing strategies to recruit patients,[23] especially those patients who are not established within their system.[24] Second, the government treats the offer of transportation to access non-medically necessary services, like housing, as impermissible remuneration under the statute.[25] These two factors mean the health care system could face punishment under the AKS, which includes facing fines, imprisonment, and also potential to be barred from Federal Health Care Programs like Medicare and Medicaid.[26] As a result, Jane would likely have never accessed health care for her pregnancy until she was admitted to the hospital, likely through an emergency department, to deliver. Further, the odds that her delivery would be high-risk are great given the lack of prenatal care, her low-income status, and stressful housing situation.[27] It is therefore likely that Jane's total costs for her childbirth would be significantly higher to the Medicaid program than if the transportation service would have simply been available.

The above scenario illustrates the dichotomy between the AKS and the ACA goals. Under the AKS, the government seeks to control situations that increase costs to Federal Health Care Programs. For example, it controls providers forgoing their medical judgment in exchange for increased referrals, which would result in increased income for the provider as well as the possibility of unnecessary or inferior care.[28] The triple aims of the ACA seek to promote access

[22] 42 U.S.C. §1320a-7b (2018).
[23] 81 Fed. Reg. 88,368, 88,386-87.
[24] *Id.* at 88,381-82.
[25] *Id.* at 88,384.
[26] 42 U.S.C. §1320a-7b (2018).
[27] *See* Anthony M. Vintzileos et. al., *The impact of prenatal care in the United States on preterm births in the presence and absence of antenatal high-risk conditions*, 187 Am. J. Obstetrics and Gynecology 1254 (2002).
[28] James F. Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*, 22 Am. J. L. and Med. 205, 208 (1996).

to care and increased quality to drive health care costs lower and produce healthier people.[29] The tension between these two laws arises due to the payment systems and structures employed in U.S. health care and the failure of Congress and HHS to take measures proactively to implement appropriate provisions recognizing that health care fraud and reimbursement practices are changing. As the FFS system is phased out in favor of value-based payments, the principles of the ACA should receive additional emphasis. If this were to happen, situations like Jane's could result in an overall increase in health and a potential reduction in Federal Health Care Program spending,[30] all without increasing the risk of fraud.[31]

B. The Shift from Fee for Service to Value-Based Payments

Health care in the United States has historically been reimbursed on a FFS basis either by patients themselves, or third-party payors.[32] Under FFS, payers pay providers for each service performed, rather than on their quality or efficiency of care.[33] Under normal economic conditions, the FFS model would be appropriate.[34] However, in the health care setting, the combination of financial rewards based on quantity, not quality, combined with higher reimbursement for more complex procedures, leads to an inefficient system that frankly incentivizes abuse.[35] Providers seek to maximize both the volume of the services they offer, and to utilize the highest

[29] J.B. Silvers, *The Affordable Care Act: Objectives and Likely Results in an Imperfect World,* 11 Ann Fam Med 402 (2013).
[30] *See* Joshua M. Wiener, *Strategies to Reduce Medicaid Spending: Findings from a Literature Review*, The Henry J. Kaiser Family Foundation at 7 (June 2017), http://files.kff.org/attachment/Issue-Brief-Strategies-to-Reduce-Medicaid-Spending-Findings-from-a-Literature-Review.
[31] *See* American Hospital Association, *Legal (Fraud and Abuse) Barriers To Care Transformation and How to Address Them* at 8-10 (Feb. 28, 2017), https://www.aha.org/system/files/content/16/barrierstocare-full.pdf.
[32] Nicholas Hodges, *Accountable Care Organizations: Realigning the Incentive Problems in the U.S. Health Care System*, 26 U. Fla. J.L. & Pub. Pol'y 99, 100 (2015).
[33] *Id.* at 100-01.
[34] Hodges, *supra* note 32, at 104.
[35] *Id.*at 104; This is further complicated by "moral hazard", which is when individuals do not fully realize the cost of their medical care and thus are inclined to over utilize, driving up costs and further burdening the health care system. The existence of health insurance moves health care out from the parameters of a "normal" market, and into a category of its own, which makes application of existing theories troublesome.

reimbursement rate available for a particular service.[36] Further complicating this matter is the fact that providers face no penalties or rewards for their impact on patients' future health.[37] As a result, FFS stimulates the provision of services in general, even those that are marginally appropriate or even outright inappropriate.[38]

Abuses of the FFS system can be seen in a variety of ways, none more obvious than when providers own or invest in other health care facilities. For example, when providers maintain ownership or compensation arrangements with other referral locations or services, they are more likely to utilize those services.[39] Even when their ownership is not based in their location, they refer patients 50% more than non-owners.[40] In any other business no one would bat an eye, but in the arena of health care patients are being subjected to additional services that are likely unnecessary and potentially harmful because the system incentivizes the behavior. The only things that exist to rein in FFS providers are patients who take an active role in monitoring the cost and provision of services, the professional ethics of the providers, the willingness of the patients to spend time for the procedures, and the willingness of the insurers to pay.[41] Unfortunately, these constraints alone are not enough to defeat the provider incentives of FFS and therefore the health care system had to evaluate and implement other methods of cost control.

Managed care (MC) represents an alternative delivery and payment approach that holds the promise of inhibiting overutilization and other costly practices.[42] MC organizes health care

[36] Jost, *supra* note 16, at 251.
[37] Hodges, *supra* note 32, at 107.
[38] Blumstein, *supra* note 28, at 209.
[39] *Id.* (patients whose doctors had an ownership interest in laboratory services received 45% more lab services than patients whose doctors did not have such ownership interests); *Id. (*providers who owned diagnostic imaging equipment or services ordered tests 400% more than non-owners).
[40] *Id.*
[41] *See id.* (The major barrier providers face in driving up the bills of their patients is cost, eventually the patient will either run out of money or challenge the necessity of the services. This barrier is all but eliminated once an individual has good insurance and never notices the charges because their "skin in the game" is minimal.).
[42] *Id.* at 205.

providers in an integrated and coordinated way to reduce costs.[43] Under MC, providers are reimbursed a set amount for the care of each patient (capitation) and are subject to utilization review, which serves as a check on the quantity of services being ordered for patients.[44] Utilization review is when an organization monitors and works with its participating providers to ensure that care is delivered in a cost-effective manner.[45] The insurer acts as a gatekeeper, and vetoes any procedures that are deemed to be unnecessary from a cost perspective.[46] Capitation seeks to control costs by shifting the risk of increased costs onto the providers themselves.[47] Providers are paid a flat fee per patient for a given unit of time, if they are able to control costs and spend less than their fee, they keep the excess.[48] If the patient consumes more resources than the fee allotted, the provider is responsible for the loss.[49] Capitation therefore discourages volume-enhancing services that are typical in FFS fraud, as payment based on a flat rate removes incentives to increase number of services.[50] Collectively, MC creates incentives to reduce costs by eliminating unnecessary care and performing less intensive procedures.[51]

This new alignment of MC arrangement reduces the risks of fraud inherent in the FFS model, but invites new fraud and abuse issues.[52] For instance, entities who employ MC engage in cherry-picking, where they intentionally seek to enroll healthier individuals so they do not have to expend as much of their capitated rate, thereby increasing their margin.[53] As a result of this

