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A Laboratory of Regulation: the Untapped Potential of the HHS Advisory Opinion Power

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NOTES

A Laboratory of Regulation: The Untapped Potential of the HHS Advisory Opinion Power

I. INTRODUCTION 1761
II. THE ANTI-KICKBACK STATUTE AND THE LAW OF REGULATORY INERTIA 1767
A. *The Federal Anti-kickback Regime* 1767
B. *Regulatory Safe Harbors* 1770
1. Competing Values in Safe Harbor Development 1771
2. The Law of Regulatory Inertia 1775
III. A DREAM DEFERRED: A CRITICAL ANALYSIS OF THE ADVISORY OPINION PROCESS IN PRACTICE 1777
A. *The Purpose of the OIG Advisory Opinion Power* 1778
B. *The OIG Advisory Opinion Power in Practice* 1782
1. Advisory Opinions as Case-Specific Safe Harbors 1782
2. The Advisory Opinion Process as a Laboratory of Regulation 1785
IV. OVERCOMING REGULATORY INERTIA: USING THE DATA ASSEMBLED IN THE LABORATORY OF REGULATION 1790
V. CONCLUSION 1793

I. INTRODUCTION

Of late, the federal government's approach to regulation of hospitals and other healthcare providers asks them to do more with less. Both the government and private insurers have increasingly assigned hospitals and other providers with financial responsibility for

the quality of the care they provide to federal beneficiaries.[1] At the same time, experts predict that reimbursement rates by both the government and private insurers will fall as a result of the Affordable Care Act's recent efforts to increase access to healthcare.[2] Facing a widening gap between expectations of quality and availability of financial resources, healthcare providers will need to pursue innovative business solutions that allow them to reduce their costs without negatively affecting the quality of their services.[3]

In a free market, the disruption associated with increased accountability for sellers is not a problem in and of itself. Indeed, market disruption can incentivize development of novel solutions to

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1. *See* Sylvia M. Burwell, *Setting Value-Based Payment Goals*, NEW ENG. J. MED., (Jan. 26, 2015), http://www.nejm.org/doi/full/10.1056/NEJMp1500445 [http://perma.cc/NM8W-D6R7] (announcing the intention of HHS "to have 85% of all Medicare fee-for-service payments tied to quality or value by 2016, and 90% by 2018"); Suzanne Delbanco, *The Payment Reform Landscape: Pay-For-Performance*, HEALTH AFF. BLOG (Mar. 4, 2014), http://healthaffairs.org/blog/2014/03/04/the-payment-reform-landscape-pay-for-nperformance/ [http://perma.cc/KN9M-TZ89] (describing the general structure of pay-for-performance reimbursement models, in which payment to providers is partially based upon attainment of certain quality benchmarks).

2. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (seeking to increase access to healthcare services by mandating that individuals purchase health insurance); *see also* M.P. McQueen, *Less Choice, Lower Premiums*, MOD. HEALTHCARE, (Aug. 17, 2013), http://www.modernhealthcare.com/article/20130817/MAGAZINE/308179921 [http://perma.cc/T6G2-V2XM] (noting the industry expectation that reimbursement rates by private payers will begin to fall towards Medicare reimbursement levels in coming years).

3. This Note refers frequently to "innovative" or "novel" business arrangements as an important way for providers to meet increasing quality expectations in the midst of declining reimbursement from both private and public payors. These references are meant to include arrangements that are nominally prohibited under the anti-kickback statute but that pose relatively low risk of fraud or abuse and would be able to provide significant cost-savings to producers without compromising the quality of care provided to patients.

Examples of such arrangements are as infinite as the imaginations of healthcare business leaders. One helpful example is the possibility of establishing "preferred hospital" networks by Medigap plans—that is, private insurers who cover Medicare beneficiaries' deductible payments—whereby hospitals would discount Medigap policy beneficiaries' deductible payments in exchange for "in-network" status. *See* Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 15-05, at 2–3 (Apr. 29, 2015) (discussing one such arrangement). Although technically violative of the anti-kickback law, these arrangements can be valuable tools for hospitals to attract new patients and for Medigap insurers to increase access to their coverage by using the savings to reduce the cost of coverage. *See* Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 15-09, at 2–3 (July 23, 2015) (discussing a Medigap plan's program to pass along savings associated with preferred hospital arrangements to beneficiaries in the form of premium discounts for using in-network hospitals). And if these arrangements are structured to avoid restricting beneficiaries' ultimate choice of hospital and to allow any hospital to participate, the risk of quality-based decisionmaking and anti-competitive activity seem to be of little concern. *See id.* (discussing the importance of these features in Medigap preferred hospital networks). Thus, such arrangements would be termed innovative and novel since they promise to reduce the costs of and increase access to health care services without compromising the quality of the services provided. For additional examples of "innovative" business arrangements, see Part II.B.2.

longstanding problems. However, such policy shifts can lead to market failure when they occur in an industry that is subject to broad restrictions on the types of business arrangements into which parties may voluntarily enter. This is so because such restrictions often substantially reduce firms' abilities to pursue novel means of production and organization in response to the market disruption.

Healthcare is just such an industry. The federal anti-kickback statute ("AKS") and related statutes impose severe liability upon parties who enter into arrangements involving the exchange of any type of remuneration for the referral of beneficiaries of federal healthcare entitlement programs.[4] This rule is intended to prevent the corruption of providers' medical judgment by economic considerations.[5] Indeed, there are many shocking examples of doctors compromising their professional judgment for personal profit.[6] However, this rule can be particularly troublesome in cases involving less morally repugnant conduct because of the role referrals play in the healthcare industry. Indeed, without referrals, specialists and other ancillary providers would have few patients and, by extension, little revenue or profit.[7] Thus, if providers are unable to exchange remuneration for referrals in order to grow their businesses, many firms may be unable to cover the expenses associated with their quality-of-care responsibilities.[8]

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4. 42 U.S.C. § 1320a-7b (2012). The AKS broadly defines "remuneration" to include kickbacks, bribes, or rebates paid "directly or indirectly, overtly or covertly, in cash or in kind." § 1320a-7b(b). The term "refer" is used in the AKS, but is never defined; it has been held to include both direct requests made to a provider for a specific type of service as well as formulation or approval of a plan of care that will require provision of a specific type of service. *See, e.g.*, United States v. Patel, 17 F. Supp. 3d 814, 830 (N.D. Ill. 2014) (holding that physician-defendant's recertification of a patient's need for home health services constituted a referral within the meaning of the AKS).

5. *See Patel*, 17 F. Supp. 3d at 826 (noting that the "overarching purpose" of the AKS is to prevent healthcare fraud, increased costs to Medicare and Medicaid, and the misuse of federal funds).

6. *See, e.g.*, United States v. Hughes, 895 F.2d 1135, 1138 (6th Cir. 1990) (involving a "disreputable medical clinic" that billed Medicaid for unnecessary blood tests performed on drug addicts in exchange for prescriptions for controlled substances).

7. *See* Ateev Mehrotra, *Dropping the Baton: Specialty Referrals in the United States*, 89 MILBANK Q. 39, 40 (2011) (describing the robust role of referral to the specialty physician practice).

8. Faced with such a proscription, a rational firm might still choose to violate the statute if the marginal benefits of a forbidden arrangement exceeded the marginal cost, opting to pay any resulting penalties out of the marginal profits flowing from the arrangement (call this "efficient fraud"). However, that option is effectively shut off under the AKS because the penalties for violation are so large that it is difficult to imagine any arrangement where the resulting increase in profits would be greater than the penalties associated with violation of the statute. The possibility of criminal sanction also confounds such an economic analysis. For a discussion of the phenomenon of efficient fraud in the context of contract law, see Emily Sherwin, *Nonmaterial Representation: Damages, Rescission, and the Possibility of Efficient Fraud*, 36 LOY. L.A. L. REV. 1017, 1023 (2003).

However, not all of the arrangements within the AKS's broad prohibition are harmful. Accordingly, a number of statutory and regulatory exceptions to AKS liability permit providers to pursue certain categories of otherwise-prohibited arrangements. Under the AKS regime, two types of exceptions can confer providers with immunity from the strictures of the AKS: safe harbor provisions and advisory opinions. Safe harbor provisions are generally applicable exceptions to the AKS's broad prohibition on the exchange of remuneration for referrals.[9] Such provisions are preferable for arrangements that are categorically "prosocial"[10]—that is, arrangements that exert neither upward pressure on cost, nor downward pressure on quality—because these generally applicable exceptions provide the industry with much-needed certainty about which types of business arrangements will give rise to AKS liability. Unfortunately, both Congress and the Department of Health & Human Services ("HHS") have been loath to create additional safe harbor provisions despite dramatic legislative and economic changes within the healthcare industry over the past five years.[11] This governmental reluctance to promulgate additional safe harbors creates a significant barrier to providers who seek to cope with increased financial pressures by entering into innovative business arrangements.

Luckily, providers are not foreclosed from pursuing innovative business arrangements simply because they are unable to secure passage or promulgation of new, generally applicable safe harbor provisions. Providers may alternatively resort to the advisory opinion process to insulate themselves from administrative sanctions associated with violation of the AKS. Under that process, providers may petition the Office of the Inspector General ("OIG") within HHS for *case-specific* exceptions from AKS liability.[12] In contrast to HHS's reluctance to promulgate safe harbors, OIG consistently grants favorable advisory

9. These provisions insulate from prosecution certain types of conduct that would otherwise be violations of the statute, but do not constitute the type of conduct targeted by Congress's strong policy preference against healthcare entitlement fraud. 42 U.S.C. § 1320a-7b(b)(3) (statutory safe harbor provisions); 42 C.F.R. § 1001.952 (2015) (regulatory safe harbor provisions).

10. The term "prosocial" is used here to refer to arrangements that exert neither upward pressure on cost, nor downward pressure on quality.

11. *See* Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (representing a major legislative overhaul of the domestic healthcare delivery system). Although twenty-five regulatory safe harbors currently exist, none have been promulgated since the passage of the ACA. The last new regulatory safe harbor was promulgated in 2007. Safe Harbor for Federally Qualified Health Centers Arrangements Under the Anti-Kickback Statute, 72 Fed. Reg. 56,632, 56,632 (Oct. 4, 2007) (codified at 42 C.F.R. pt. 1001).

