TAF
TAXPAYERS AGAINST FRAUD
THE FALSE CLAIMS ACT LEGAL CENTER

October 26, 2018

*Submitted Electronically*

Daniel R. Levinson
Inspector General
Department of Health and Human Services
330 Independence Avenue, SW, Room 5250
Washington, DC 20201

**Re: File Code OIG—0803—N**
**Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements CMP**

Dear Mr. Levinson:

As the leading non-profit organization dedicated to the promotion and protection of the effectiveness of federal whistleblower programs, Taxpayers Against Fraud (TAF) takes this opportunity to respond to the Department of Health and Human Services' Request for Information Regarding the Anti-Kickback Statute and Beneficiary Inducements Civil Monetary Penalty (RFI).

## A. TAF Represents the Interests of Whistleblowers and Taxpayers

TAF is a non-profit organization whose mission is to maintain the integrity and advance the effectiveness of whistleblower reward and private enforcement provisions contained in federal and state laws, including the federal and state False Claims Acts, the Securities Exchange Act, the Commodity Exchange Act, the Internal Revenue Code, and the Motor Vehicle Safety Whistleblower Act. These laws empower and encourage citizens and organizations in the private sector to report incidents of fraud, waste and abuse that improperly divert taxpayer funds from government agencies and programs.

TAF is uniquely situated to comment on proposed changes in law that may affect the government's enforcement efforts to identify, remedy and prevent fraud, waste and abuse in the healthcare arena. Since 1986, TAF's members, in partnership with the Department of Justice (DOJ), have represented whistleblowers in False Claims Act (FCA) matters that have generated

tens of billions of dollars in civil and criminal recoveries in healthcare cases. The FCA's whistleblower provisions are recognized as DOJ's chief civil fraud enforcement tool and have served as a model for the states and for other federal agencies that have adopted whistleblower statutes. FCA whistleblower enforcement has also yielded serious efforts to improve internal compliance within various sectors of the U.S. economy, including the healthcare industry, and is estimated to have saved tens of billions of dollars through deterrent effects.

Many of the FCA whistleblower cases that TAF members have brought to the attention of the DOJ and successfully litigated have involved illegal kickbacks between healthcare providers and suppliers, including pharmaceutical manufacturers, hospitals, pharmacies, clinical diagnostic laboratories, nursing homes, drug wholesalers, health plans and physicians. In 2010, recognizing the prevalence of fraud in the healthcare system, Congress amended the Anti-Kickback Statute to expressly provide that a claim to the government that includes items or services resulting from a violation of the Anti-Kickback Statute (AKS) "constitutes a false or fraudulent claim" for purposes of the FCA. 42 U.S.C. § 1320a-7b(g). Consequently, TAF members have a strong interest in ensuring that any changes to the Anti-Kickback Statute protect, rather than undermine, the interests of honest patients and providers, and those of taxpayers generally.

### B. "Care Coordination" and "Value-Based Care" Must Not Open the Door to More Healthcare Fraud and Abuse

As part of the RFI, OIG seeks comments on "potential arrangements that the [healthcare] industry is interested in pursuing, such as care coordination, value-based arrangements, alternative payment models, arrangements involving innovative technology, and other novel financial arrangements that may implicate the anti-kickback statute or beneficiary inducements CMP."

TAF supports OIG's ongoing efforts to improve the quality of patient care in Medicare, Medicaid, and other federal healthcare programs, and to reduce the cost of these programs to taxpayers. To the extent that new initiatives under the umbrella of "value-based care" achieve these twin goals, without opening the door to new fraud schemes or undermining the ability of the government (or private relators) to successfully bring FCA complaints to address existing fraud schemes, TAF has no objection. However, in the experience of TAF members, unscrupulous healthcare providers and suppliers frequently attempt to justify the offer or receipt of remuneration intended to induce the referral of business on the basis that such remuneration is merely a "novel financial arrangement" with no harmful effects on patient care. Pharmacy sales representatives, for example, who give physicians expensive meals, speaker fees for little or no work, or free drug samples that are later billed to Medicare, rationalize that the drugs they sell are safe and effective and the physicians would have prescribed them anyway. But Congress has long recognized that financial inducements of any kind—whether a bag of cash, discounts, free

samples, the promise of a favor, or anything else of value—have a tendency to compromise clinical judgment and divert limited taxpayer dollars away from medically appropriate treatments. OIG should therefore proceed with utmost caution in crafting any new safe harbors to the AKS or broadening the scope of existing ones.