[43] Hodges, *supra* note 32, at 107.
[44] *Id.*
[45] *Id.*
[46] *Id.*
[47] *Id.*
[48] *Id.*
[49] *Id.*
[50] Blumstein, *supra* note 28, at 206.
[51] Hodges, *supra* note 32, at 127.
[52] Sharon L. Davies & Timothy Stoltzfus Jost, *Managed Care: Placebo or Wonder Drug for Health Care Fraud and Abuse?*, 31 Ga. L. Rev. 373, 385 (Winter 1997).
[53] *Id.* at 389.

practice, the provision of quality care to those in need goes down. One view is that providers who operate under a capitated basis will want to avoid, rather than gain, referrals thereby reducing the likelihood of overspending.[54] However, due to the nature of the system, an entity under MC needs a certain number of covered lives in order to maintain viability, and therefore referrals into the system are a necessary part of staying in business. Of course, the most important fact about the MC system is that FFS still exists, and there are few MC arrangements where all providers operate in a fixed cost basis.[55] As the health care system continues to examine fraud and abuse practices, it becomes more apparent that regardless of the payment system employed, fraud and abuse practices remain in some form.[56]

C. The Affordable Care Act's Impact

The rising costs of health care, combined with patients' rejection of managed care[57], prompted the government to devise an alternative delivery and reimbursement model that accomplished the goals of increased access to care and controlling Federal spending. Enacted in 2010, the ACA represented Congress' response to these imperatives.[58] Of particular focus is the inefficiency and high-cost of the FFS system and the extreme variations in access to quality care.[59] To this end, the ACA aims to shift reimbursement from one based on volume of services, to one based on the actual value of care.[60] Tools employed by the ACA include accountable care

[54] *Id.* at 409.
[55] *Id.* at 390.
[56] *See id.* at 410 (every payment system has its weak spots, where those issues reside is dependent on the model employed).
[57] One possible reason for this is that consumers have rejected managed care arrangements in favor of fewer restrictions on their access to health care.
[58] *See* Melinda Abrams et al., *Affordable Care Act's Payment and Delivery System Reforms: A Progress Report at Five Years*, The Commonwealth Fund at 1 (May 2015), http://www.commonwealthfund.org/~/media/files/publications/issue-brief/2015/may/1816_abrams_aca_reforms_delivery_payment_rb.pdf.
[59] *Id.*
[60] *Id.* at 2.

organizations (ACOs) and patient-centered medical homes (PCMHs).[61] Operating under a complex reimbursement formula, a Medicare ACO assumes responsibility for the overall health of the population of patients to which it is assigned.[62] The ACO comprises institutional and individual providers that collectively calibrate the quality and costs of its patient group with the goal of maintaining or improving overall health.[63] The rationale for ACOs is that comprehensive, coordinated, and well-targeted care can reduce per-patient costs and improve patient outcomes.[64] This same philosophy is at the heart of PCMHs, which engage in comprehensive care coordination, patient engagement, and population health management.[65] In both ACO and PCMH models, focus is on the provider's ability to improve quality of care.[66]

The ACA is also implementing quality-centric programs for all FFS providers.[67] This year HHS has indicated it would like 90% of all traditional Medicare payments to be linked to either ACOs, PCMHs, bundled payments or other value-related approaches.[68] These improvements in both access and quality are directed at many of the issues in FFS, specifically removing incentives to engage in unnecessary care.[69] However, increasing coverage and improving quality of the system alone are not enough to produce the improvements in health outcomes the ACA seeks to create. The health care system still needs to integrate and coordinate services across providers and settings, connecting to social supports and other services that address the broad range of social and environmental factors that impact health before the full potential of ACA cost-reduction can be

[61] *Id.*
[62] *See id.*
[63] *Id.*
[64] *Id.*at 4.
[65] *Id.*
[66] *Id.*
[67] *Id.* (for example, bundled payments, which are a single reimbursement for all services given for a specific medical condition or procedure, incentivizing all providers to work cooperatively to enhance patient health).
[68] S. M. Burwell, *Setting Value-Based Payment Goals—HHS Efforts to Improve U.S. Health Care*, 372 New Eng. J. Med. 897 (2015).
[69] *See* Greaney, *supra* note 1, at 39.

realized.[70] One method of reducing the disparities faced by underserved populations is by targeting SDH like transportation, which affords the opportunity to enter into gainful employment, access affordable foods, and engage in the health care system.[71]

III. Health Care Fraud and Abuse Enforcement in the United States

A. Why is Fraud and Abuse a Priority?

Conservative estimates show that health care comprises 18% of the United States' Gross Domestic Product (GDP).[72] This figure is expected to rise to 20% by 2020.[73] With almost a trillion dollars at stake, it is not surprising that fraud and abuse are a rampant problem. Fraud and abuse account for between $82 billion and $272 billion of the waste our health care system experiences every year.[74] This figure represents upwards of 30% of the total waste in health care which includes other complex issues like failure of care delivery, lack of care coordination, over-treatment, administrative complexities, and pricing failures.[75] As a result, the United States directs at least 10% of its total health care spend towards eliminating, or at least mitigating, fraud, waste, and abuse.[76]

The proliferation of health care fraud and abuse is due in part to the structure of the payment systems in place, which create incentives for certain kinds of provider behavior.[77] From an ethical perspective, providers should focus on the legitimate provision of high-quality and cost-effective care, that is both conscientious and competent.[78] However, FFS creates significant risks that

[70] Heiman, *supra* note 3, at 8.
[71] *See id.*
[72] Irene Papanicolas, Liana R. Woskie & Ashish K. Jha, *Health Care Spending in the United States and Other High-Income Countries*, 319 JAMA 1025, 1027 (2018).
[73] Donald M. Berwick & Andrew D. Hackbarth, *Eliminating Waste in US Health Care*, 307 JAMA 1513 (2012).
[74] *Id.* at 1514.
[75] *Id.* at 1513-1514.
[76] Davies, *supra* note 52, at 378.
[77] Jost, *supra* note 16, at 250.
[78] *See id.* at 253.

providers will behave illegitimately, utilizing fraudulent recruiting practices or offering kickbacks to steer beneficiaries.[79] When a particular act by a health care provider can have a benevolent or malevolent motivation or purpose, it can be incredibly challenging to determine into which category the act falls.[80] Fraud and abuse laws are designed to help mitigate this issue, but there is no failsafe system for the financing and delivery of health care.[81] As a result, fraud laws that were developed around the FFS model can negatively affect genuine providers whose "prohibited" actions are designed solely to benefit their patients.[82]

Despite the fact that fraud enforcement can affect innocent parties, the executive administration has continued to highlight health care fraud as a top priority.[83] Under the Health Insurance Portability and Accountability Act (HIPAA) of 1996, the Health Care Fraud and Abuse Control Program (HCFAC) was established,[84] and while the HCFAC has been successful,[85] the ever-changing nature of health care fraud and abuse necessitates constant review and continuous strategy update. In 2016, the Obama administration committed to reducing fraud, waste, and abuse across Medicare and Medicaid programs.[86] Part of this announcement indicated an emphasis on detecting fraud through the use of sophisticated data analysis, predictive analytics, and modeling