12. *See* 42 U.S.C. § 130a-7d(b) (obliging the Secretary of HHS to issue written advisory opinions as to whether a proposed arrangement involves prohibited remuneration or inducement under the AKS).

opinions so long as the proposed arrangement "contains limitations, requirements, or controls that give adequate assurance that Federal health care programs cannot be abused."[13]

While the advisory opinion process ensures providers have some means of obtaining legal cover for a given business arrangement short of a generally applicable safe harbor, this process is not a perfect substitute for such safe harbors. First, advisory opinions are only binding upon HHS and the requesting party.[14] To that end, a provider that received a favorable advisory opinion could still face both criminal and civil liability under the AKS and the False Claims Act ("FCA"), respectively.[15] And even if the sheer number of favorable advisory opinions for a given type of arrangement makes prosecution unlikely, requiring specific permission to enter into a specific type of business arrangement still fails to create the complete certainty that accompanies a generally applicable safe harbor.[16] Second, securing an advisory opinion can be expensive since the requesting party is responsible for paying the costs associated with drafting the opinion.[17] And while some firms may be willing to pay the cost in exchange for the certainty of HHS's treatment, more cost-conscious providers may find themselves unable to pursue an otherwise prosocial business arrangement.

HHS could solve these seeming problems with the advisory opinion process by codifying the standards it applies to individual applications for advisory opinions into generally applicable safe harbors.[18] To appropriately guard against undue risk of fraud or abuse,

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13. Issuance of Advisory Opinions by the OIG, 63 Fed. Reg. 38,311, 38,313 (July 16, 1998) (codified at 42 C.F.R. pt. 1008). Indeed, since the advent of the advisory opinion power in 1997, OIG has issued 314 opinions, 84% of which were favorable to the requesting party. *See infra* Part III.B (presenting empirical findings regarding OIG's exercise of the advisory opinion power).

14. 42 U.S.C. § 1320a-7d(b)(4)(A) (2012) ("Each advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion.").

15. The advisory opinion process only insulates covered parties from administrative sanctions by HHS. It does not protect them against civil or criminal enforcement by the Department of Justice. *See* 2 AM. HEALTH LAWYERS ASS'N, HEALTH LAW PRACTICE GUIDE § 36:115 (2015) ("[T]he Department of Justice is not bound by OIG advisory opinions.").

16. *Cf.* Dale F. Rubin, *Private Letter and Revenue Rulings: Remedy or Ruse*, 28 N. KY. L. REV. 50, 56 (2001) (discussing the lower deference accorded to IRS private letter rulings).

17. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-05-129, MEDICARE: ADVISORY OPINIONS AS A MEANS OF CLARIFYING PROGRAM REQUIREMENTS 13 (2004) (describing the expenses that providers must bear to secure an advisory opinion).

18. HHS recently recognized the value of its experience in the advisory opinion process in a slightly different context. In explaining its rationale for proposing a safe harbor for cost-sharing waivers for emergency ambulance services, HHS noted that such arrangements had been the subject of numerous favorable advisory opinions over a period of several years. Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing, 79 Fed. Reg. 59,717, 59,720–21 (proposed Oct. 3, 2014).

this would only be appropriate after HHS had gained sufficient experience with a given arrangement within the advisory opinion process to be convinced that it is generally prosocial.

This course of action would simultaneously benefit providers and the public at large. Providers would benefit from the certainty of the government's treatment of their business ventures and from the elimination of the expenses associated with obtaining an advisory opinion whose result is almost guaranteed in light of the government's past treatment of identical arrangements. Similarly, this policy would benefit the public in terms of both reduced costs and increased access to care by allowing providers to pursue novel arrangements with other providers that enable them to provide services more efficiently.[19] The approach proposed here might be thought of as a "laboratory of regulation" permitting HHS to "test out" the appropriateness of certain types of arrangements on a case-by-case basis before promulgating a uniform safe harbor from AKS liability.

This Note suggests that OIG should remedy the shortcomings of the advisory opinion process and the AKS regime generally by treating advisory opinions as a proving grounds for certain types of innovative business arrangements prior to the promulgation of generally applicable safe harbors. Part II parses the intricacies of the AKS regime and posits a theoretical explanation for HHS's historic unwillingness to promulgate new regulatory safe harbors. Part III examines the advent of the advisory opinion power and analyzes the exercise of that power in practice. Finally, Part IV proposes that HHS should promulgate regulatory safe harbors for certain categories of arrangements that have been the subject of uniformly favorable advisory opinions over a sufficiently long period of time. A brief conclusion follows.

A notable difference between this safe harbor and those proposed in this Note is that the advisory opinions cited found that these types of arrangements were not even *technically* violative of the AKS—that is, they involved no prohibited remuneration in the first place. *See* Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 13-14, at 6 (concluding that such arrangements do not generate "prohibited remuneration" under the AKS). While the recognition of the value of the advisory opinion process as a laboratory of regulation is an important step, this Note goes a step farther and suggests that HHS promulgate safe harbors for certain types arrangements that are granted favorable advisory opinions despite the fact that they are technically violative of the AKS. *See infra* Part IV.

19. *See supra* note 3 (providing a working definition of "novel" business arrangements for purposes of this Note).

II. THE ANTI-KICKBACK STATUTE AND THE LAW OF REGULATORY INERTIA

A. The Federal Anti-kickback Regime

Congress and HHS have honed the AKS to prevent corruption of the professional judgment of physicians and other providers by economic influences.[20] To that end, Congress drafted the statute as a broad prohibition on certain types of business arrangements to be tailored by narrow safe harbor provisions immunizing specific types of otherwise-prohibited conduct.[21] In this way, the statute inverts the usual presumption in American law that "everything that is not forbidden is permitted" by declaring an extremely broad category of healthcare business arrangements illegal unless a specific statutory or regulatory safe harbor expressly protects that conduct.[22]

In relevant part, the AKS forbids the knowing or willful solicitation or receipt of "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind" in exchange for referral of a patient for services reimbursable under a federal healthcare entitlement program.[23] Violation of this statutory prohibition constitutes a felony punishable by up to five years in prison and substantial criminal fines.[24] In addition to criminal prosecution directly under the AKS, the government may also enforce the AKS in a civil suit under the FCA and in an HHS administrative proceeding.[25]

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20. *See* James F. Blumstein, *What Precisely is "Fraud" in the Health Care Industry?*, WALL ST. J., Dec. 8, 1997, at A25 (noting that the AKS was "designed to eliminate incentives for the overutilization of services").

21. 42 U.S.C. § 1320a-7b (2014).

22. *See* John Laws, *The Rule of Reason—An International Heritage*, *in* 2 JUDICIAL REVIEW IN INTERNATIONAL PERSPECTIVE 247, 256 (Mads Andenas & Duncan Fairgrieve eds., 2000) (describing the traditional English law presumption that individuals' actions are legal absent "a settled prohibitory rule" to the contrary).

23. 42 U.S.C. § 1320a-7b(b)(1)(A); *see supra* note 4 and accompanying text (defining the terms "referral" and "remuneration"). The AKS also forbids the solicitation or receipt of remuneration in exchange for "purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item" reimbursable under federal healthcare entitlement programs. 42 U.S.C. § 1320a-7b(b)(1)(B).

24. 42 U.S.C. § 1320a-7b.

25. Upon finding that a provider has violated the AKS, HHS may exclude the provider, impose civil monetary penalties, or both. 42 U.S.C. § 1320a-7 (exclusion); 42 U.S.C. § 1320a-7a (civil monetary penalties). Similarly, providers who submit claims for payment to the federal government for services rendered in violation of the AKS can be held civilly liable for a penalty of between $5,000 and $10,000 per claim and treble damages under the FCA. 31 U.S.C. § 3729(a)(1); 42 U.S.C. § 1320a-7b(g) (deeming knowing submission of a claim for services rendered in violation of the AKS to be a false claim for purposes of the FCA).

In order to establish the requisite intent to prove a violation of the AKS, the prosecution need only show that "one purpose" of the remuneration at issue was to induce referrals of Medicare or Medicaid patients.[26] It is no defense that inducement of referrals was not the principal (or even a significant) purpose of the remuneration so long as sufficient evidence suggests that it was *one* of the purposes of the remuneration.[27]

However, the mere fact that a given transaction runs afoul of the broad prohibitions of the AKS does not mean that liability is inevitable. Indeed, if a given business arrangement falls squarely within a safe harbor provision, then the arrangement will not give rise to AKS liability.[28] As of this writing, there are thirty-five such safe harbor provisions (ten statutory and twenty-five regulatory) that shield certain business arrangements from AKS liability under specific, narrow circumstances.[29] While an exhaustive discussion of all thirty-five safe harbors is beyond the scope of this Note, a few examples of business arrangements that have been found to merit a safe harbor include certain profit-sharing arrangements between group practice members,[30] payments made to providers based on risk-sharing agreements with managed care organizations,[31] and payments made to

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26. *E.g.*, United States v. Greber, 760 F.2d 68, 69 (3d Cir. 1985) (holding that the inducement element of the AKS statute is satisfied so long as "one purpose" of a payment is to induce Medicare/Medicaid referrals, even if that is not the "primary" purpose of the payment).

27. *Id.* Recognizing that providers rarely make business decisions without considering the potential referral value of the decision, at least one court applying the one-purpose test has attempted to draw a line between a "purpose" to induce referrals and a mere "collateral hope" that a transaction will result in referrals. *See* United States v. McClatchey, 217 F.3d 823, 834–35 (suggesting evidence of a mere hope or anticipation of referrals that would flow from a transaction alone is not enough to prove sufficient intent to induce referrals under *Greber*'s reading of the AKS).

28. *See* 42 U.S.C. § 1320a-7b(a)(3); § 1320a-7d(a) (requiring the Secretary to solicit proposals for new regulatory safe harbor provisions annually and to promulgate additional safe harbors "as appropriate").

29. For a listing of the ten statutory safe harbors currently in effect, see 42 U.S.C. § 1320a-7b(b)(3). For a listing of all twenty-five regulatory safe harbors currently in effect, see 42 C.F.R. § 1001.952 (2010). The Secretary of HHS has also issued notices of proposed rulemaking for four additional safe harbor provisions. Revisions to Safe Harbors Under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing, 79 Fed. Reg. 59,717, 59,719 (proposed Oct. 3, 2014) (proposing to protect certain cost-sharing waivers, remuneration between federally qualified health centers and Medicare Advantage organizations, discounts on drugs furnished under the Medicare Coverage Gap Discount Program, and local transportation services). For a proposal advocating for a safe harbor provision for "harmless remunerations" which do not increase cost or reduce quality, see generally Cameron T. Norris, Comment, *Reviving* Hanlester Network*: A Safe Harbor for Harmless Remunerations Under the Anti-Kickback Statute*, 67 VAND. L. REV. EN BANC 137 (2014).

