No. _____

In the Supreme Court of the United States

PFIZER INC., PETITIONER

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

ILANA H. EISENSTEIN
DLA PIPER LLP (US)
One Liberty Place
1650 Market Street
Suite 5000
Philadelphia, PA 19103

DOUGLAS HALLWARD-DRIEMEIER
Counsel of Record
SAMANTHA BARRETT BADLAM
STEFAN P. SCHROPP
ROPES & GRAY LLP
2099 Pennsylvania Ave., N.W.
Washington, DC 20006
(202) 508-4600
Douglas.Hallward-Driemeier@ropesgray.com

WILSON-EPES PRINTING CO., INC. – (202) 789-0096 – WASHINGTON, D. C. 20002

QUESTION PRESENTED

The Anti-Kickback Statute (AKS) makes it a felony to "knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) * * * to induce" the purchase or recommendation of federally insured medicines. 42 U.S.C. 1320a-7b(b)(2).

Petitioner is the manufacturer of the only FDA-approved drug that provides life-extending treatment for a rare, devastating, and fatal cardiac condition. Petitioner seeks to provide financial assistance to needy Medicare patients to help them access this breakthrough treatment when appropriately prescribed by a physician. Respondents, however, adopted the position that it is a crime to provide such assistance under the AKS, which they interpret to outlaw the provision of anything of value that merely *influences* a Medicare patient's ability to access necessary, prescribed medical treatment, without any requirement of an intent to improperly skew medical decision-making. The courts below endorsed that interpretation.

The question presented is:

Whether the AKS is violated only if the person offering the "remuneration * * * to induce" the purchase of federally reimbursed healthcare intends to corrupt the recipient's medical decision-making.

PARTIES TO THE PROCEEDINGS BELOW AND RULE 29.6 STATEMENT

Petitioner Pfizer Inc. was the plaintiff in the district court and the appellant in the Second Circuit.

Respondents, who were the defendants in the district court and appellees in the Second Circuit, are: United States Department of Health and Human Services (HHS); Xavier Becerra, Secretary, HHS; HHS Office of Inspector General (OIG); Christi A. Grimm, Inspector General, OIG.

In accordance with Supreme Court Rule 29.6, Petitioner discloses that it is a public company. Pfizer has no parent corporation, and no publicly held corporation owns 10% or more of its stock.

RELATED CASES

- *Pfizer Inc.* v. *United States Department of Heath and Human Services*, No. 21-2764-cv, U.S. Court of Appeals for the Second Circuit. Judgment entered July 25, 2022.
- *Pfizer Inc.* v. *United States Department of Heath and Human Services*, No. 1:20-cv-4920, U.S. District Court for the Southern District of New York, Judgment entered September 30, 2021.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner Pfizer Inc. respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Second Circuit.

OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-25a) is reported at 42 F.4th 67. The district court's opinion and order (App., *infra*, 26a -64a) is unreported in the Federal Supplement but is available at 2021 WL 4523676.

JURISDICTION

The judgment of the court of appeals was entered on July 25, 2022. This Court has jurisdiction under 28 U.S.C. 1254(1).

STATUTORY PROVISIONS INVOLVED

The pertinent provisions of the Anti-Kickback Statute, 42 U.S.C. 1320a-7b are set forth in the Appendix, App., *infra*, 136a-145a.

In relevant part, the AKS makes it a felony and provides substantial monetary and other penalties for anyone:

> Who[] knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) * * * to any person to induce such person * * * to purchase, lease, order, or arrange for or recommend purchasing * * * any good [or] service * * * for which payment may be made in whole or in part under a Federal health care program.

42 U.S.C. 1320a-7b(b)(2)(B).

INTRODUCTION

This case is about how respondents' overbroad interpretation of a criminal statute outlaws a wide swath of routine, beneficial conduct in connection with federally funded healthcare. Respondents issued an advisory opinion ("Advisory Opinion") that precludes petitioner from helping financially needy patients access critical, life-extending care. But the court of appeals' ruling is even more all-encompassing, threatening almost any activity that facilitates patient access to federally funded healthcare—including commonplace transactions and charitable programs. Over the past two decades, this Court frequently has granted certiorari to review and restrain the government's expansive construction of similar fraud and public corruption statutes. This case calls for a similar exercise of the Court's authority.