[79] *Id.*
[80] *See id.* at 254-55.
[81] *See* Davies, *supra* note 52, at 373.
[82] *See id.* at 250.
[83] Davies, *supra* note 52, at 376; *Id.* (noting that the Clinton administration placed enforcement of health care fraud as its second priority, only behind violent crimes in 1996); *Id.* (emphasis has been placed on a coordinated effort between the FBI, who investigates fraudulent practices, and the HHS OIG which focuses on ferreting out Medicare and Medicaid fraud and abuse claims).
[84] The Department of Health and Human Services And The Department of Justice Health Care Fraud and Abuse Control Program Annual Report for Fiscal Year 2016 (Jan. 2017), https://oig.hhs.gov/publications/docs/hcfac/FY 2016-hcfac.pdf (HCFAC coordinates Federal and local enforcement activities concerning health care fraud and abuse).
[85] *Id.* (since inception the HCFAC has returned approximately $30 billion to Medicare, a $6.10 per dollar return on investment).
[86] Press Release, U.S. Dep't of Justice, *Fact Sheet: The Health Care Fraud and Abuse Control Program Protects Consumers and Taxpayers by Combating Health Care Fraud* (Feb. 26, 2016), https://www.justice.gov/opa/pr/fact-sheet-health-care-fraud-and-abuse-control-program-protects-conusmers-and-taxpayers.

to find both existing fraud patterns and to identify suspect fraud trends.[87] Combined with the shift in the health care payment system to value-based care, incentives to engage in fraudulent practices are being reduced. Notwithstanding these changes, the AKS still remains a primary enforcement tool to curb health care fraud and abuse.

B. The Anti-Kickback Statute

The AKS, written in the context of the FFS system[88], provides criminal penalties for individuals or entities that knowingly and willfully offer, pay, solicit, or receive remuneration in order to induce or reward the referral of business reimbursable under Federal Health Care Programs.[89] Remuneration includes any kickback, bribe, or rebate that can be offered directly or indirectly, overtly or covertly, in cash or in kind.[90] The AKS centers on health care providers who are motivated by their own financial interest, and as such will over-utilize medical services through the referral of patients for unnecessary medical treatments.[91] Congress established strong penalties for an AKS violation, including fines up to $25,000, imprisonment for up to 5 years, and the possibility of limiting, restricting, or suspending for up to one year the violator's eligibility to participate in Federal Health Care Programs.[92] Importantly, actual knowledge of this statute, or the specific intent to violate this statute, is not required to be found guilty of a violation.[93]

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[87] *Id.*; Michael Parker & Dennis Bentley, *The Affordable Care Act Has Improved the Way the Federal Government Fights Health Care Fraud, But the Rate of Return on the Investment is Still Being Measured*, The Fed. Law. at 33 (Dec. 2016) (the use of proactive information-technology platforms and comprehensive data-mining which has led to an increase in recovery for Federal Health Care Programs of approximately $1 billion each year).
[88] Stephanie Zaremba, *A healthcare law held together by duct tape*, aetnainsight (Aug. 12, 2016) https://www.athenahealth.com/insight/health-care-fraud-and-abuse-laws.
[89] 81 Fed. Reg. 88,368 (Dec. 7, 2016) (codified at 42 C.F.R. pts. 1001 and 1003), *see also 42 U.S.C. §1320a-7b (2018);* 42 U.S.C. § 1320a-7a(a) (in addition to AKS criminal action, OIG may seek civil monetary penalties of up to $50,000 for each improper act and damages of up to three times the amount of remuneration at issue, regardless of whether some of the remuneration was for a lawful purpose).
[90] *Id.*
[91] Michael E. Paulhus, Note, *The Medicare Anti-Kickback Statute: In Need of Reconstructive Surgery for the Digital Age*, 59 Wash. & Lee L. Rev. 677, 691 (2002).
[92] 42 U.S.C. §1320a-7b (2018).
[93] *Id.*

The regulatory structure of AKS has been criticized for being overly broad, sweeping in "technical" fraud, behavior that would not constitute fraud under the ordinary legal term.[94] Due to this concern, many believe the AKS limits development of the health care system by threatening innovative business arrangements that focus on novel, value-maximizing approaches.[95] The notion that the AKS is so blunt in its structure, that it could prohibit arrangements that are actually more efficient and cost-effective than existing programs, is supported by the use of the "one-purpose test."[96] In *United States v. Greber*, the Third Circuit held that if one purpose of a payment was to induce future reciprocal referrals, the payment violated the AKS.[97] The court assumed the services were needed, medically appropriate, and reasonably priced, but nevertheless constituted an AKS violation.[98] Under *Greber* the use of financial incentives or remuneration for the purpose of inducing patient flow, even if small, is problematic.[99] Having now been codified in the AKS, *Greber* precludes a defense that the targeted innovation advances efficient and economical care.[100]

A further criticism of the AKS is that it is inefficient and not designed to adapt easily with changes in the health care system.[101] Providers are technically stuck between adhering to the FFS-based AKS and trying to align practices with the new wave of alternative health payment models.[102] Rather than amending or updating the AKS to reflect these changes, the primary tool OIG has employed in recognizing the alternative payment models has been safe harbors. While

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[94] *See* Christopher J. Climo, Note, A Laboratory of Regulation: The Untapped Potential of the HHS Advisory Opinion Power, 68 Vand. L. Rev. 1761, 1769 (2015). *See also Paulhus, supra* note 91, at 693 (noting that because Congress intended courts to interpret "remuneration" broadly, both unscrupulous providers and innocuous and socially beneficial arrangements would be treated similarly).
[95] *See id.*
[96] *See* Jost, *supra* note 16, at 210.
[97] 760 F.2d 68, 72 (3d Cir. 1985).
[98] *Id.* at 71.
[99] Blumstein, *supra* note 28, at 213.
[100] *Id*. at 214.
[101] James G. Sheehan & Jesse A. Goldner, *Beyond The Anti-Kickback Statute: New Entities, New Theories In Healthcare Fraud Prosecutions*, 40 J. Health L. 167 (Spring 2007).
[102] *See generally* American Hospital Association, *supra* note 31.

safe harbors do represent an opportunity to drive positive change in the health care system, they are often reactive rather than proactive, hindering innovation.[103]

C. The Narrow Safe Harbors of the Anti-Kickback Statute

In 1987, Congress enacted §14 of the Medicare and Medicaid Patient and Program Protection Act, which allowed HHS to promulgate safe harbors that, if satisfied in their entirety, insulate actors from AKS liability.[104] Safe harbor regulations describe payment and business practices that, although they potentially implicate the AKS, the government will not treat as offenses under the statute because of a determination that the positive goals of the activity[105], and embedded protections, mitigate the risks of fraud.[106] Currently, there are 28 safe harbor provisions.[107] While the OIG has authority to create these regulatory exceptions, Congress gave little guidance as to what they should entail.[108] As a result, OIG exercises its authority cautiously and limits the exceptions only to those areas in which Congress has indicated a desire for flexibility, or where such provision of remunerations serve a government interest.[109]

OIG's goal with any safe harbor is to protect those beneficial arrangements that enhance the efficient and effective delivery of health care, and protect the best interest of the patients.[110] In order to be successful, safe harbors must be updated periodically to reflect the ever-changing