30. 42 C.F.R. § 1001.952(p).

31. 42 C.F.R. § 1001.952(t).

patient referral services made exclusively on the basis of the cost of operating the services.[32]

While Congress retains power to create safe harbor provisions by statute, it also granted the Secretary of HHS broad authority to promulgate additional regulatory safe harbors in consideration of various criteria specified in the enabling legislation.[33] Yet despite HHS's broad authority to promulgate safe harbor regulations and significant changes in the healthcare industry since Congress's passage of the ACA, the agency has declined to promulgate additional regulatory safe harbors in recent years. Indeed, as of this writing, the agency had not promulgated any new regulatory safe harbors since 2007.[34]

The regulatory structure underlying the AKS has been the subject of widespread criticism in both academia and the healthcare industry. Some commentators have decried the statute as overly broad because its prohibition reaches not only the "raw fraud" that seems to be the subject of congressional ire,[35] but also "technical fraud" that does not appear to constitute fraud in any ordinary legal use of the term and that may in fact be value maximizing.[36] Other scholars go so far as to argue that this broad prohibition on conduct functions to "stunt[ ] the development of organized medical systems" in a way that is "threatening both to conventional practices and innovative business arrangements" in the healthcare industry because of its tendency to discourage the pursuit of novel, value-maximizing business arrangements.[37]

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32. 42 C.F.R. § 1001.952(f).

33. 42 U.S.C. § 1320a-7d(a) (establishing the relevant criteria for HHS consideration when deciding whether to promulgate a given regulatory safe harbor).

34. *See* Safe Harbor for Federally Qualified Health Centers Arrangements Under the Anti-Kickback Statute, 72 Fed. Reg. 56,632, 56,632 (Oct. 4, 2007) (protecting certain arrangements in which individuals or entities donate goods, items, or services to qualifying health centers) (codified at 42 C.F.R. pt. 1001).

35. For example, billing for services that were unnecessary, of inferior quality, or never rendered. *See, e.g.*, United States v. Hughes, 895 F.2d 1135, 1138 (6th Cir. 1990) (involving a "disreputable medical clinic" that billed Medicaid for unnecessary blood tests performed on drug addicts in exchange for prescriptions for controlled substances).

36. For example, payments made in good faith for services of merchantable quality when such payment is made in exchange for referrals amounts to fraud under the AKS, but would not be construed as fraud in any general sense of the word. For a critical discussion of the AKS's expansion of the definition of fraud in the healthcare industry, see CLARK C. HAVIGHURST ET AL., HEALTH CARE LAW AND POLICY: READINGS, NOTES, AND QUESTIONS 458–59 (2d ed. 1999).

37. Nicholas Bagley, *Bedside Bureaucrats: Why Medicare Reform Hasn't Worked*, 101 GEO. L.J. 519, 567 (2013); Mark A. Hall, *Making Sense of Referral Fee Statutes*, 13 J. HEALTH POL. POL'Y & L. 623, 624 (1988); *see also supra* note 3 (providing a working definition and examples of of "novel" and "innovative" business arrangements for purposes of this Note).

Some commentators argue that the traditional practice of prosecutorial discretion is enough to ensure that only truly fraudulent activities are subject to prosecution under the AKS.[38] This argument, however, is unavailing. Although the AKS itself does not expressly create a private cause of action for violation thereof, private individuals may enforce the strictures of the AKS through the qui tam provisions of the False Claims Act ("FCA").[39] As a result, any reliance on prosecutorial discretion as a mechanism to avoid AKS liability in cases involving purely technical fraud is illusory because private individuals remain free to press such claims without the consent of the executive, so long as they qualify as a relator under the FCA.[40] Thus, reliance on prosecutorial discretion is an inadequate solution to the problem of the overly broad nature of the AKS's prohibitions.[41] For this reason, it is even more important to ensure that safe harbor provisions covering prosocial business arrangements are promulgated as soon as practicable in order to ensure that the healthcare industry can take advantage of the benefits of such arrangements without fear of the possibility of AKS liability.

B. Regulatory Safe Harbors

Regulatory safe harbor provisions are essential components of the AKS regime because they ensure that the breadth of the statute's prohibition does not stifle necessary and prosocial business arrangements in the healthcare industry. By permitting HHS to independently promulgate safe harbor provisions, Congress intended that the agency would use its expertise to protect business arrangements that would not create undue risk of fraud or abuse, even

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38. *See* Scott J. Kelly, Comment, *The Health Insurance Portability and Accountability Act of 1996: A Medicare Fraud Advisory Opinion Mandate Sends the Inspector General "Shopping for Hats"*, 59 OHIO ST. L.J. 303, 321 (1998) (suggesting that the binding advisory opinion process inappropriately forces OIG to pick and choose between various modes of agency action and that it is an inappropriate tool to clarify the strictures of the AKS).

39. 31 U.S.C. § 3730(b) (2012) (permitting individuals to bring qui tam suits to enforce the FCA); 42 U.S.C. § 1320a-7b(g) (2012) (expressly providing that providers who render in violation of the AKS may be prosecuted under the qui tam provisions of the FCA).

40. 31 U.S.C. § 3730(e)(4)(B) (establishing the qualifications in order for a relator to bring a qui tam action to enforce the AKS via the FCA).

41. *See* James F. Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*, 22 AM. J.L. & MED. 205, 224–25 (1996) (comparing the current system of enforcement to a Prohibition-era speakeasy because prosecutorial discretion insulates technically illegal conduct from liability so long as the enforcement authorities view it as "harmless," and noting that the questionable predictability of such a system is further undermined by the possibility of *qui tam* actions, which are not policed against even a harmlessness standard).

though they involved an exchange of remuneration for referrals.[42] Despite the importance of this portion of the AKS regime and dramatic changes in the healthcare industry since the passage of the ACA, HHS has not promulgated a new safe harbor provision in over seven years.[43] This Section first discusses the various values at play when HHS contemplates promulgation of a new safe harbor provision. It then explores a theoretical explanation for HHS's recent failure to act.

1. Competing Values in Safe Harbor Development

The AKS, by virtue of its extremely broad prohibition on economic conduct that would be altogether appropriate in other markets, provides insight into the difficult task before Congress to root out fraud in federal healthcare programs. The subjects of congressional ire that instigated the passage of the AKS—that is, raw fraud and corruption of medical judgment—are exceedingly difficult to define in a way that is not dramatically over- or underinclusive.[44] Faced with this dilemma, Congress opted to adopt an overinclusive definition to be narrowed by statutory and regulatory safe harbors.[45] Although safe harbors can unlock otherwise inaccessible efficiency gains, the decision to use a safe harbor to tailor the broad prohibition of the AKS should not be made lightly. Indeed, safe harbors can also create loopholes through which crafty providers can perpetrate frauds under color of law.[46] As such, the decision to enact a given safe harbor provision should

42. *See, e.g.*, H.R. REP. NO. 104-496, pt. 1, at 84 (1996), *as reprinted in* 1996 U.S.C.C.A.N. 1865, 1884–85 (noting the advisory opinion power's role in supporting providers' attempts "to structure new and innovative health care delivery systems to contain health care cost").

43. *See supra* note 11 and accompanying text (observing that HHS last promulgated a new safe harbor regulation in 2007). While HHS has tweaked the safe harbors since, their changes have taken the form of amendments to existing safe harbor regulations. *See* Electronic Health Records Safe Harbor Under the Anti-Kickback Statute, 78 Fed. Reg. 79,202 (Dec. 27, 2013) (codified at 42 C.F.R. pt. 1001) (amending an existing regulatory safe harbor governing payments made to providers related to electronic health records systems). A proposal to amend the gainsharing safe harbor provision is also outstanding at time of writing. Revisions to Safe Harbors under the Anti-Kickback Statute, and Civil Monetary Penalty Rules Regarding Beneficiary Inducements and Gainsharing, 79 Fed. Reg. 59,717 (Oct. 3, 2014) (to be codified at 42 C.F.R. pts. 1001, 1003).

44. *See* Blumstein, *supra* note 20 (discussing the many faces of fraud in the healthcare industry and the shortcomings of the definition adopted the AKS).

45. *See* 42 U.S.C. § 1320a-7b (2012) (establishing the AKS's broad prohibition and carving out several specific statutory safe harbors).

46. For example, a hypothetical safe harbor for payments in exchange for referrals for medically necessary services would certainly cover some merely technical fraud, but might also cover arrangements involving raw fraud where the referral was made on the basis of the payment and not the provider's medical judgment.

always involve a detailed assessment of the potential risks and anticipated benefits.

The benefits that accrue from promulgation of safe harbor provisions are clear: providers can tap into potential efficiencies associated with certain business arrangements that are not otherwise permissible under the AKS.[47] And in a healthcare market facing increasing pressure to reduce costs, these cost reductions have the potential not only to reduce skyrocketing prices, but also to allow firms to stay in business.[48] Moreover, promulgating a safe harbor for arrangements that constitute the only method of conferring certain benefits upon consumers may yield consumer surplus by reducing prices, increasing quality, increasing access to care, or a combination of all three.[49]

In addition to the benefits that flow generally from the promulgation of appropriate safe harbor provisions, further benefits would accrue if HHS were to issue safe harbors to cover arrangements that have received uniformly favorable treatment in the advisory opinion process. First, promulgating safe harbors to cover arrangements that are uniformly approved in the advisory opinion process would provide greater legal certainty about the arrangements. The safe harbors would ensure that the parties to the arrangement could not be prosecuted by any governmental agency (as opposed to protecting them exclusively from HHS administrative sanctions) since the arrangement would no longer be a violation of the AKS at all.[50] Second, the procedural requirements associated with amending a generally applicable safe harbor would provide additional protection to parties who have already received favorable treatment in the advisory opinion process. Unlike repeal of a generally applicable regulatory safe harbor, which requires compliance with the procedural requirements

47. For example, if physicians did not have the benefit of the safe harbor enabling them to invest in a group practice, they would be unable to tap the cost-saving efficiencies associated with shared office space and staff. *See* 42 C.F.R. § 1001.952(p) (2015) (establishing the group practice investment safe harbor).