As OIG recognized in the proposed rules that became the AKS safe harbors, health care "is a highly competitive market that is constantly expanding with new drugs, medical devices and tests." 54 Fed. Reg. 3088, 3089 (Jan. 23, 1989). It is important to preserve this competitive marketplace, and "it is necessary for the fiscal integrity of the Medicare and Medicaid programs to assure that physicians exercise sound, objective medical judgment when controlling admittance to this market." *Id.* When medical care is offered in a transparent, open marketplace by providers acting free of financial inducements, patients are empowered – they have more options for medical care and greater assurance that physicians are acting in their best interests. Taxpayers also benefit because government health programs are protected from over-utilization and medically inappropriate therapies. *See, e.g., HHS OIG, Special Fraud Alert: Laboratory Payments to Referring Physicians*, 79 Fed. Reg. 40115-01 (July 11, 2014) (identifying the "four major concerns typically associated with kickbacks" to be "corruption of medical judgment, overutilization, increased costs to the Federal health care programs and beneficiaries, and unfair competition."). TAF members have repeatedly seen first-hand the harm to patients and the damage to the public fisc that follows in the wake of financial inducements aimed at securing orders or referrals of particular medical care.

Unfortunately, as the healthcare system has grown larger and more complex, fraud and abuse, and specifically the problem of illegal inducements, have not diminished but have increased commensurably. The size and complexity of the healthcare system appears to be matched only by the ingenuity of those who create schemes to profit from federal and state programs at patient and taxpayer expense.

For example, shortly after Medicare Part D was launched in 2006, the DOJ and HHS OIG learned that long-term care pharmacies were paying kickbacks to nursing homes in the form of discounts on the Medicare Part A *per diem* rate for their residents in order to induce the referral of the nursing homes' Medicare Part D and Medicaid prescription business. These discounts were not disclosed to the government or reflected in the costs charged to Medicare, and therefore did not fall within the AKS "discount safe harbor." The nation's largest long-term care pharmacy, Omnicare, Inc., paid $124 million to resolve FCA allegations brought by a whistleblower in one such matter. *See* DOJ Press Release 14-670, June 25, 2014, https://www.justice.gov/opa/pr/nation-s-largest-nursing-home-pharmacy-company-pay-124-million-settle-allegations-involving. By using anti-competitive discounts to lock in a prescription referral stream, these types of "swapping" schemes discourage nursing homes from switching to competing pharmacies that provide better quality pharmacy services, thereby

adversely affecting the quality of medication services to nursing home residents. In the absence of such hidden discount arrangements, pharmacies are required to compete honestly with each other for nursing home business. In the long run, taxpayers and patients benefit from more competition in the pharmacy marketplace.

Another new scheme that could not have been predicted twenty years ago involves pharmaceutical companies "score-carding" and then compensating pharmacies based on their success in persuading patients to order refills of so-called "specialty drugs," a euphemistic term that the industry uses for the most expensive medications in the marketplace – drugs that often cost hundreds of thousands of dollars per patient each year. The industry cloaks this scheme in the mantle of "adherence programs," *i.e.*, programs designed to help patients by keeping them on their prescribed medications, when in reality the schemes are all about profits and not about patients. Pharmacy staff – sometimes lay individuals with no medical training – are tasked with advising patients about drug side effects and complications with the goal of keeping patients on these expensive drugs, while the patients' doctors unknowingly are shut out of the loop.

Similarly, with the rise of managed care, new fraud schemes have arisen that target Medicare Advantage and comparable state Medicaid programs. These schemes are still evolving but include: (1) managed care plans paying kickbacks to medical clinics to switch dual eligible beneficiaries to the plan, and to physicians in order to obtain patient names for this purpose (*e.g., U.S. ex rel. Wilkins v. United Health Group, Inc.*, 659 F.3d 295, 312 (3d Cir. 2011); (2) pharmacy benefit managers paying kickbacks to health plans for favorable treatment under Medicare Advantage contracts, and soliciting and receiving kickbacks from drug companies to switch patients' prescriptions to their drugs (*e.g., U.S. ex rel. Hunt v. Merck-Medco Managed Care LLC,* 336 F. Supp. 2d 430, 448 (E.D. Pa. 2004); (3) benefit management companies automatically approving prior authorizations for diagnostic procedures covered by Medicare Advantage (MA) in order to avoid contractual penalties for failing to meet claim processing deadlines (*e.g.*, https://www.justice.gov/usao-sdny/pr/acting-us-attorney-announces-54-million-settlement-civil-fraud-lawsuit-against-benefits;
(4) managed care providers hiring auditors tasked with adding diagnosis codes without correcting incorrect diagnosis codes in patient records in order to boost risk adjustment scores and MA payments (*e.g.*, https://www.justice.gov/opa/pr/medicare-advantage-organization-and-former-chief-operating-officer-pay-325-million-settle); and (5) pharmaceutical companies writing off MA insurer's debt in order to get their drug on the insurer's formulary (*e.g., U.S. ex rel. Derrick v. Roche Diagnostics Corp.*, 318 F. Supp. 3d 1106 (N.D. Ill. 2018)).