[103] *See* Zaremba, *supra* note 88.
[104] 81 Fed. Reg. 88,368, 88,369.
[105] Climo, *supra* note 94, at 1764 (safe harbors are seen as prosocial, meaning they do not exert pressure on the costs or quality of Federal Health Care Programs, and providers are able to invest in value-maximizing approaches).
[106] Office of Inspector Gen., U.S. Dep't of Health & Human Servs., *Safe Harbor Regulation* (last visited March 24, 2018), https://oig.hhs.gov/compliance/safe-harbor-regulations/index.asp; Adrienne Dresevic, Clinton Mikel & Robert Dindoffer, In This Issue, *Significant Changes to Anti-Kickback Statute Safe Harbor/Exceptions to the Civil Monetary Penalty Law*, 29 Health Law. 23 (Aug. 2017) (if a particular arrangement meets the safe harbor it is found to comply with the AKS and is not subject to prosecution).
[107] *See* 42 C.F.R. § 1001.952 (2018).
[108] *See* 67 Fed. Reg. 72,892 (December 9, 2002) (codified at 42 C.F.R. pt. 1001).
[109] *See id.* at 72,983.
[110] 79 Fed. Reg. 59,717, 59,719 (Oct. 3, 2014) (codified at 42 C.F.R. pts. 1001 and 1003).

business and technology changes in the health care industry.[111] Using guidelines in §1128D(a)(2) of HIPAA, the Secretary of HHS may consider a variety of factors when examining a payment practice.[112] Given the breadth of the factors, one would assume that OIG would be promulgating multiple safe harbors to advance practices that are beneficial to Federal Health Care Programs as payment models move beyond FFS. However, since the passage of the Affordable Care Act (ACA) in 2010 only three safe harbors have been finalized.[113] Rather than encouraging health system development through flexible and appropriate safe harbors, OIG has stymied providers' ability to innovate and implement programs that can create cost-savings and increase quality of health care.

The obstruction in innovation is further restricted by how narrow OIG constructs safe harbors. A party's conduct must fall completely within the contours of the safe harbor to be immune from prosecution.[114] If a single provision is missed, or incorrectly applied, the party is subject to prosecutorial discretion, which emphasizes the requisite intent to violate the AKS.[115] Because the intent standard for AKS is so low, providers undertake large risks in implementing programs whose nonconformance is minute.[116] When implementing potentially valuable programs that do not appear to completely conform to existing safe harbors, providers are left with two options: hope that prosecutors do not notice or care, or seek an advisory opinion. This means that

[111] 81 Fed. Reg. 88,368.
[112] *Id.* (These include an increase or decrease in: access to health care services; the quality of health care services; patient freedom of choice among providers; the ability of health care providers to offer services to medically underserved areas or populations; the cost to Federal Health Care Programs; the potential overutilization of health care services; the existence or nonexistence of any financial benefit to a health care provider; and any other factors the Secretary deems appropriate in preventing fraud and abuse in Federal Health Care Programs.).
[113] Office of Inspector Gen., U.S. Dep't of Health & Human Servs., *Safe Harbor Regulation* (last visited March 24, 2018), https://oig.hhs.gov/compliance/safe-harbor-regulations/index.asp.
[114] Jeffrey B. Hammond, *What Exactly is Healthcare Fraud After the Affordable Care Act?*, 42 Stetson L. Rev. 35, 66 (2012).
[115] *See id.*; The party then has to show that their conduct is not violative, but instead seeks to satisfy goals that the government approves, while still maintaining sufficient protections against using remuneration to induce referrals.
[116] *See id.*; *see also Dresevic, supra* note 105, at 23 (A party can avoid AKS liability if they do not have the requisite intent to induce referrals or if other elements of the AKS are not met. However, unfamiliarity with the AKS is not a defense and if one-purpose of the activity is to induce referrals then the party is liable.).

there are likely a number of appropriate, innovative, and socially beneficially programs in the marketplace that safe harbors have failed to protect, and which providers are unwilling to implement for fear of prosecution.[117]

Many providers are uncomfortable relying on prosecutorial discretion so they seek an advisory opinion, which can clarify the meaning and applicability of the AKS to a particular arrangement.[118] While advisory opinions are only binding on the requesting party,[119] other providers use them as guideposts for assessing likelihood of AKS enforcement. Unfortunately, much like safe harbors, advisory opinions are issued infrequently, averaging fewer than 20 per year.[120] Further confounding the issue is that advisory opinions are cost-prohibitive, and many smaller practices and low-resource providers are unable to access these individualized opinions in order to evaluate their arrangements under AKS liability.[121] Greater OIG flexibility is needed to give providers the freedom to create innovative programming that can reduce the burden on Federal Health Care Programs and increase health care system efficiencies. One solution to responding to the changes in the health care marketplace is the modification or expansion of safe harbors to create stronger alignment with the current payment trends.

IV. The Free Transportation Safe Harbor

A. History and Development

The SDH impact our lives in many complex ways, and none has more touchpoints than transportation.[122] Transportation is necessary to access goods and services like health care, food,

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[117] Blumstein, *supra* note 28, at 225.
[118] 42 U.S.C. §1320a-7d(b)(4) (2018).
[119] *Id.*
[120] *See* Climo, *supra* note 94, at 1782.
[121] See U.S. Gov't Accountability Office, *MEDICARE: Advisory Opinions as a Means of Clarifying Program Requirements* (2004), https://www.gao.gov/assets/250/244922.pdf (describing the expenses that providers must bear to secure an advisory opinion), *see also* Office of Inspector Gen., U.S. Dep't of Health & Human Servs., *Advisory Opinions FAQ* (2018), https://oig.hhs.gov/faqs/advisory-opinions-faq.asp.
[122] *Id.* at 6.

education, employment, and social engagement.[123] Transportation barriers to health care are incredibly significant, as people who do not have adequate transportation experience poor health outcomes, increased health care utilization, and increased health care costs.[124] The issue is not minor, every year almost four million people fail to obtain any medical care due to transportation barriers.[125] Of those who are able to obtain health care, many are unable to make necessary appointments.[126] These effects are felt most strongly by vulnerable groups like children, older adults, less educated, minorities, and low income families.[127] If transportation barriers are not addressed, there will continue to be missed appointments, failed prescription fills, and other issues which lead to delayed care, disease progression and increased hospital visits.[128] It is estimated that missed appointments and delays in care cost the U.S. health care system $150 billion each year.[129] Providers are positioned to positively impact the health of the populations they serve by addressing transportation issues.[130] Without appropriate safeguards in place however, the provision of transportation can bring AKS liability.