48. See *supra* Section II.B for discussion of the importance of ensuring firms have the ability to pursue novel and innovative methods of providing care in view of new cost and quality pressures.

49. For example, HHS has promulgated broad-based waivers of AKS liability for accountable care organizations (ACOs) out of recognition that these arrangements (although technically violative of the AKS) can spin off substantial benefits if they are legal. Final Waivers in Connection With the Shared Savings Program, 76 Fed. Reg. 67,992, 67,993 (Nov. 2, 2011) (codified at 42 C.F.R. ch. V). For a full discussion of the benefits and risks that accrue to both consumers and the healthcare industry as a result of ACOs, see Elliott S. Fisher et al., *A Framework For Evaluating the Formation, Implementation, and Performance Of Accountable Care Organizations*, 31 HEALTH AFF. 2368, 2368–70 (2012).

50. *See supra* notes 14–16 and accompanying text (noting that advisory opinions are binding upon HHS, but not upon other governmental agencies).

for notice-and-comment rulemaking,[51] revocation or termination of a favorable advisory opinion merely requires notice to the affected parties of the change in circumstances supporting the government's threatened action and an adequate opportunity for the affected parties to respond.[52] Finally, codification of generally applicable safe harbors covering arrangements uniformly approved in the advisory opinion process reduces the cost of entering into such an arrangement by providing free immunity from prosecution (as opposed to requiring providers to foot the bill for potentially expensive advisory opinions).[53] These savings could then be passed onto consumers. When combined with the increased legal certainty associated with a generally applicable safe harbor, these cost savings would incentivize parties to invest more heavily in value-maximizing, covered arrangements without fear of unexpected enforcement action.

Despite the many benefits of issuing safe harbor provisions for apparently beneficial arrangements, there are also significant costs. First and foremost, a poorly drafted or improvidently granted safe harbor provision can provide legal cover to a scheme to defraud federal healthcare entitlement programs.[54] Given the robust policy preference

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51. 5 U.S.C. § 553 (2012) (requiring agencies engaged in notice-and-comment rulemaking to issue a Notice of Proposed Rulemaking, solicit public comments on the proposed Rule, and promulgate of a Final Rule indicating their reasoning); *see also* Motor Vehicles Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co., 463 U.S. 29, 43–44 (1983) (holding that arbitrary and capricious review applied to agency decisions to rescind regulations and that it required the agency to establish on the record "rational connection between the facts found and the choice made").

52. 42 C.F.R. § 1008.45(a) (2015) (establishing the procedural requirements for termination, revocation, and modification of OIG advisory opinions). Notably, OIG has (and has exercised) the legal authority to terminate an advisory opinion. *See* Office of Inspector Gen., U.S. Dep't of Health & Human Servs., Final Notice of Termination of OIG Advisory Opinion No. 11-18, at 1 (Apr. 8, 2014) (terminating an advisory opinion because OIG no longer believed that the factors cited in the original opinion provided sufficient controls to "mitigate against the risk that the discount could be an improper payment to induce referrals").

53. *See* U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 17, at 14 (discussing the cost of OIG advisory opinions issued as of December 2004).

While some may argue that issuing a generally applicable safe harbor after a number of providers have invested the funds to secure favorable advisory opinion results in a sort of forfeiture to the providers who initially sought the opinion, this view ignores the fact that they were able to take advantage of the otherwise-inaccessible efficiencies available under the arrangement while it was being "tested out" by HHS/OIG. Additionally, the first-movers gain the benefit of the certainty associated with being completely insulated from AKS liability by any governmental actor (as opposed to being insulated from administrative enforcement actions by HHS, but not from civil and criminal prosecutions by the Department of Justice). *See supra* notes 15–16 and accompanying text.

54. Imagine that the safe harbor covering agreements with patient referral services did not contain the requirement that payments be related exclusively to the cost of operating the service and instead allowed the payments to be made on the basis of the profitability of the patients referred. In such a case, providers would be able to short-circuit the foundational purpose of the

against submission of fraudulent or abusive claims on federal healthcare dollars,[55] HHS should ensure that it bases its decisions to promulgate safe harbor regulations on a sufficient body of proof that an arrangement will not result in fraud or abuse in practice. In this way, HHS is correct to initially review certain types of high-risk arrangements on a case-by-case basis by means of the advisory opinion power.[56] Indeed, to promulgate generally applicable safe harbors for such arrangements would be unduly risky and would likely exceed HHS's delegated authority to promulgate regulatory safe harbors.[57] However, after OIG has determined and consistently applied a set of criteria that describe a subclass of an otherwise-suspicious category of arrangements—namely, those that are worthy of legal protection and are approved without incident over a long enough period of time—the risk of fraud or abuse in fact would seem to be extremely low.

Any decision regarding whether to promulgate a safe harbor for a given set of business arrangements should be rooted in an analysis of both the costs *and* benefits associated with promulgating such a rule.[58] However, empirical evidence described in Part III of this Note suggests that HHS may not be properly balancing these costs and benefits in light of its failure to promulgate regulatory safe harbors for arrangements that receive consistently favorable treatment in the advisory opinion process.[59] The following Section argues that there is a point in time where the social benefit of the "regulatory flexibility" retained by HHS by reviewing certain arrangements on a case-by-case basis within the advisory opinion process no longer exceeds the social cost of the agency's decision to withhold the certainty associated with a

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AKS simply by engaging a patient referral service (as opposed to seeking referrals from a physician).

55. *See supra* Section II.A (discussing the structure of the AKS); *infra* Section III.A (discussing the legislative history behind the advisory opinion power).

56. *See, e.g.*, Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 01-14, at 5–6 (Sept. 4, 2001) (discussing OIG's general concern with cost-savings sharing plans between hospitals and physicians).

57. *See* 42 U.S.C. § 1320a-7d(a)(2) (2012) (specifying the criteria for HHS to consider when promulgating a regulatory safe harbor).

58. *Id.* (requiring HHS to consider the extent to which a given regulation would impact the potential for overutilization of services, but also the extent to which the regulation would impact competition among healthcare providers).

59. Indeed, this behavior suggests that HHS may not be properly considering the benefit that certainty with respect to the legality of a given arrangement that would accrue to regulated individuals and firms as a result of formal promulgation of HHS's policy regarding such arrangements. *See supra* Section II.B (discussing the benefits that safe harbor treatment provides to regulated parties).

generally applicable safe harbor covering those same arrangements.[60] It is precisely at this point that HHS should promulgate its standard approach to a given type of arrangement as a generally applicable safe harbor.[61]

2. The Law of Regulatory Inertia

Faced with the problem of HHS's recent regulatory inaction, the first logical inquiry is: why has HHS failed to actively exercise its power to promulgate regulatory safe harbor provisions to ensure providers have adequate latitude to pursue value-maximizing transactions? Any answer is necessarily speculative, but the mere existence of the question brings us to the topic of regulatory inertia.

Regulatory inertia is a descriptive theory aiming to explain why agencies fail to promulgate or amend regulations within their discretion when such a regulation would appear to benefit the public.[62] The potential reasons supporting an agency's decision not to promulgate an apparently beneficial regulation are numerous. Indeed, scholars have attempted to explain this agency behavior with theories ranging from agency capture[63] to the growing prioritization of "regulatory flexibility" in administrative law.[64]

The cause of the regulatory inertia that plagues the development of new regulatory safe harbor provisions is not entirely clear, but one explanation may be that it is the result of an abundance of caution about declaring potentially fraudulent arrangements legal given the extreme cost such a decision may impose on federal entitlement

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60. *See infra* Section II.B.2 (discussing regulatory flexibility and the problem of regulatory inertia).

61. *See* David A. Super, *Against Flexibility*, 96 CORNELL L. REV. 1375, 1407–09 (2011) ("[L]aw seeks to optimize its social returns by conducting its productive efforts at the time when its inputs are least costly and its decision will be most valuable.").

62. *See* Joseph A. Grundfest, *Advice and Consent: An Alternative Mechanism for Shareholder Participation in the Nomination and Election of Corporate Directors*, *in* SHAREHOLDER ACCESS TO THE CORPORATE BALLOT 7, 14 (Lucian Bebchuk ed., 2004):

> Experience teaches that regulations are subject to a variant of Newton's First Law of Mechanics, also known as the Law of Inertia: A regulation, once adopted, stays adopted, even if its costs exceeds its benefits, unless it is acted upon by a sufficiently powerful political force—which is a rare event indeed.

63. *See* Susan Webb Yackee, *Sweet-Talking the Fourth Branch: The Influence of Interest Group Comments on Federal Agency Rulemaking*, 16 J. PUB. ADMIN. RESEARCH & THEORY 103, 114–17 (2006) (suggesting such decisions are largely influenced by either formal or informal pressure from interest groups).

64. *See* Super, *supra* note 61, at 1382 (suggesting that a desire to preserve "regulatory flexibility" by delaying decision on whether or not to promulgate a given rule is a significant cause of agency inaction and regulatory inertia in cases involving complex regulations with potentially high social costs).

programs.[65] Even if a given regulation only conferred one percent of purportedly fraudulent billing activity with legal cover, that regulation would effectively impose a cost on federal entitlement programs of between $300 million and $980 million each year.[66] Because of the high cost of an ill-advised safe harbor, HHS justifiably seeks to accumulate as much information as possible regarding the risks and potential benefits of any given business arrangement, both in theory and in fact, before it decides whether to promulgate a given safe harbor provision.[67] As discussed at greater length below, the advisory opinion power provides HHS with a valuable way to accumulate this type of record of proof without committing to a potentially costly, generally applicable safe harbor provision.