Many of these recent schemes have involved euphemistic jargon employed by the wrongdoers in an attempt to legitimize their misconduct, such as "promoting patient adherence." We predict that should OIG adopt the new safe harbors proposed by the American Hospital Association, hospitals and other providers will do likewise, and disguise traditional kickback

schemes that corrupt independent decision-making as supposed "value-added care" or "coordinated care."

It is difficult if not impossible to anticipate what new forms of remuneration unscrupulous actors will use to induce the referral of healthcare business. If HHS OIG carves out of the kickback statute the so-called value-based payment systems that meet the broad and ambiguous criteria in the American Hospital Association's proposed safe harbor, it is virtually guaranteed that a host of new schemes will arise within those systems that violate the central goals of the AKS: leveling the playing field for free competition; preserving the independence and objectivity of clinical decision making; and preventing overutilization of health care billed to the taxpayers.

### C. OIG Should Anticipate the Unintended Consequences of Any Changes to the Safe Harbors and Proceed with Utmost Caution

In evaluating proposals such as those coming from the American Hospital Association, it is critical for OIG to anticipate, as best it can, the unintended consequences of safe harbors that can severely undercut the AKS's goals of fostering free competition and independent medical decision making. For example, as reflected in dozens of comments from physicians across many specialties in response to this OIG Request for Information, the so-called "GPO Safe Harbor," found at 42 1001.952(j), has operated at cross-purposes to the goals of the AKS, restricting physician and patient options as well as creating life-threatening shortages and escalating costs of medical devices and medications. As one commenter observed, "these arrangements have repeatedly resulted in recurrent shortages in critical basic medications . . . that have nearly forced me to shut down my practice on several occasions over the past few years." As another commenter observed, because of this safe harbor, "insulin in 1996 was only $20 per vial, today it is over $400."

TAF's concerns about the unintended consequences of ostensibly well-meaning safe harbors are not theoretical. These concerns have already played out in cases where defendants argued that safe harbors applied to their fraudulent schemes, but that have resulted in FCA liability nonetheless. For instance, in *United States ex rel. Lisitza v. Johnson & Johnson*, 765 F. Supp. 2d 112 (D. Mass. 2011), the defendants' motion to dismiss was denied and the defendants ultimately settled claims that pharmaceutical manufacturers entered into an unlawful kickback scheme with Omnicare, the nation's largest supplier of drugs to nursing homes, to promote the defendants' branded drugs over less costly alternatives, and caused claims for payment to be submitted to government healthcare plans in violation of the FCA. The relators and the government alleged that Omnicare employed "consultant" pharmacists whose job was to review patient charts and make recommendations to physicians regarding prescription drugs based on the formulary. In theory, providing assistance to physicians in treating patients sounds like a

good idea. However, the relators and the government alleged that Omnicare, in collaboration with the pharmaceutical companies, "exploited its quasi-fiduciary status as an 'independent' reviewer of patient medications to recommend J&J drugs in exchange for kickbacks disguised as payments for 'physician data' and as purported grants and sponsorship fees." *See Lisitza,* 765 F. Supp. 2d at 115.

These issues are also arising increasingly in connection with patient assistance programs, where drug companies engage nominally "non-profit" foundations and organizations to defray the cost of patients' co-payments or cover other expenses. Helping needy patients get access to the information and medications that they need is undoubtedly a worthy cause, but these relationships are often exploitive and can result in patient harm. For instance, in *United States ex rel. Clarke, et al. v. Aegerion Pharmaceuticals, Inc., et al.,* No. 13-CV-11785 (D. Mass.), the government and relator alleged that the drug manufacturer Aegerion defrayed patients' copayment obligations for its drug Juxtapid by funneling funds through Patient Services Inc., an entity claiming to be a non-profit patient assistance program. The defendant settled claims that it used the patient assistance program to induce patients to use its product by defraying copayments for uses of Juxtapid outside of the medically accepted indications for the drug, a very dangerous medication that came with a "black box" warning that it may cause liver toxicity and gastrointestinal adverse reaction. Aegerion entered into a Corporate Integrity Agreement (CIA) in connection with the settlement requiring it to strengthen internal controls, and as Chief Counsel to the HHS OIG Gregory Demske noted, "[i]mportantly, the CIA also requires that Aegerion implement controls and monitoring designed to ensure true independence from any charity patient assistance programs to which it donates in the future." *See* Department of Justice Press Release, No. 17-1044, September 22, 2017, https://www.justice.gov/opa/pr/drug-maker-aegerion-agrees-plead-guilty-will-pay-more-35-million-resolve-criminal-charges-and.