The OIG is aware that transportation impacts health care costs, and has been discussing a safe harbor for local transportation, colloquially known as the "Free Transportation" safe harbor, since 2002.[131] In its first appearance for solicitation of comments, OIG noted that while Congress had intended not to preclude the provision of free local transportation of a nominal value, the limitation was potentially overly restrictive.[132] OIG was therefore interested in learning what

[123] *Id.*
[124] *Id.*at 4.
[125] *Id.* at 6.
[126] *Id.* (every year three million children miss a health care appointment due to lack of transportation, and older adults cite lack of transportation as the third most common barrier to accessing health services).
[127] *Id.*
[128] *Id.* at 9.
[129] *Id.*
[130] *Id.*
[131] 42 C.F.R. § 1001.952(bb) (2018); 67 Fed. Reg. 72,892.
[132] *Id.* at 72,893. (at the time $10 per transaction and $50 annually).

forms of transportation should be protected, what geographic area limitations should be placed on the transportation, and what other potential eligibility criteria, if any, commentators would deem appropriate to increase availability of transportation without increasing the potential for fraudulent activities.[133]

After the solicitation of comments, a series of advisory opinions discussing provision of transportation services was released. As they are only applicable to the individual Requestor, under the facts of the proposed arrangement, advisory opinions only indicate what type of arrangements OIG thinks do not raise significant fraud and abuse concerns. From the opinions on transportation services, it is apparent that OIG is focused on several issues: eligibility criteria for the service, type of transportation, geographic area, advertisement and marketing practices, availability of transportation options, cost-shifting to Federal Health Care Programs, and whether or not the arrangement is designed to induce referrals. These overarching concepts were present in the first advisory opinion on the topic[134], which was for a skilled nursing facility offering free transportation for its residents' friends and family, likely to increase perceived value.[135] OIG noted that free transportation has important and beneficial effects on patient care, especially where it is narrowly tailored to address financial need, limited resources, and treatment compliance or safety, even going as far to allow local newspaper ads promoting the service.[136] At the same time, OIG

[133] *Id.*

[134] Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 09-01, 5-6 (March 6, 2009) (the analytical factors used in deciding whether the arrangement was an AKS violation: if transportation was offered in a manner related to referrals, specifically the relation to the volume or value of Federal Health Care Program business; the use of luxury or specialized transportation is suspect; the geographic area, transportation outside of a primary service area is suspect and leap-frog arrangements (bypassing other providers) is problematic; availability of alternative transportation, including public transit or affordable alternatives; marketing or advertising brings greater risk of referral inducement; transport outside of the offeror's network is suspect; cost of the transportation should be borne by the offeror; and where the offeror is also a provider, there is concern the purpose is to gain access to beneficiaries for unnecessary or inappropriate services).

[135] *Id.*at 4-5.

[136] *Id*.

explained that transportation services can be used in fraud and abuse schemes to steer patients, leading to overutilization and provision of medically unnecessary services.[137] This balance between risk of fraud due to the problematic incentives of FFS, and the offering of transportation arrangements that are beneficial to the community, is the central tension of the safe harbor.

After the comment period, OIG began to refine its analyses through several additional opinions and a notice of proposed rulemaking. Three advisory opinions in 2011 helped further delineate the rationale OIG was employing in deciding whether free transportation arrangements promoted access to care without increasing the risk of fraud, but analysis still existed under a FFS framework and not the ACA's proposed shift toward value-based payments. In the first advisory opinion of 2011 the Requestor, a charitable pediatric hospital, sought to implement transportation assistance for its patients.[138] Under the arrangement, the Requestor would pay for local and long-distance transportation for families in need, based on the exigent circumstances of the case and the availability of funds.[139] OIG concluded that it would not seek administrative action against the transportation assistance program because it promoted access to care with a focus on the medical and financial need of the patients, and did not engage in any other suspect practices outlined above (e.g. no advertising or cost-shifting to Federal Health Care Programs).[140]

Two months later, OIG analyzed a Requestor's proposed arrangement to use an EMT to transport patients across its campus, from provider offices to the Requestor's hospital when further evaluation or treatment was required and patients were unable to transport themselves.[141] While

[137] *Id.*
[138] Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 11-01 at 2-3 (Jan. 3, 2011).
[139] *Id.* at 7.
[140] *Id*. at 13.
[141] Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 11-02 (March 17, 2011).

the proposed arrangement did implicate the AKS, again OIG refused to enforce administrative sanctions, noting the arrangement did not engage in any suspect practices.[142] The final transportation advisory opinion of 2011 targeted transportation to the Requestor's facility, which treated catastrophic disease in children.[143] Because more than 70% of the Requestor's patients lived over 35 miles away, the proposed arrangement offered assistance to the patient and one parent or guardian who expressed a need for assistance in order to make accessing services easier.[144] There were three levels of assistance available depending on distance from the Requestor's facility, with greater assistance available as distance between the patient and Requestor increased.[145] The OIG declined to take administrative action due to lack of the same suspect practices from earlier opinions.[146] Of importance in this request was that the unique nature of the service made it unlikely that patients would engage in unnecessary services or that the patient would bypass other facilities to receive treatment.[147] OIG felt that due to the substantial public benefits of the Requestor and the type of care that was offered the risk of fraud was minimal.[148]

Just prior to the issuance of Advisory Opinion No. 11-16, OIG issued a proposed rule to revise the safe harbors under the AKS.[149] Similar to the discussion under the solicitation of public comments nine years earlier, OIG was concerned that the nominal value limitations were overly restrictive on transportation services.[150] The proposed rule noted that certain types of entities may

[142] *Id*. at 5.
[143] Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 11-16 at 1-2 (Nov. 8, 2011).
[144] *Id.* at 2.
[145] *Id.*at 4 (patients within 35 miles had access to a shuttle service if they had no other means of transport; patients who were between 35-300 miles had access to bus or rail travel, or could be reimbursed for mileage; and patients over 300 miles had the addition of air travel reimbursement).
[146] *Id.*at 7.
[147] *Id*. at 7-8
[148] *Id*.
[149] 79 Fed. Reg. 59,717.
[150] *Id.*at 59,722.

have legitimate financial and patient care interests in providing transportation, and that they, depending on the particular circumstances, could benefit Federal Health Care Programs by reducing costs and improving beneficiaries care and access.[151] Responding to the ACA, OIG was interested in creating an exception for those arrangements which promoted access to care and posed a low risk of harm to patients and Federal Health Care Programs.[152] OIG defined promoting access to care as improving a particular beneficiary's ability to obtain medical necessary services, and wanted to know if the definition should be expanded to include non-clinical services that reasonably related to the patient's medical care, specifically social services.[153]

Prior to the final rule, OIG issued one more advisory opinion concerning the provision of free transportation services via shuttle service.[154] Under the proposed arrangement, a shuttle would transport patients of the Requestor's system between multiple facilities and the town where their main facility was located.[155] OIG concluded that the proposed arrangements presented a minimal risk of fraud and abuse under the AKS for similar reason that had been articulated in all previous advisory opinions.[156] Interestingly, in each of the advisory opinions relating to free transportation OIG discussed the same factors that were mostly delineated in Advisory Opinion 09-01, which was written before the passing of the ACA. After the passage of ACA, OIG acknowledged that access to care was an additional consideration that pertained to the specific facts and circumstances of each arrangement, but analyses did not change, nor did it appear that the OIG understood the need to work outside of the FFS model.

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[151] *Id.*
[152] *Id*. at 59,725.
[153] *Id.*
[154] Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 15-13 (Oct. 24, 2015).
[155] *Id.* at 3.
[156] *Id.* at 6.