However, HHS has failed to promulgate even one new safe harbor within the last seven years, even though certain types of arrangements have been the subjects of uniformly favorable treatment within the advisory opinion process over the same interval.[68] Professor David Super suggests that this type of agency behavior may be rooted in an agency's desire to maintain flexibility to change its position on a given arrangement if confronted with conflicting evidence regarding the possibility of fraud or abuse.[69] According to Professor Super, an agency facing a shortage of relevant information has three possible options: (1) it can promulgate a regulation despite having imperfect information by either "paying the required premium" to obtain perfect information or by "producing a lower-quality decision" on the basis of imperfect

65. Although HHS does not publish any estimate of the proportion of Medicare and Medicaid's combined $1 trillion in expenditures that is the result of fraudulent billing practices, a landmark 2012 study suggested that anywhere from 3–9.8% (i.e., between $30 and $98 billion) of such spending is attributable to fraud. *See* CENTERS OF MEDICARE & MEDICAID SERVICES, NATIONAL HEALTH EXPENDITURES 2013 HIGHLIGHTS 2, https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/downloads/highlights.pdf [http://perma.cc/U5KE-D59W]; Donald M. Berwick & Andrew D. Hackbarth, *Eliminating Waste in US Health Care*, 307 J. AM. MED. ASS'N 1513, 1514 (2012).

66. *See* Berwick & Hackbarth, *supra* note 65, at 1514 (estimating that between $30 billion and $98 billion of annual Medicare and Medicaid payments involve fraudulent behavior by the provider).

67. Indeed, some commentators have suggested that the quantity of information required before HHS is willing to make the policy decision regarding whether or not to create a safe harbor combined with the heavy focus on enforcement of the AKS may lead regulators "to delay difficult policy decisions in the hopes that the desired results instead may be achieved through the litigation process." Joan H. Krause, *A Conceptual Model of Health Care Fraud Enforcement*, 12 J.L. & POL'Y 55, 136–37 (2003).

68. *See infra* Section III.B.2 (discussing two types of arrangements that have not been protected by generally applicable safe harbors despite receiving uniformly favorable treatment in the advisory opinion process over significant periods of time without subsequent issuance of a favorable advisory opinion).

69. Super, *supra* note 61, at 1382.

information, (2) it can completely refrain from taking any regulatory action at all, or (3) it can delay its regulatory action until perfect information is available.[70] Professor Super proposes that an undue prioritization of flexibility has caused many agencies to opt for the third option by delaying decisions on important regulatory actions because of a shortage of information.[71] However, this dilatory approach imposes substantial costs upon the public. Making a decision on the basis of imperfect information, he argues, is often preferable to waiting for perfect information because the "benefits of new information or other important resources" are often less than the "costs of [a] decrease[ ] in the . . . value of the decision rendered."[72]

This logic is particularly relevant with respect to the AKS since its structure forecloses a vast swathe of valuable business arrangements that are available to firms in virtually every other industry. The information available to HHS in support of new safe harbor provisions will almost always be lacking since there is no way to know with absolute certainty how a given safe harbor will function in reality. As such, the relevant question should be whether the benefit of better information outweighs the costs borne by the industry and society at large as a result of the lack of a relevant safe harbor.[73] This Note argues that when the answer to this question is yes, HHS should promulgate a safe harbor provision on the basis of existing, albeit imperfect, information.[74]

III. A DREAM DEFERRED: A CRITICAL ANALYSIS OF THE ADVISORY OPINION PROCESS IN PRACTICE

The power to issue advisory opinions is commonly vested within federal administrative agencies, especially when an agency oversees an area governed by a particularly complex statutory or regulatory regime.[75] This power is most often delegated to such agencies so that they can clarify the meaning and applicability of statutes and

70. *Id.* at 1380.

71. *Id.* at 1382.

72. *Id.*

73. Examples of such costs include higher supply and lower prices flowing from efficiencies that might otherwise flow from foreclosed business relationships.

74. While this determination is essentially a matter of policy discretion, there is certainly a point at which the incremental value of the information gleaned from additional favorable advisory opinions based on the same criteria as the other opinions provides so little additional information as to make promulgation of a safe harbor a no-brainer. For a discussion of arrangements approaching that point, see *infra* Part IV.

75. *See, e.g.*, 2 U.S.C. § 437f (2012) (FEC advisory opinions); 16 C.F.R. § 1.3 (2015) (FTC advisory opinions).

regulations to given sets of circumstances at the request of private parties. While advisory opinions are usually not legally binding upon the agency,[76] Congress has granted a small number of administrative agencies the power to issue advisory opinions that carry the force of law.[77] One such agency is HHS.[78] This Part explores the history of the HHS advisory opinion power and how OIG has exercised it over the past two decades.

A. The Purpose of the OIG Advisory Opinion Power

Congress granted OIG the power to issue legally binding advisory opinions regarding the applicability of certain provisions of the AKS through the Health Insurance Portability & Accountability Act of 1996 ("HIPAA").[79] HIPAA is best known for its delegation of authority to HHS to promulgate standards governing the use and distribution of patients' healthcare information. More relevant to this Note's inquiry, however, the legislation also vested OIG with the power to issue binding advisory opinions as to the meaning of "prohibited remuneration" for purposes of the AKS and as to whether a given arrangement constitutes a violation of the AKS.[80]

This provision was the topic of substantial debate in both Congress and the public square. Most of the debate centered on the impact that such a process would have on the government's ability to prosecute fraud and abuse effectively.

Within Congress, the House Committee on Ways and Means endorsed the provision, reasoning:

> Providers want to comply with the fraud and abuse statute, but many are unsure of how the statute affects them. These providers should be able to receive guidance from the government regarding financial arrangements. Little or no guidance is currently provided because there are no regulations and only insufficient safe harbors. Without this ability,

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76. *E.g.*, 16 C.F.R. § 1.3 ("Any advice given by the Commission is without prejudice to the right of the Commission to reconsider the questions involved and, where the public interest requires, to rescind or revoke the action.").

77. Such opinions are typically only binding with respect to the party requesting the opinion or identically situated parties, and only so long as all of the material facts are included within the request for an opinion. *See, e.g.*, 2 U.S.C. § 437f(c) (providing for binding effect of an FEC advisory opinion on the party seeking the opinion as well as parties engaged in activities "indistinguishable" from the activities addressed in an advisory opinion). For a description of situations in which agencies are empowered to waive statutory or regulatory requirements for all parties governed thereby, see David J. Barron & Todd D. Rakoff, *In Defense of Big Waiver*, 113 COLUM. L. REV. 265, 272–90 (2013).

78. 42 U.S.C. § 1320a-7d(b)(4) (2012).

79. Health Insurance Portability and Accountability Act of 1996, § 205, Pub. L. No. 104-191, 110 Stat. 1936, 2001–02 (codified at 42 U.S.C. § 1320a-7d(b)).

80. *Id.* § 205(b)(2) (codified at 42 U.S.C. § 1320-7d(b)(2)).

> a chilling effect is placed on legitimate arrangements, particularly when providers are attempting to structure new and innovative health care delivery systems to contain health care cost.[81]

In response to that argument, certain dissenting committee members voiced concern that the bill as recommended would substantially hinder OIG's ability to prosecute healthcare fraud by "creating an unprecedented advisory opinion mechanism for criminal and certain other intent-based statutes."[82] Despite the controversy surrounding the provision, Congress's intent can be discerned from: the relevant legislative history, the fact that Congress refused to remove the advisory opinion provision despite certain legislators' concerns, and the overwhelming margin with which HIPAA was passed. These all suggest that Congress intended the advisory opinion power to provide OIG with substantial flexibility to accommodate "new and innovative health care delivery systems to contain health care cost" through case-specific exceptions to AKS liability.[83]

HIPAA's advisory opinion provision also spurred debate outside Congress. The debate was essentially between two competing conceptions of the advisory opinion process: The first viewed it merely as a mechanical tool to assess the existence of liability under the statute and existing safe harbors on a given set of facts. The second viewed it primarily as a tool to create case-specific safe harbor provisions to protect prosocial, but technically violative, business arrangements from AKS liability.

June Brown Gibbs, the then-sitting Inspector General of HHS, championed the first view. With respect to the proposed advisory opinion power, she argued that "[a]dvisory opinions on intent-based statutes (such as the anti-kickback statute) are impractical if not impossible" because of the difficulty of assessing intent on the paper record accompanying a request for such an opinion.[84] By centering the inquiry upon the intent element of the AKS, proponents of the first view conceptualize the advisory opinion as a preemptive decision regarding the legality of a given arrangement on the basis of existing law without

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81. H.R. REP. NO. 104-496, pt. 1, at 84 (1996), *as reprinted in* 1996 U.S.C.C.A.N. 1865, 1884–85.

82. *Id.* at 279, *as reprinted in* 1996 U.S.C.C.A.N. 1865, 1985.

83. *Id.* at 85, *as reprinted in* 1996 U.S.C.C.A.N. 1865, 1885.

84. Letter from June Gibbs Brown, Inspector General of the Dep't or Health & Human Servs., to Sen. Tom Harkin (Sep. 29, 1995), *in* 141 CONG. REC. S15158, S15159 (1995); *see also* Kelly, *supra* note 38, at 318–21 (1998) (summarizing congressional and governmental concerns with the advisory opinion power and suggesting it passed only because of the proximity of a federal election).

consideration of whether the existing legal protections ought to be expanded.

Scholars espousing the second, contrary view defend the advisory opinion power in light of its ability to "reestablish[ ] the rule of law" by providing a "case-by-case opportunity for the government to determine what structures and organizations are beneficial." These scholars also defend the advisory opinion power as a tool to clarify the outer boundaries of the general applicability of the AKS.[85] This camp's approach conceptualizes advisory opinions as case-specific safe harbors capable of insulating otherwise-illegal arrangements from AKS liability when a generally applicable safe harbor would be inappropriate due to HHS's lack of experience with a given type of arrangement.

The second camp's view that the advisory opinion should be used as a tool to define the outermost contours of the AKS finds further support in the regulatory preamble to the final rule establishing the administrative requirements governing the advisory opinion process.[86] In that document, OIG described its conception of the advisory opinion power as a tool to create "case specific" safe harbor provisions when the benefit or practicability of a "generalized" safe harbor is unclear.[87] The Office further explained its view of the purpose of the advisory opinion process:

> The statutory and regulatory safe harbors to the anti-kickback statute describe generalized, hypothetical arrangements that are protected. In contrast, an advisory opinion is a means of relating the anti-kickback statute . . . to the facts of a particular arrangement. There are likely to be factors that make some specific arrangements appropriate for a favorable advisory opinion, even in subject matter areas where a generalized safe harbor may be impractical. Thus, we believe that particularized or "case specific" safe harbor treatment is appropriate where the specific arrangement contains limitations, requirements, or controls that give adequate assurance that Federal health care programs cannot be abused.[88]

Under this formulation of the advisory opinion power, OIG is empowered to grant favorable advisory opinions not only to proposed arrangements that squarely comply with the requirements of the AKS, but also to arrangements that constitute technical violations of the AKS, so long as they "contain[ ] limitations, requirements, or controls that give adequate assurance that Federal health care programs cannot

85. *E.g.*, James F. Blumstein, *Rationalizing the Fraud and Abuse Statute*, HEALTH AFF., Winter 1996, at 118, 126.