This year, pharmaceutical manufacturer Pfizer settled similar claims that it used a foundation as a conduit to underwrite the copayments of Medicare patients taking three Pfizer drugs. *See* Department of Justice Press Release, No. 18-686, https://www.justice.gov/opa/pr/drug-maker-pfizer-agrees-pay-2385-million-resolve-false-claims-act-liability-paying-kickbacks. The government alleged that, in order to generate revenue, Pfizer transitioned certain patients to a third-party non-profit foundation, and the foundation then covered the patients' Medicare copayments. In turn, Pfizer allegedly made donations to the foundation to enable it to cover the cost of these copayments. The drug company United Therapeutics Corporation settled similar claims last year for $210 million. *See* United States District Attorney's Office, District of Massachusetts Press Release, December 20, 2017, https://www.justice.gov/usao-ma/pr/united-therapeutics-agrees-pay-210-million-resolve-allegations-it-paid-kickbacks-through. These are new and innovative fraud schemes that involve conduct that appears on the surface to help patients but actually lines the pockets of

pharmaceutical companies. The same kinds of exploitation would be rampant under the second safe harbor proposed by the American Hospital Association.

Based on decades of experience monitoring and supporting whistleblower cases involving alleged violations of the AKS, TAF perceives a significant risk that enactment of the AHA-proposed safe harbors likewise will bring about many of the evils that the AKS is intended to mitigate. First, the AHA's proposed language is so broad and replete with undefined terms that industry players wishing to violate the spirit of the AKS would have free rein to take advantage of the new safe harbors. Second, the AHA and other commenters supporting the AHA's proposals have for the most part failed to provide specific examples of the types of arrangements they aim to protect and, to the extent they have done so, the examples on their face create enormous risk of nefarious activities detrimental to the goals of the AKS.

For example, several of the AHA-aligned commenters reference a need to protect arrangements in which hospitals donate electronic health record systems to medical groups to allow for better coordination of care. While at first blush this goal appears laudable, a closer analysis reveals the serious risks that these arrangements pose to the goals underlying the AKS. Hospitals would have to create eligibility criteria lest they be on the hook to purchase electronic records systems for every medical group in the country. The most likely eligibility criteria that hospitals would adopt, such as a medical practice's volume of referrals to the hospital, or geographic location, would skew medical decision making and restrain free competition. Thus, to "earn" these electronic systems, doctors would be incentivized to refer more patients to the hospital offering the gift, or move their offices closer to the hospital, from which a higher volume of referrals to the hospital logically would follow, regardless of whether that hospital was best for the needs of the patient in question. In addition, once a medical group had accepted the gift, in order to optimize communication about health information it would be limited in its future referrals to those hospitals with compatible electronic records software – which likely would be the hospitals owned by the chain that had made the gift. A far better solution, consistent with the goal of preventing fraud and abuse, would be for AHA members collectively to fund a program, operated by a neutral party subject to HHS oversight, which would underwrite the costs of establishing a nationwide health records electronic system aimed at ensuring secure and efficient communications among all health care providers.

### D. OIG Should not Adopt the AHA's Proposed Safe Harbors

The AHA seeks a "value-based payment" safe harbor for virtually any remuneration, including incentive fees, that has just one of the following purposes:

- Promoting accountability for the quality, cost or overall care for patients;
- Managing and coordinating care for patients;

- Encouraging investment in infrastructure and redesigned care processes for high quality and efficient service delivery for patients.

TAF opposes the adoption of the value-based safe harbor proposed by the AHA. On its face, it is nothing more than a license to pay kickbacks in any payment system that the participants characterize as one that adds value, quality, efficiency or coordination in the provision of care. The health care providers participating in such transactions will always be able to point to some aspect of their "value-based" payment arrangement that arguably improves patient care in one of these ways, and the shrewder ones will carefully design their payment arrangements accordingly, thereby successfully planting their arrangements within the AHA's proposed safe harbor. But being able to point to such features doesn't mean that the payment arrangement doesn't also include kickbacks that unacceptably compromise the independence of clinical decision making and/or close out competition in the medical field from those unwilling to "play ball" with large hospital systems offering these inducements. There are no protections whatsoever against fraud and abuse in the structure of the AHA's proposed safe harbor, and its adoption would constitute wholesale abandonment of the goals of the federal AKS.