B. The Final Rule

On December 7, 2016, OIG issued the final rule for the free transportation safe harbor,[157] which has since been codified at 42 C.F.R. § 1001.952(bb).[158] According to OIG, the purpose of this safe harbor is to protect Federal Health Care Programs and patients from fraud and abuse while

[157] 81 Fed. Reg. 88,368.

[158] (bb) Local Transportation. As used in section 1128B of the Act, "remuneration" does not include free or discounted local transportation made available by an eligible entity (as defined in this paragraph (bb)):

(1) To Federal health care program beneficiaries if all the following conditions are met:

(i) The availability of the free or discounted local transportation services—

(A) Is set forth in a policy, which the eligible entity applies uniformly and consistently; and

(B) Is not determined in a manner related to the past or anticipated volume or value of Federal health care program business;

(ii) The free or discounted local transportation services are not air, luxury, or ambulance-level transportation;

(iii) The eligible entity does not publicly market or advertise the free or discounted local transportation services, no marketing of health care items and services occurs during the course of the transportation or at any time by drivers who provide the transportation, and drivers or others arranging for the transportation are not paid on a per-beneficiary-transported basis;

(iv) The eligible entity makes the free or discounted transportation available only:

(A) To an individual who is:

(1) An established patient (as defined in this paragraph (bb)) of the eligible entity that is providing the free or discounted transportation, if the eligible entity is a provider or supplier of health care services; and

(2) An established patient of the provider or supplier to or from which the individual is being transported;

(B) Within 25 miles of the health care provider or supplier to or from which the patient would be transported, or within 50 miles if the patient resides in a rural area, as defined in this paragraph (bb); and

(C) For the purpose of obtaining medically necessary items and services.

(v) The eligible entity that makes the transportation available bears the costs of the free or discounted local transportation services and does not shift the burden of these costs onto any Federal health care program, other payers, or individuals; and

(2) In the form of a "shuttle service" (as defined in this paragraph (bb)) if all of the following conditions are met:

(i) The shuttle service is not air, luxury, or ambulance-level transportation;

(ii) The shuttle service is not marketed or advertised (other than posting necessary route and schedule details), no marketing of health care items and services occurs during the course of the transportation or at any time by drivers who provide the transportation, and drivers or others arranging for the transportation are not paid on a per-beneficiary-transported basis;

(iii) The eligible entity makes the shuttle service available only within the eligible entity's local area, meaning there are no more than 25 miles from any stop on the route to any stop at a location where health care items or services are provided, except that if a stop on the route is in a rural area, the distance may be up to 50 miles between that that stop and all providers or suppliers on the route; and

(iv) The eligible entity that makes the shuttle service available bears the costs of the free or discounted shuttle services and does not shift the burden of these costs onto any Federal health care program, other payers, or individuals.

still allowing providers the enhanced flexibility to engage in innovative health care business arrangements. [159] Specifically, the safe harbor advances patients' choice of high quality providers, the appropriate utilization of health care services, and positive health care competition.[160] The new rule also protects against increased health care costs, inappropriate patient steering, and the general harms associated with prohibited remuneration.[161] OIG considered how health care delivery system and payment reform affected Federal Health Care Programs, but did not address emerging payment arrangements.[162] Interestingly, Congress intended for safe harbors to evolve along with changes in the health care system , which include alternative payment models,[163] but the failure to develop the rule under these changes is troubling. Despite this issue, OIG believes that the rule meets the goals of the AKS and ACA by balancing flexibility for industry stakeholders in providing efficient, well-coordinated, and patient-centered care with protections against known and anticipated fraud and abuse risks.[164]

Part of the final rule process entails a discussion of the commentary received and OIG's decision on whether to incorporate that commentary or to substitute its own instead.[165] A brief review of these comments is necessary to show the safe harbor's relation to provider challenges, the SDH, and the ACA. One particularly important comment focuses on the decision by OIG to decline to extend coverage of transportation services to anything that is not medically necessary.[166] According to OIG, non-medically necessary services pose an increased risk of inducing patients

[159] 81 Fed. Reg. 88,368.
[160] *Id.* at 88,369.
[161] *Id.*
[162] *See id.*
[163] *Id.*
[164] *Id.*
[165] *Id.*at 88,371 (despite the growing popularity and necessity of transportation arrangements in health care, there were only 88 individual commentators who participated in the process).
[166] *Id.*at 88,384; Medicare defines "medically necessary" as "health care services…needed to diagnose or treat an illness, injury, condition, disease, or its symptoms and that meet accepted standards of medicine." Medically necessary, Glossary, https://www.medicare.gov/glossary/m.html.

to over utilize services.[167] For example, determining whether a particular destination is actually related to health is difficult.[168] Transportation for issues like food security, via access to a grocery store in a shopping mall, may actually be used for alternative or additional purposes.[169] Furthermore, transportation for non-medical services has the potential to be more frequent[170] and this gives larger providers significant advantage over smaller entities.[171] These comments seemingly ignore the substantial benefit that non-medically necessary services can have on patients' overall health.[172] Aggravating this fact is OIG's admission that providers still can create access to non-medically necessary services via shuttle service,[173] despite the fact that shuttle services are much more limited under the safe harbor.

In addition to the above, the final rule declined to mandate specific eligibility terms or situations where transportation would be protected, leaving it up to providers to interpret the statute or request advisory opinions.[174] As noted earlier, this limitation has the potential to stifle innovation because providers either cannot afford advisory opinions, or are hesitant to engage in activities that may render them liable under the AKS. While the rule does place providers with greater financial resources in a stronger position to implement transportation programs, OIG believes that the specified criteria of the safe harbor mitigates that risk.[175] For example, because no provider can advertise or market these programs, having more resources does not necessarily equate to increased participation.[176] In a similar vein, OIG stated that the safe harbor will not

[167] *Id.*
[168] *Id.*
[169] *Id.*
[170] People access the grocery store more often than medical care.
[171] *Id.*
[172] For example, a patient who has significant food security issues may receive substantially more benefit from access to healthy, affordable food as compared to the ability to get a physical.
[173] *Id.*
[174] *Id.* at 88,384.
[175] *Id.*
[176] *Id.*

negatively affect competition among providers, because overall patients will now be able to select from a larger pool of providers,[177] but this assumes that providers have the resources and will chose to offer the service.