Petitioner developed tafamidis, a breakthrough therapy for a rare, progressive, and fatal cardiac disease called Transthyretin Amyloid Cardiomyopathy (ATTR-CM). Tafamidis is the only medical treatment for this condition approved by the Food and Drug Administration (FDA). Because many middle-income Americans cannot afford the out-of-pocket costs of tafamidis, petitioner sought an advisory opinion from respondents to confirm that providing financial assistance to enable these patients to access tafamidis would not violate the AKS. Petitioner explained that its proposed program would not induce improper utilization of tafamidis because a physician already would have independently diagnosed the patient with ATTR-CM and prescribed this life-extending treatment, and because no approved alternative exists.

Respondents, however, deem it a crime under the AKS to provide any financial assistance to patients who are federal healthcare beneficiaries, even if that rule means many ATTR-CM patients will be unable to afford treatment for that progressively debilitating and ultimately fatal condition. Under respondents' view, it does not matter whether the program is beneficial, appropriate, or even necessary for patient health: providing financial help that merely *influences* a Medicare patient's *ability* to access the only FDA-approved medical treatment for their condition violates the AKS. The courts below affirmed and even expanded this sweeping interpretation of the AKS, establishing a rule that puts everyday interactions with participants in the federal health system in the statute's crosshairs.

In reaching this categorical rule, respondents and the courts below have strayed from congressional intent by reading out of the AKS any element of corruption or

inherently bad conduct. To conclude that the AKS criminalizes any financial assistance—no matter how benign—respondents, with the court of appeals' approval, failed to consider properly the text, structure, and history of the AKS, which demonstrate the statute's focus on corrupt transactions. In so doing, respondents and the courts below disregarded the specific examples of corrupt transactions, "kickback, bribe, or rebate," that Congress provided. That approach is out of step with this Court's longstanding efforts to ensure that criminal laws do not sweep more broadly than Congress intended and to give effect to the full text of federal statutes. It also converts the AKS's advisory opinion process from a meaningful way to clarify statutory boundaries into nothing more than a plea for executive grace to avoid criminal exposure.

The risks of overcriminalization are not limited to petitioner's proposed program. Unless corrected by this Court, the court of appeals' construction of the AKS will curtail a range of routine commercial interactions and chill, or even foreclose, charitable efforts to enable access to essential medical care. Although the court of appeals credited the government's representation that charities and generous family members will not be prosecuted for assisting financially needy patients, that view is contradicted by the government's history of aggressively enforcing the AKS against charitable programs supporting patient access to medicines. Indeed, citing the court of appeals' decision, OIG recently rejected a request from a 501(c)(3) charitable organization seeking to assist cancer patients to afford a wide range of prescribed therapies.

Because of the draconian punishments for violating the AKS, there are unlikely to be many opportunities for

the Court to consider this important issue that has substantial impact on patients, providers, and manufacturers. Unfortunately, many programs to help patients will simply never be undertaken in light of respondents' position. This case is an optimal vehicle for addressing the scope of the AKS as it presents a pure legal question on an undisputed administrative record.

The Court should therefore grant certiorari to settle this important question for the nation's healthcare and pharmaceutical industries.

STATEMENT OF THE CASE

A. Statutory Background

Congress enacted the AKS in 1972 with the goal of protecting Medicare from waste, fraud, and abuse. See Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972). Congress created misdemeanor penalties for the offer or solicitation of any "kickback or bribe" in connection with Medicare or Medicaid services as well as any "rebate of any charge or fee for referring" a patient for such service. *Ibid.*; 42 U.S.C. 1395nn(b), 1396h(b) (1976). The terms "kickback," "bribe," and "rebate" "each involve[d] a corrupt payment * * * in violation of the duty imposed by Congress on providers of services to use federal funds only for intended purposes." *United States* v. *Zacher*, 586 F.2d 912, 916 (2d Cir. 1978); see also *Skilling* v. *United States*, 561 U.S. 358, 412-413 (2010) (noting the established meanings for "bribe" and "kickback" as involving "improper" or "corrupt" conduct).