The AHA also proposes a safe harbor for "items and services offered to beneficiaries to promote better care or reduce overall costs." TAF opposes the adoption of this safe harbor as well. As the whistleblowers and counsel in our membership have often seen, but for the fact that patients have "skin in the game" through co-payments, deductibles and other cost sharing obligations, many of the fraud and abuse schemes successfully investigated by the DOJ and HHS-OIG would have gone undetected. For example, in 2011 DOJ and HHS OIG recovered approximately $150 health services provider that was billing nationwide for home health visits it simply did not perform. *See* Department of Justice Press Release, No. 11-1169, https://www.justice.gov/opa/pr/maxim-healthcare-services-charged-fraud-agrees-pay-approximately-150-million-enact-reforms. This blatant, egregious fraud scheme had gone undetected by regulators and auditors and unreported by those within the company who witnessed the fraud. It was a single patient who carefully scrutinized his explanation of benefits statements and brought the matter forward. Moreover, eliminating patients' financial stake in the cost of their health care is an open invitation to over-utilization. While the government may have assumed this risk for the truly indigent individuals who qualify for Medicaid, it is unreasonable to assume the risk for those patients who have the resources to contribute towards their own health care. Moreover, there are viable alternatives to lighten the financial impact on non-Medicaid patients without the risk of steering patients to particular drugs, hospitals or other health care providers, such as disease-specific patient assistance funds, insulated from manufacturer involvement, that help patients with the costs of drugs used for approved purposes.

## E. Conclusion

TAF and its members have a strong interest in supporting laws, including the AKS, that protect the integrity of decisions involving taxpayer funds in the healthcare industry and elsewhere. TAF submits that the AKS is not an impediment to efforts to increase the ability of government-funded healthcare programs to move successfully to a system that rewards higher value, coordinated health care.

As is typical in conflict of interest laws, the AKS contains a number of exceptions to the rule and provides safe harbors for persons who can demonstrate that their conduct does not create the risk of improper inducements. In recognition of circumstances in which financial relationships might be unrelated to the financial interest in referrals, Congress crafted specific exceptions to the AKS's broad prohibition. Congress also authorized the U.S. Department of Health and Human Services to develop these exceptions through regulations, which the agency has done over the years in close consultation with the medical community. In addition, members of the regulated community who have questions about whether their conduct fits within one of the exceptions may seek an advisory opinion from HHS. The agency also issues additional guidance on the application of the AKS to specific situations.

As the Department of Justice has stated, its enforcement of the AKS illustrates the importance that the government places on ensuring that healthcare decisions are based upon patient interest and not the financial interests of providers. These were not matters involving technical violations or mistakes. Each of these cases could no doubt be described as a situation in which the entity sought to provide value and improve coordinated care and in which the AKS impeded the ability to deliver it. But they are also situations in which large amounts of money changed hands to promote referrals of Medicare or Medicaid business, creating the risk that financial self-interest took precedence over the interests of individual patients.

The move to value-based and coordinated care does not eliminate the fundamental concern at the core of the AKS – limiting the role that profit plays in healthcare decisions affecting individual patients and subsidized in large part by the taxpayers. Before proposals to amend the law are seriously considered, we recommend that the Department carefully examine the claimed barriers to modernization and whether mechanisms do not already exist to address them. In addition, the Department should carefully consider whether the proposed "fixes," which involve exempting providers, suppliers and manufacturers and various unspecified arrangements from a critical anti-fraud law, would allow conflicts of interest to improperly affect medical decision-making. Years of deliberate evaluation have produced substantial gains in reducing the role of financial self-interest in delivering patient care funded by the government, and the Department should not rush to take steps that could undermine that progress.

Thank you for providing TAF with the opportunity to submit comments in response to the RFI. Because of the importance of the AKS to the government's fraud-fighting efforts, TAF hopes that HHS will not inadvertently open the door to new fraud schemes as part of its "Regulatory Sprint to Coordinated Care." In order to help protect the interests of taxpayers, whistleblowers, providers and patients, TAF and its members look forward to participating in HHS's formal rule-making process if any changes to the AKS harbors are ultimately proposed.

Sincerely,

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