A series of comments centered on the definition of an established patient and allowable recruitment practices.[178] In order to qualify as an "established," a patient is not required to have already been seen by the provider; instead they only need to have scheduled an appointment.[179] This initial contact establishes the relationship, which then allows the provider to engage the patient in a discussion of transportation needs.[180] If a provider does offer transportation services, they cannot place limits on which service or provider the patient chooses.[181] This serves a dual-purpose of promoting increased access via competition and reduces ability of providers to self-refer. In addition, providers cannot take an individual's status as a Federal Health Care Program beneficiary into account, only the need for transportation services.[182] While this will likely result in a disproportionate number of individuals who are elderly and low-income,[183] the decision is not based on insurance type which is a concern of the AKS.[184]

Three other comments are worth noting. First, OIG encourages but does not require the provider to document its free transportation activities, as OIG recognizes it can be a burdensome practice.[185] This means that providers are not required to keep any records of the transportation services they offer, which is a focus of fraud enforcement and is unlike the detailed records

[177] *Id.* at 88,380-81.
[178] *Id.* at 88,383.
[179] *Id*.
[180] *Id.* at 88,383, 88,387.
[181] *Id*. at 88,381-82 (providers offering transportation cannot only offer transportation within their network, patients must be able to access any provider of the service the patient seeks to obtain).
[182] *Id.* at 88,384.
[183] These two groups are more likely to be Federal Health Care Program beneficiaries.
[184] *Id.*
[185] *Id.* at 88,383.

required for the provision of health care services. Second, specific mileage limits were selected because they were a simple, bright line test that is easier for providers to apply.[186] Rather than creating a formula that could be applied, providers must determine whether they are in an urban or rural location as defined by the Metropolitan Statistical Area or New England County Metropolitan Area.[187] Finally, OIG did not think the shuttle service poses an increased risk of fraud or abuse because it is subject to other limitations, like a marketing restriction, that will reduce the ability of the provider to recruit patients using the offer of free transportation.[188] While it may appear at first glance that OIG tried to balance the mandates of both the AKS and ACA, the safe harbor is still too restrictive. As the payment incentive system continues to shift, providers will be limited in their ability to provide necessary services, like transportation, for at-risk populations.

V. How We Can Get the Boat and Harbor Back in Alignment

In order to effectively showcase the shortcomings of the final Free Transportation safe harbor, it is helpful to break out both the individual and shuttle transportation provisions into their separate conditions. From there, each provision will be analyzed under both the AKS and ACA frameworks to delineate which conditions are appropriate and which conditions need to be removed, modified, or expanded in order for the safe harbor to more closely align with the current goals of the ACA, with emphasis shift to value-based payments. Specific attention will be devoted to describing that while risk of fraud may appear to increase, the potential savings to Federal Health Care Programs, through impact on the SDH, should outweigh any AKS concerns.

There are multitude ways to break down the safe harbor, but for purposes of this analysis the individual transportation provision is separated into ten components: (1) the services are set

[186] *Id.* at 88,388.
[187] *Id.* at 88,387 (any area that is not defined as urban under these systems is classified as rural).
[188] *Id. at* 88,389-90.

forth in a policy that is uniformly and consistently applied; (2) eligibility is not based on past or anticipated volume or value of Federal Health Care Program business; (3) documentation for each individualized transportation service is not required; (4) transportation cannot be provided via air, luxury, or ambulance; (5) providers cannot market or advertise both the transportation services nor services the provider offers; (6) drivers of the transportation service cannot be paid on a per-beneficiary transported basis; (7) only established patients are eligible for the services; (8) transportation is limited to a radius of 25 miles in urban settings, 50 miles in rural settings; (9) the provider cannot shift the costs onto Federal Health Care Programs, payors, or individuals; and (10) transportation is only available for medically necessary services.[189]

Of these ten conditions, five are appropriate to achieve the goals of both the ACA and AKS frameworks. The first is the condition that providers must establish a policy that is applied uniformly and consistently. Under this condition, providers can have a needs-based policy, but they must apply that to all participants. If individualized decisions could be made, there is a high likelihood that providers would only utilize the service to attract patients who were of the greatest "value". Not only would this increase the chances of fraudulent practices, but it would jeopardize the provision of quality care to those in need. The second condition is not basing eligibility on past or anticipated volume or value of Federal Health Care Program business. This condition is a relatively straightforward application of the AKS. Providers cannot place burdens on Federal Health Care Programs by encouraging overutilization of services as compared to other types of payment. From the perspective of the ACA, while Medicare and Medicaid patients tend to be vulnerable, restrictions solely to these populations would not promote overall access to care. The third condition is the limitation on the type of transportation. Specialized

[189] 42 C.F.R. § 1001.952(bb) (2018).

transportation can only serve the purpose of inducing referrals, and whether the ride is in a limo or a van makes no difference in increasing access to services. Directly related to this condition, is the requirement that drivers cannot be paid on a per-beneficiary basis. Without this condition, drivers would be incentivized to bring as many patients as possible to the provider, likely increasing unnecessary services and increasing costs on the Federal government. The final condition is that the provider cannot shift costs of the transportation service onto any payor. Under the AKS reducing spending for Federal Health Care Programs is of particular focus, and this condition prevents increases costs. Under the ACA, some assumption of risk by the provider is good, as providers will only deliver appropriate care, reducing the government spend. The five conditions left represent the potential to inhibit the goals of the ACA, and in some cases are in direct tension with the AKS. Utilizing the Jane Smith case study, each of these conditions will be expounded upon to show its shortcomings and potential solutions to improve the safe harbor.

At first review, the marketing and advertising condition fits right into the AKS framework. Allowing providers to showcase a valuable service across their catchment area does present the potential to induce referrals. However, much like Jane Smith, many individuals who are in the most need of health care services may never take the initial step in contacting a provider, and therefore never utilize the transportation service. More importantly is that it appears OIG only considered FFS reimbursement. However, as the market shifts towards value-based payment, providers are rewarded for keeping the population healthy, not for rendering more services. Patients like Jane would actually benefit the provider if she was kept healthy through preventative care, rather than accessing expensive emergency procedures. Furthermore, Jane's admission into the NICU would consume more Federal Health Care Program resources than consistent pre-natal visits. This is exactly what the ACA emphasizes: utilizing preventative

to drive positive health outcomes. By removing the ability of providers to notify the community, especially those who may not reach out on their own, the risks of delayed care and missed appointments are increased, which can enlarge costs to Federal Health Care Programs. Because providers' reimbursement is driven by value and not volume, the risk of advertising being used inappropriately is minimal as compared to 10 years ago. Modifying the condition to allow for marketing and advertising services within limits, as was done in Advisory Opinion 09-01 which permitted advertising on a limited local basis, holds promise. Containing the promotion within a defined area limits risk of leapfrogging and reduces the pool of patients that could be referred inappropriately. Furthermore, under the new payment models, as long as appropriate medical care is being rendered, risk of fraud is minimal.

The established patient condition shares some of the same flaws and potential solutions as advertising. If patients are not engaged in their own health care, then they will likely never become "established". Without being established, the same problem that Jane experienced above will repeat itself. Failure to receive appropriate care at appropriate times leads to an increased risk that emergency services, or other high-cost services, will be utilized, which in turn creates higher costs to Federal Health Care Programs. The OIG likely included this condition out of fear that providers would cold-call patients and use free transportation to induce referrals. While that type of behavior should not be allowable, even if it increased access to care, there is room to modify the condition and still protect against fraud. Following a similar rationale from the advertising and marketing expansion, allowing providers limited ability to reach out to social service providers to target those in need of transportation services to access care could be beneficial and have a limited risk of fraud. Agencies that provide social services are mission-driven and seek to provide for their clients first, not serve the health care providers. As a result,

the agencies will not over-refer patients to receive a kickback. By shifting the power of referrals outside of the provider's hands, risk of fraud is automatically reduced. At the same time access to care increases, as resource gaps in social service agencies are filled by providers.