86. Issuance of Advisory Opinions by the OIG, 63 Fed. Reg. 38,311 (July 16, 1998) (codified at 42 C.F.R. pt. 1008).

87. *Id.* at 38,313.

88. *Id.* at 38,314.

be abused."[89] This conception of the advisory opinion power provides OIG with a flexible tool to gain experience with novel business arrangements and assess the wisdom of new, generally applicable safe harbor provisions to cover such arrangements.[90] In this way, the advisory opinion power might be thought of as a tool to overcome regulatory inertia by providing HHS with the means to acquire additional information to support the agency's decision on whether to promulgate a generally applicable safe harbor.[91]

The first camp's arguments that such use of the advisory opinion would exceed OIG's delegated authority because it would expressly authorize actions otherwise "contrary to law" are of little force. This is especially so in light of HHS's broad power to craft generally applicable safe harbor provisions and Congress's specific intent that the advisory opinion power be used as a flexible tool to encourage providers to "structure new and innovative health care delivery systems to contain health care cost."[92] Moreover, the straightforward structure of the fraud and abuse statutes—that is, broad prohibitions on conduct that may only be excused by falling squarely within a safe harbor provision or exception—suggests that advisory opinions would amount to little more than surplusage. This is so because of the ease with which counsel can determine the availability of a safe harbor on the facts of any given case.[93] Thus, the relevant legislative history, the fact that Congress refused to remove the advisory opinion provision despite the concerns voiced by certain legislators, the overwhelming margin with which HIPAA passed, and a functional reading of the provision creating the

89. *Id.* For a recent example of an opinion in which OIG authorized an arrangement despite the fact that it would have constituted a violation of the AKS if the requisite intent to induce referrals had existed, see Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 14-10, at 2 (Oct. 21, 2014) ("[A]lthough the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, [OIG] would not impose administrative sanctions . . . in connection with the Proposed Arrangement.").

90. This type of system would drastically reduce the social cost of "testing out" potential safe harbor provisions by confining any potentially deleterious effects on the healthcare system to a single provider. Conversely, as more and more of a similar type of arrangement demonstrate success in reducing cost and increasing quality, HHS would be able to build up a valuable record of demonstrated success with a given type of arrangement to support any future efforts to create a generalized statutory or regulatory safe harbor or exception provision.

91. *See supra* notes 57–60 and accompanying text.

92. H.R. REP. NO. 104-496, pt. 1, at 84 (1996), *as reprinted in* 1996 U.S.C.C.A.N. 1865, 1885; *see* 42 U.S.C. § 1320a-7d(b)(2) (2012) (providing that OIG should use advisory opinions to determine whether certain conduct "constitutes grounds for imposition of sanctions" under the fraud and abuse laws, not to determine whether certain conduct constitutes a violation of the laws).

93. The straightforward, elements-based structure of the safe harbors makes it relatively easy to determine whether a given arrangement would fall within the protection of the relevant safe harbor.

advisory opinion power all suggest that Congress sought to provide HHS with an additional tool to define the outer boundaries of AKS liability even when there was no generally applicable safe harbor on point.

B. The OIG Advisory Opinion Power in Practice

While Congress may have intended the advisory opinion to be a laboratory of regulation to test and validate the appropriateness of safe harbor provisions for certain types of business arrangements,[94] a critical analysis reveals that HHS has never taken the next step of promulgating generally applicable safe harbors to cover arrangements receiving uniform approval within the advisory opinion process.[95] This Section summarizes empirical findings that OIG has consistently used the advisory opinion power to define the outer bounds of AKS liability by authorizing providers to enter into otherwise-impermissible arrangements when such arrangements are likely to be prosocial. It then notes that HHS has failed to use the advisory opinion as a laboratory of regulation, as evidenced by the agency's failure to adopt safe harbors to cover certain types of arrangements that have received uniformly favorable treatment in the advisory opinion process.

1. Advisory Opinions as Case-Specific Safe Harbors

In the seventeen years since OIG began issuing advisory opinions regarding AKS liability, it has issued 326 such opinions.[96] The number of opinions issued each year has fluctuated from six in 1997 to twenty-six in 2010 (the year in which the ACA was passed).[97] Of these 326 opinions, 273—or 84%—were at least partially favorable to the

94. Concerned with the potential "chilling effect" that the AKS may bear on "new and innovative health care delivery systems" in light of the need to "contain health care costs," it seems clear that Congress intended that the advisory opinion power was to be used as a sort of laboratory of regulation to give HHS and OIG a sufficient basis of experience with novel arrangements to make an informed decision about whether the potential efficiencies available outweigh the risk of fraud and abuse in fact. *See* H.R. REP. NO. 104-496, pt. 1, at 84 (1996), *as reprinted in* 1996 U.S.C.C.A.N. 1865, 1884–85.

95. *See infra* Section III.B.1.

96. The statistics presented in the following paragraphs are the result of an empirical analysis conducted by the author of all of the advisory opinions that have been issued by OIG from the advent of the power in 1997 until September 5, 2015. For a complete listing of those opinions, see *Advisory Opinions*, OFFICE OF INSPECTOR GEN., U.S. DEP'T OF HEALTH & HUMAN SERVS., http://oig.hhs.gov/compliance/advisory-opinions/ (last visited Sept. 9, 2015) [http://perma.cc/2U47-2MA5].

97. *Id.*

party who requested the opinion.[98] The remaining 52 opinions resulted in a declaration that the proposed arrangement involved prohibited remuneration, which could lead to AKS liability if the requisite intent to induce referrals were present.[99]

There is some controversy regarding the extent to which the advisory opinion process has been used to confer immunity upon potentially beneficial arrangements that constitute technical violations of the AKS.[100] However, an empirical assessment of the outcomes of the process shows that OIG has actually been largely willing to grant favorable advisory opinions to insulate novel arrangements from AKS liability, so long as the arrangements contain adequate safeguards against fraud and abuse. As such, OIG appears to be exercising its advisory opinion power in a fashion consistent with the enacting Congress's intent.[101]

To evaluate the validity of criticisms that the advisory opinion process has not been used as a tool to authorize arrangements that are otherwise impermissible under the AKS, this author reviewed all 273 favorable advisory opinions issued since 1997 and sorted them into two categories: (1) opinions whose result was compelled by a preexisting interpretation of the AKS or an existing safe harbor, and (2) opinions whose result diverged from the negative result that OIG acknowledged would generally be compelled by the statute. This determination was made on the basis of OIG's reasoning within the opinion. If OIG stated its conclusion was compelled because the arrangement did not offend the prohibitions of the statute or because the arrangement fell squarely within an existing safe harbor provision, it was sorted into the first category.[102] The remaining opinions were sorted into the second category because OIG granted a favorable opinion despite its

98. Data aggregated and analyzed by the author (on file with author). To be classified as a favorable or partially favorable opinion, the requesting party must have received a case-specific immunization from administrative sanction for at least one of the arrangements they submitted to OIG for review.

99. Data aggregated and analyzed by the author (on file with author); *see also supra* note 26–27 (discussing the intent requirement under the AKS).

100. *See* CLARK C. HAVIGHURST ET AL., HEALTH CARE LAW AND POLICY: READINGS, NOTES, AND QUESTIONS, 123–24 (Supp. 2007) (citing OIG's approach in Advisory Opinion 07-02 as evidence of a broader hostility toward "market-oriented competition").

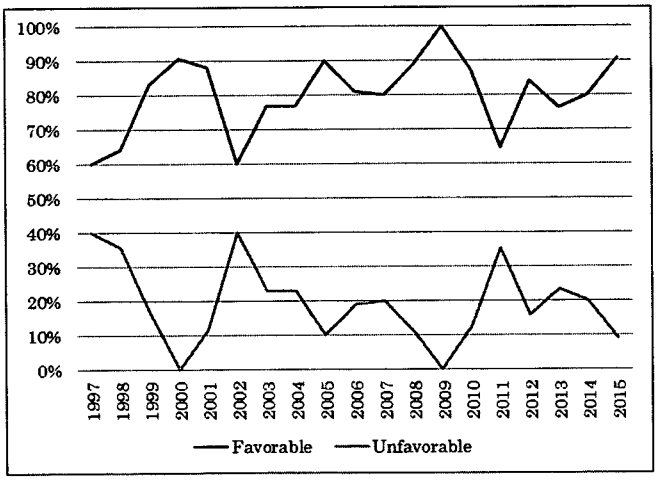
101. *See supra* note 92 and accompanying text.

102. *See, e.g.*, OIG Advisory Opinion No. 13-14, *supra* note 18, at 6 (Oct. 22, 2013) ("[T]he Proposed Arrangement would not generate prohibited remuneration under the anti-kickback statute.").

recognition that the conduct would otherwise constitute a violation of the statute if the requisite intent to induce referrals were present.[103]

As an initial matter, OIG has issued a relatively consistent number of advisory opinions each year—between ten and twenty-six per year—since its assumption of the power in late 1997.[104] If OIG were generally declining to exercise its power to confer immunity upon prosocial arrangements despite the fact that they constitute technical violations of the AKS, one would expect the proportion of opinions in the second category to be relatively low. Similarly, if OIG were actively exercising its power to achieve that end, we should expect a higher proportion of the opinions to be included in the second category. After tabulation, the results indicate that a staggering 82.8% of the 273 favorable advisory opinions fell into the second category.[105] In other words, favorable opinions were issued for 226 arrangements despite the fact that they would have constituted technical violations of the AKS if the parties had the requisite intent to induce referrals. As demonstrated in Figure 1 below, this approach has been employed consistently since the advent of the advisory opinion power.

Figure 1: Proportion of Favorable and Unfavorable Advisory Opinions in Cases Without Controlling Authority



103. *E.g.*, OIG Advisory Opinion No. 14-10, *supra* note 89 ("[A]lthough the Proposed Arrangement could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, [OIG] would not impose administrative sanctions . . . in connection with the Proposed Arrangement.").

104. Data aggregated and analyzed by the author (on file with author).

105. Data aggregated and analyzed by the author (on file with author).

This finding is strong evidence that OIG has exercised its advisory opinion power in a manner consistent with the enacting Congress's intent that the opinions be used as "case-specific" safe harbors for arrangements that contain "limitations, requirements, or controls that give adequate assurance that Federal health care programs cannot be abused."[106] While some commentators have cited negative responses to specific requests for advisory opinions as evidence of a shifting focus away from the advisory opinion as a tool to create "case-specific" safe harbors, the evidence above certainly calls that claim into question. To the contrary, OIG has consistently provided legal cover to novel arrangements that would have otherwise violated the strictures of the AKS, so long as these arrangements contained adequate controls to reduce the risk of fraud and abuse.[107] In short, an exhaustive analysis of existing advisory opinions suggests that OIG has made real efforts to give effect to the congressional intent that the advisory opinion power be used as a tool to create case-specific safe harbors as opposed to a tool to apply the existing law to the facts of a given case.

2. The Advisory Opinion Process as a Laboratory of Regulation

In contrast to the OIG's success in giving effect to congressional intent surrounding advisory opinions as case-specific safe harbors, HHS has failed to use its experience with these case-specific safe harbors as a basis for promulgating generally applicable safe harbor provisions to provide cover for similarly prosocial arrangements.[108] Indeed, it has been more than seven years since HHS has promulgated a new regulatory safe harbor despite the fact that OIG has uniformly granted favorable advisory opinions to providers seeking to enter into certain types of business arrangements during that same period (and beyond).

106. Issuance of Advisory Opinions by the OIG, 63 Fed. Reg. 38,311, 38,314 (July 16, 1998) (codified at 42 C.F.R. pt. 1008). My analysis merely confirms that favorable opinions are being issued to arrangements that might otherwise constitute technical violations of the AKS. A detailed analysis of the adequacy of OIG's evaluation of the limitations, requirements, and controls within each proposal would be necessary to determine that these decisions are appropriate as a matter or policy.

107. *See* HAVIGHURST ET AL., *supra* note 100 at 123–24 (citing OIG's approach in Advisory Opinion 07-02 as evidence of a broader hostility toward "market-oriented competition"). It is important to note that the claims that certain requests for favorable advisory opinions were unwisely denied by OIG remain justifiable; I merely take issue with the use of those anecdotes as evidence that OIG has veered away from its policy of using the advisory opinion power to create case-specific safe harbors (as opposed to merely applying the law to the facts).

108. *See supra* note 83 and accompanying text (indicating Congress's intent that the advisory opinion process be used to foster "new and innovative health care delivery systems").

As discussed earlier, this course of behavior has real costs because it denies providers the increased legal certainty associated with generally applicable safe harbors[109] and deprives consumers of the lower prices and increased access that flow from allowing providers to unlock the value and efficiencies associated with novel business arrangements.[110]

Several types of novel business arrangements remain impermissible under the AKS despite years of uniformly favorable treatment within the advisory opinion process. Two useful examples are: (1) arrangements involving the use of a "preferred hospital" as part of a Medicare Supplemental Health Insurance ("Medigap") policy, and (2) savings sharing arrangements between hospitals and physician groups.[111] Indeed, regulatory action on these (and other)[112] types of arrangements seems appropriate because favorable advisory opinions have been invariably granted to such arrangements, so long as they meet the criteria specified in the relevant standards. The criteria in these standards could serve as a blueprint for the relevant regulatory language.[113]

In 2007, OIG issued its first advisory opinion on an arrangement between a network of hospitals and a Medigap plan.[114] In that opinion, OIG reviewed the plan's proposal to contract with various hospital networks for a discount on the inpatient deductibles incurred by its members at those hospitals.[115] OIG ultimately opined that it would not

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109. *See supra* notes 50–53 and accompanying text (describing the benefits of generally applicable safe harbors to both providers who already have advisory opinions as well as those who do not).

110. *See supra* notes 47–49 (discussing the price reductions associated with safe harbors generally).

111. *E.g.*, OIG Advisory Opinion No. 14-10, *supra* note 89, at 2–3 (preferred hospital arrangement); Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 09-06, at 4–7 (June 30, 2009) (shared savings arrangement).

112. Similar clusters of favorable advisory opinions have been issued without any generally applicable regulatory action for arrangements involving exclusive agreements for the provision of ambulance services to municipalities, charitable contributions to defray out-of-pocket costs for financially needy individuals, and provision of complimentary insurance preauthorization services by various specialty group practices. *See, e.g.*, Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 13-13, at 1–3 (Oct. 15, 2013) (arrangement involving provision of free dental services to children with demonstrated financial need when such services were otherwise billable to Medicare/Medicaid); Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 13-05, at 1–3 (June 21, 2013) (exclusive ambulance services arrangement); Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 12-10, at 1–3 (Aug. 30, 2010) (preauthorization services arrangement).

113. These arrangements are provided only as illustrative examples; many other types of arrangements have received equally permissive treatment by OIG.

114. Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 07-15 (Dec. 10, 2007).

115. *Id.* at 2.

impose administrative sanctions upon either party in connection with the proposal even though the arrangement "could potentially generate prohibited remuneration under the AKS, if the requisite intent to induce or reward referrals of Federal healthcare program business were present." In support of its decision, OIG reasoned that favorable treatment was warranted because the arrangement posed a "low risk of fraud or abuse" and had the potential to accrue "significant savings for beneficiaries."[116] OIG cited four factors supporting its conclusion: (1) the discounts would not increase or affect per-service Medicare payments, (2) the discounts were unlikely to increase utilization (since they would have been effectively invisible to patients who would have already purchased coverage from the plan), (3) the discounts were unlikely to unfairly affect competition among hospitals since membership in the network was open to substantially all accredited hospitals, and (4) the discounts were unlikely to affect professional medical judgment since no remuneration would have been received by physicians and the patient was free to go to any hospital without incurring additional out-of-pocket expense.[117]

Since issuing that favorable opinion, OIG has issued sixteen additional advisory opinions on similar arrangements—all favorable.[118] Moreover, all of the sixteen arrangements proposed after the initial favorable opinion was issued in 2007 were assessed against substantially the same criteria used in the 2007 opinion.[119] Indeed, many of the subsequent opinions not only employ the same standard of decision, but also contain largely identical "Analysis" sections.[120] Taken collectively, the uniformly favorable treatment of such arrangements upon satisfaction of the criteria discussed above over a period of seven years suggests that HHS is largely comfortable with such arrangements in both theory and practice.

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116. *Id.* at 2, 5.

117. *Id.* at 4–5.

118. Data aggregated and analyzed by the author (on file with author).

119. *E.g.*, Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 11-19, at 4–6 (Dec. 20, 2011). Beginning in 2013, OIG began considering whether the plan expressly disclosed to plan members "that they have the freedom to choose any hospital without incurring additional liability or penalty." *See, e.g.*, Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 13-01, at 4 (Mar. 26, 2013). However, it is unclear whether that requirement is necessary for issuance of a favorable opinion going forward. *See* Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 13-12, at 5–6 (Aug. 27, 2013) (granting a favorable advisory opinion without consideration of such disclosures); Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 13-06, at 4–7 (June 27, 2013) (same).

120. *Compare* OIG Advisory Opinion No. 07-15, *supra* note 114, at 4–5, *with* OIG Advisory Opinion No. 13-12, *supra* note 119, at 5–6.

Moreover, it seems unlikely OIG would continue to grant favorable opinions on the basis of the same standard if it were uncomfortable with the effects of arrangements previously approved under that standard. Put another way, the marginal benefit of any additional information gained from additional testing of these Medigap plan-preferred network arrangements in the regulatory laboratory of the advisory opinion process is likely minimal when compared with the potential financial benefits associated with generally applicable protection for this type of arrangement.[121] Thus, this type of arrangement appears to be a strong candidate for a generally applicable regulatory safe harbor under Professor Super's framework, since the marginal benefit of additional information is small and the marginal benefit of regulatory action is high.

OIG has accorded similarly favorable treatment to arrangements involving payment of a certain portion of the savings arising from a physician group's implementation of cost-reduction measures. In 2001, OIG issued a favorable advisory opinion regarding a hospital's proposal to pay a surgical group practice a share of the cost savings achieved by the hospital as a direct result of changes in the practice style by the group practice's membership.[122] Despite finding that the arrangement might constitute a technical violation of the AKS, OIG granted a favorable opinion, relying upon three criteria: First, the arrangement limited the likelihood that it would be used to attract referring physicians or to increase referrals from existing physicians by limiting participation to physicians already on the hospital's medical staff and capping the size of the maximum savings payment on the basis of the previous year's admissions.[123] Second, the structure of the arrangement eliminated the risk that the payment would be used to reward other physicians who refer patients to the physician group because the physician group was comprised of physicians of a single type of specialty, the payment would be divided equally among all partners, and the agreement was only for a term of one year.[124] Finally, the arrangement set out with specificity the actions that would generate the cost savings upon which the payment would be based, and those actions were actual and appropriate changes in practice style.[125] In view of the proposal's satisfaction of these criteria, OIG found that it

121. *See, e.g.*, OIG Advisory Opinion No. 13-01, *supra* note 119, at 5 (suggesting that these arrangements are positioned to achieve "significant savings for beneficiaries").

122. Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 01-1, at 3–6 (Jan. 18, 2001).

123. *Id.* at 12–13.

124. *Id.* at 13.

125. *Id.* at 13–14.

"pose[d] a low risk of fraud or abuse," and held that it would not impose administrative sanctions upon either party in connection with the proposal.[126]

Since the issuance of the above-discussed opinion, OIG has approved fourteen additional cost-savings sharing arrangements on the basis of substantially the same factors.[127] While OIG has expressed doubts about arrangements that do not satisfy all of the above criteria,[128] those doubts should not serve as a disincentive to promulgate a regulation protecting those arrangements that do. Indeed, this is exactly the type of arrangement the narrowly written safe harbors were designed to protect.