One of the more perplexing conditions is that providers are not required to maintain any individualized documentation of the services they provide, henceforth known as data collection. As noted by the Department of Justice, data analytics has become one of the most powerful tools to disrupt and prevent fraudulent abuses of the health care system. Despite this, OIG failed to require that providers maintain data on their transportation services, only stating that it is a best practice. The failure to make data collection mandatory, at least in some capacity, seems contradictory to cost-effective fraud prevention. If a provider is rendering transportation services that are suspect, OIG is not guaranteed an efficient method of reviewing the process other than through "boots on the ground" investigative work which likely require more time and money than data analysis. Besides actual enforcement procedures, data collection increases transparency, reducing the likelihood that providers will engage in inappropriate behavior. Of course this will be burdensome to providers, and may increase the number of providers who forgo offering services due to the cost-prohibitive nature, but if the concern is prohibiting fraudulent activity then record-keeping is essential. Another important concept is that data is necessary for improvement and growth. Records can be used for strategic planning to drive population health improvements, which under value-based system results in increased savings. For example, if the provider in Jane's city collected data regarding participants in their transportation program, they may be able to identify key areas for expansion, increasing access points and revenue. To limit complexity, the safe harbor could mandate the collection of specific data points that are beneficial, which would create uniformity and consistency for easier fraud

analysis. The ability to differentiate between legitimate and improper use of free transportation services would prevent fraudulent practices or at least explicitly show that risk of fraud is so minimal that recordkeeping is unnecessary. If the latter is the case, then an overly restrictive safe harbor would seem inappropriate.

Since its early discussions of free transportation services, OIG has indicated concern with leap-frogging.[190] As a result, OIG placed a condition on the distance that providers can go in offering free transportation. Unfortunately, while the rural area limitation of 50 miles may seem appropriate, a 25-mile radius for urban areas allows for leap-frogging relatively easily. Take for instance in New Jersey, where the top-rated hospital has over 20 hospitals within a 25-mile radius, many of which are significantly under-funded. Under the current safe harbor, the "best" hospitals have the ability to expend considerable resources to poach patients from providers. While there may be an increase in access to quality care, it comes at the expense of every other institution.[191] Support for modifying this condition is found in the fact that most people travel less than 10 miles to access a hospital.[192] If the AKS is concerned about providers using transportation as an inducement to take patients from other entities, this condition seems to be problematic. What makes the situation worse is that the opposite effect could happen, and lower-quality hospitals might use the extended reach to take patients away from better performing providers. For example, perhaps Jane is actually closer to a higher-quality hospital, but due to their reputation they do not need to drive volume by providing transportation services. Instead, a

[190] When providers recruit patients from another provider's service-area, bypassing one entity in favor of another.
[191] Granted there are important exceptions to his blanket statement, for example a hospital with a neo-natal intensive care unit and 24-hour neonatologist may be the best facility for a high-risk pregnancy, and therefore leap-frogging would be appropriate. However, these represent outliers that would likely utilize ambulance services, as compared to non-emergent situations where there presents greater incentive to induce referrals.
[192] *See* Amy M. Brown, Sandra L. Decker & Frederic W. Selck, *Emergency Department Visits and Proximity to Patients' Residences, 2009-2010*, NCHS Data Brief (March 2015), https://www.ncbi.nlm.nih.gov/pubmed/25932892.

low-performing institution that has some expendable income uses the safe harbor to pull Jane out from the catchment area of the safer provider and into their network. A reduction of the conditions radius may be a viable solution, but more likely elimination of this condition all together is more appropriate. No matter what, some providers will be able to offer transportation services at a greater frequency than others, and despite prohibitions on advertising, things like social media and news stories will create imbalances. The result will be either that more patients have access to care, ideally through higher quality faculties, or competitors will be required to offer those services to compete, increasing overall access to care.

The final condition that poses problems for the safe harbor is the limitation to transportation for medically necessary services. This particular condition may be the one that is most at odds with the goals of the ACA and current research on social determinants of health. Many, like the OIG, seem to construe the term "access to care" or "health care" as being limited to medical care. However, under the ACA these terms are more properly understood as services that impact an individual's overall health, which includes physical, mental, and social well-being. By limiting the safe harbor to only medical care, the OIG failed to give weight to the impact SDH have on health. For example, assume Jane suffers from asthma, one day she is having particular difficulty and reaches out to a provider who offers her transportation to an appointment. Jane is given treatment and sent home. A week later Jane suffers another issue, except this time she has to go to the emergency room, where once against she is treated and released. It turns out that Jane lives in an older property with poor ventilation which is triggering her asthma. Since Jane lacks transportation, and the safe harbor prevents her provider from transporting her to anything other than a medically necessary service, she is unable to access a social service agency that targets remediation of older homes for the underserved. If the provider

was allowed, they could have offered this service early on in their relationship, and reduced Jane's overall expense on the system, regardless of whether the system employed FFS or value-based payments. Here the tie-in with data collection is important, as it is difficult to track whether a provider is using the transportation for the specific service and not just to induce referrals without data. Another potential modification would be to expand the definition of "medically necessary services" to include those services that are part of the SDH makeup. Under this shift, Jane would be able to use transportation for issues like food and housing only, and providers would be required to keep track to reduce fraudulent activity.

In addition to the individualized transportation provisions, the safe harbor also adds a provision for shuttle services. OIG included the shuttle provision to help alleviate some of the concerns of reduced access, see medically necessary services, through more relaxed conditions. In particular, the shuttle service only has five conditions as compared to the individualized's ten., They are: (1) transportation cannot be provided via air, luxury, or ambulance; (2) providers cannot market or advertise both the transportation services nor services the provider offers; (3) drivers of the transportation service cannot be paid on a per-beneficiary transported basis; (4) transportation is limited to a radius of 25 miles in urban settings, 50 miles in rural settings; and (5) the provider cannot shift the costs onto Federal Health Care Programs, payors, or individuals.[193] While each of these conditions has been discussed above, the shuttle represents an interesting take on meeting AKS and ACA goals. Based on the discussion above, it appears that the prohibition on advertisement is the largest concern. Shuttles cannot be a failsafe for the rest of the safe harbor, as alone it is inadequate to accomplish the underlying goals of expanded access for under-served populations. Because shuttles also face prohibitions on marketing and

[193] 42 C.F.R. § 1001.952(bb) (2018).

advertising, patients like Jane may never learn about the service. The idea that Jane could simply call a provider is problematic, because it puts the cart before the horse. If Jane doesn't think she can access a provider, why would she call to make an appointment?

A further problem with the final shuttle service provision is that OIG thinks that the mere provision of shuttle services will eliminate many of the access limitations of individualized transportation. Unfortunately, the mere provision of shuttle services does not equate to actual utilization. There is a significant cost-benefit analysis burden placed on providers to determine shuttle routes, and how to structure them to create a beneficial program. If the route selected is underutilized, the provider will shut it down, leaving patients where they started. Rather than solely relying on the shuttle services to fill gaps in access, it would make more sense to resolve the issues inherent in the individualized transportation addressed above, and leave shuttles as the backup strategy.

VI. Conclusion

While the Free Transportation Safe Harbor has many provisions that meet the needs of both the AKS and ACA, it is in need of modifications to move away from framing in a FFS system and incorporate the philosophy and goals of the ACA. Specifically, understanding that as the health care system shifts into value-based payments, the increased access to health care services, social services, and other "non-traditional" care that are part of the social determinants of health will result in less burden to the Federal Health Care Programs and positive health outcomes across the country.