In light of the mounting pressure to reduce costs across the healthcare industry, hospitals are desperate for tools to incentivize physicians to reduce their expenses. Shared-savings arrangements have proved to be a highly effective way to reduce healthcare costs because they align physicians' incentives with hospitals'. Given that the types of shared-savings arrangements discussed here have been uniformly approved over the course of fourteen years, it seems likely the benefit of any additional information to be gained from confining such arrangements to the advisory opinion process is vanishingly small.[129] On balance, at least under Professor Super's framework, these factors weigh in favor of a move toward codifying the standard discussed above as a generally applicable safe harbor.[130]

To summarize, an empirical examination of OIG's exercise of its advisory opinion power suggests that Congress's will for the advisory opinion remains half-fulfilled. OIG has unquestionably given effect to the congressional intent that the advisory opinion process be used to create case-specific safe harbors for otherwise-violative arrangements. This success is evidenced by the fact that the vast majority of favorable

126. *Id.* at 14.

127. *E.g.*, OIG Advisory Opinion No. 09-06, *supra* note 111, at 11–13. Certain cost-savings sharing arrangements have been decided under different standards, but this is attributable to the different structures of the arrangements at issue. *See* Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 12-22, at 12–14 (Oct. 30, 2012); Office of Inspector Gen., U.S. Dep't of Health & Human Servs., OIG Advisory Opinion No. 08-16, at 8–11 (Oct. 14, 2008).

128. *E.g.*, Office of Inspector Gen., Dep't of Health & Human Servs., OIG Advisory Opinion No. 05-01, at 13 (Feb. 4, 2005) (noting OIG's "concerns regarding many arrangements between hospitals and physicians to share cost savings").

129. This seems especially true given the thirteen years of experience HHS has with such arrangements.

130. Super, *supra* note 61, at 1407–09. Indeed, so long as the safe harbor provision is drafted narrowly, HHS can maintain flexibility to approve or sanction cost-savings sharing plans that do not fall squarely within the narrow category of acceptable arrangements.

opinions cover arrangements that, according to OIG, would otherwise constitute technical violations of the AKS.[131] At the same time, the evidence also suggests that HHS has failed to give effect to Congress's desire that the advisory opinion be used as a laboratory of regulation in support of additional regulatory safe harbors.[132] While this policy of inaction may be a result of a desire to maintain "regulatory flexibility," the following Part argues that such a policy—in addition to being contrary to Congress's intent—unduly prioritizes the value of flexibility at the expense of benefits to be achieved from the certainty of generally applicable safe harbors.

IV. OVERCOMING REGULATORY INERTIA: USING THE DATA ASSEMBLED IN THE LABORATORY OF REGULATION

HHS's decisions regarding whether to promulgate a regulatory safe harbor to cover a specific type of business arrangement—as opposed to confining the arrangement to the case-by-case analysis of the advisory opinion process—may be properly thought of as decisions on the extent to which the agency wishes to maintain "regulatory flexibility" to prosecute similar arrangements under the AKS.[133] In fact, HHS has specifically explained its failure to take formal action on at least one safe harbor as the result of imperfect information.[134] This Part argues that this flexibility-maximizing approach is appropriate for new arrangements with which HHS lacks experience, but not for arrangements that receive consistently favorable treatment within the regulatory laboratory of the advisory opinion process.

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131. *See supra* Section III.B.1.

132. *See supra* notes 92, 94 (discussing Congress's desire for the advisory opinion process to be used as a testing grounds for the appropriateness of generally applicable safe harbors to cover novel business arrangements).

133. Promulgation of a safe harbor provision over a certain type of business arrangement can be viewed as an effective surrender of the government's ability to prosecute individuals or corporations for participating in such an arrangement since it functions as a perfect defense to liability so long as the arrangement falls squarely within the provisions of the safe harbor. *See* Super, *supra* note 61, at 1410:

> A bright-line rule is easy to understand and inexpensive to apply, yet it almost inevitably proves both over- and underinclusive. The antidote, we are told, is the additional information that will become available if we reserve discretion until the policy needs to be applied to particular cases. Although this may mean individual adjudications in some cases, it also may mean acting legislatively on a class of cases only when a decision becomes necessary . . . .

134. *See, e.g.*, OIG Advisory Opinion No. 09-06, *supra* note 111, at 14 (noting that HHS's failure to promulgate a generally applicable safe harbor for cost-savings sharing arrangements between hospitals and physicians similar to the proposed arrangement is rooted in concerns about cost-savings sharing arrangements *generally*).

Applying the logic of Professor Super's article *Against Flexibility* to the observed history of the advisory opinion process, this Note posits that HHS has inappropriately postponed promulgation of generally applicable safe harbors for arrangements that have received consistently favorable treatment in the advisory opinion process over a period of several years. Indeed, the benefits of regulatory action on the basis of the imperfect information gleaned from the advisory opinion process almost certainly outweigh the costs (including the risk of fraud or abuse associated with the promulgation of safe harbor provisions on the basis of incomplete or imperfect information).[135] This Note argues that HHS could increase social welfare by promulgating generally applicable safe harbors for specific business arrangements that have received uniformly favorable treatment within the advisory opinion process, despite a shortage of information about the potential effects of that decision.

At its core, this Note's general proposal is simple: HHS should make use of the valuable information it gains about various types of innovative business arrangements within the regulatory laboratory of the advisory opinion process to promulgate generally applicable safe harbors when the social benefits of the safe harbor outweigh the social costs of regulating on the basis of the incomplete information gleaned from the advisory opinion process. While the abstract nature of the costs and benefits involved makes it difficult to specifically define this standard, existing examples provide a helpful illustration.[136]

Certain categories of arrangements have received uniformly favorable treatment within the advisory opinion process over large spans of time and have proved unlikely to result in fraud or abuse in practice.[137] In such situations, this Note proposes that it is clear that the benefits of a narrowly drafted safe harbor exceed the costs of promulgating a safe harbor regulation on the basis of good, albeit

135. *Id.*; *see supra* notes 54–57 and accompanying text (discussing the costs associated with inappropriately granted or poorly drafted safe harbor provisions).

136. Indeed, it is exceedingly difficult to reliably quantify the cost of enacting a given rule on the basis of imperfect information when that cost would flow directly from the creation of an unforeseen loophole. Further, although we could calculate a first approximation for the benefits to flow from the safe harbor on the basis of observed economies and savings flowing from the covered arrangements, this too does not lend itself well to a mathematical definition of precisely when a safe harbor regulation should be promulgated.

137. *See supra* notes 111–12 and accompanying text. OIG's recent termination of a favorable advisory opinion for an arrangement involving a technical violation of the AKS suggests that OIG does monitor these arrangements for evidence of fraud or abuse in fact. *See* Notice of Termination of OIG Advisory Opinion No. 11-18, *supra* note 52. The fact that all other favorable advisory opinions covering technically violative arrangements have been left in place leads to the fair inference that the agency does not believe the other covered arrangements have had the practical effect of encouraging fraud or abuse.

imperfect, information. The "preferred" arrangements between hospital networks and certain Medigap insurance plans discussed in Part III are one such example.[138] Such arrangements have been granted favorable advisory opinions consistently over the past seven years, and all requests for advisory opinions for such arrangements have received favorable results.[139] Similarly favorable treatment has also been accorded to arrangements for compensation plans between hospitals and physician groups including a cost-savings sharing provision.[140] There are other examples of arrangements receiving similarly favorable treatment over long periods of time without any evidence of fraud or abuse as well.[141]

Thus, although it is difficult to articulate a quantitative standard for when a safe harbor for a given type of arrangement is appropriate in view of the evidence gleaned through the advisory opinion process, HHS should apply a qualitative standard that would assess the benefit associated with promulgating a generally applicable safe harbor on the basis of: (1) the number of existing arrangements that have received favorable treatment, (2) the uniformity of such favorable treatment when the relevant criteria are satisfied, and (3) the amount of time that the relevant arrangements have been in place. If all three factors are high—as with the examples discussed above—HHS should promulgate a generally applicable safe harbor to cover similar arrangements. This is so because the benefits of that action are most likely higher than the costs of regulating with the incomplete information gleaned from the advisory opinion process. In this way, HHS could realign its exercise of the advisory opinion power with the enacting Congress's intent that this power be used as a tool to foster "new and innovative health care delivery systems."[142]

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138. *See supra* Section III.B.2.

139. *See id.*

140. Such plans have been the subject of fifteen uniformly favorable advisory opinions over a span of fourteen years. *See supra* Section III.B.2.

141. *See supra* note 112 and accompanying text.

140. H.R. REP. NO. 104-496, pt. 1, at 84 (1996), *as reprinted in* 1996 U.S.C.C.A.N. 1865, 1884–85.

V. CONCLUSION

Facing mounting cost, quality, and reimbursement pressures, healthcare providers are in a difficult position. To adjust to these new pressures, they will need to seek economies wherever they can be found. Unfortunately, the rigid structure of the AKS restricts providers' abilities to pursue innovative business arrangements. While HHS has the power to promulgate regulatory safe harbors, it has been reluctant to exercise that power of late. Congress, understanding the challenges facing both the healthcare industry and HHS, conferred OIG with the power to issue advisory opinions that would insulate recipient parties from any administrative penalty associated with the proposed arrangement.

An examination of OIG's exercise of its advisory opinion power suggests that the Office has generally succeeded in implementing Congress's intent that the power be used to grant case-specific safe harbors for arrangements that would otherwise be technically violative of the AKS.[143] However, HHS's history of using the advisory opinion process as a regulatory laboratory to assemble a body of proof in support of certain safe harbor provisions has been less successful.[144]

Thus, this Note ultimately proposes that HHS should use its experience with novel arrangements in the advisory opinion process as a basis for promulgating new safe harbor provisions when many similar arrangements have received consistently favorable treatment over an extended period of time.[145] This use of the advisory opinion process as a laboratory of regulation would allow HHS to give effect to Congress's intent that the advisory opinion process be used to develop new safe harbors to promote the efficient delivery of healthcare services. And because those safe harbors would be promulgated on the basis of real-world experience with similar arrangements, HHS would also be able to guard against the real and worrisome risk of fraud or abuse in practice.

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143. *See supra* Section III.B.1.

144. *See supra* Section III.B.2.

145. Both the examples of preferred arrangements between hospitals and Medigap plans and cost-savings sharing arrangements between hospitals and physicians are examples of arrangements where this standard is likely satisfied, but several more exist. *See supra* note 112 and accompanying text.

Put simply, HHS has all the tools it needs to test out novel business arrangements and to develop safe harbors that give providers flexibility without creating undue risk of fraud and abuse. Now, all it needs to do is use them.

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