In 1977, "to enhance the deterrent effect of the statute," *United States* v. *Greber*, 760 F.2d 68, 70-71 (3d Cir. 1985), Congress amended the AKS to provide felony penalties and substantial monetary fines, Pub. L. No. 95-142, § 4(a), 91 Stat. 1175, 1179-1183 (1977). As revised,

the AKS prohibits "any remuneration (including any kickback, bribe, or rebate)" offered "to induce" or solicited "in return for" the purchase or recommendation of a good or service reimbursed by Medicare and Medicaid. *Ibid.*; 42 U.S.C. 1320a-7b(b). Although the intent to corrupt the medical decision-making process is inherent in the above language, the AKS as amended in 1977 had no explicit *mens rea* element.

Later amendments have expanded the scope of the statute's penalties while retaining (or narrowing) its substantive reach. In 1980, Congress required that a defendant engage in the prohibited conduct "knowingly and willfully." Pub. L. No. 96-499, § 917, 94 Stat. 2599, 2625 (1980). In 1987, Congress added a debarment penalty for violators. Pub. L. No. 100-93, § 2, 101 Stat. 680, 680 (1987). At the same time, Congress directed HHS to create regulatory safe harbors "to ensure that published interpretations of the law are not impeding legitimate and beneficial activities." H.R. Rep. 100-85 pt. 2, at 27 (1987); see also Pub. L. No. 100-93, § 14, 101 Stat. 680, 697 (1987). In 1996, Congress created a process for entities to seek an advisory opinion from HHS's OIG regarding whether an anticipated course of action would violate the AKS and, if so, whether OIG would nonetheless exercise its discretion not to impose sanctions. See Pub. L. No. 104-191, Title II, § 205, 110 Stat. 1936, 2000-2003 (1996).

In 2010, Congress made AKS violations *per se* grounds for liability under the civil False Claims Act (FCA). Pub. L. No. 111-148, § 6402(f)(1), 124 Stat. 119, 759 (2010). One of the amendment's sponsors, Senator Patrick Leahy, characterized the amendment as "help[ing] ensure that the government is able to recoup

* * * the losses resulting from * * * health care providers [who] secure business by paying illegal kickbacks." 155 Cong. Rec. S13693 (daily ed. Dec. 21, 2009). At the same time, Congress also amended the AKS to clarify that "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of this section" to be held criminally culpable. Pub. L. No. 111-148, § 6402(f)(2), 124 Stat. 119, 759 (2010).

B. Factual Background

Petitioner manufactures and sells tafamidis to treat ATTR-CM, a rare, progressive condition that causes amyloid proteins to be deposited in the heart muscle. App., *infra*, 4a.[1] Patients with ATTR-CM experience progressive heart failure, ultimately making them unable to perform basic life tasks, and have a life expectancy of 2 to 3.5 years after diagnosis if left untreated. *Ibid.* Based upon current scientific estimates, approximately 100,000-150,000 people are afflicted with ATTR-CM in the United States, with an even smaller number actually diagnosed. *Ibid.* ATTR-CM is an objectively diagnosed medical condition, and tafamidis is the only FDA-approved pharmacological treatment for it. *Ibid.* Clinical studies confirmed that tafamidis significantly reduces mortality, decreases cardiovascular-related hospitalizations, and slows the decline in quality of life for ATTR-CM patients. *Id.* at 68a.

Because of tafamidis's novel approach to ATTR-CM, which previously had no approved pharmacological treatment, FDA designated tafamidis a "breakthrough" therapy. App., *infra*, 2a. Because of the small estimated

[1] This case arises from an established administrative record, setting forth the relevant facts of the program petitioner proposed to implement.

patient population, tafamidis was designated an "orphan" drug, entitled to greater market exclusivity protections under a statute adopted to incentivize research for orphan diseases. *Id.* at 5a; see 21 U.S.C. 360bb; 21 C.F.R. pt. 316.

Reflecting its novelty, value to patients, research and development costs, and small patient population, petitioner set the original annual list price for tafamidis at $225,000. App., *infra*, 5a. The only other potential pharmacological treatment for ATTR-CM is not FDA-approved for this condition and costs $450,000 annually. *Ibid.*

Because ATTR-CM disproportionately affects older Americans, a large proportion of the population eligible for treatment with tafamidis receives Medicare. App., *infra*, 5a. Under Medicare Part D, participants are responsible for certain deductibles and copays based on the cost of the medications that doctors prescribe. *Id.* at 6a. Under Medicare Part D's coverage design, which does not cap a beneficiary's copay responsibility, the patient's annual out-of-pocket cost of tafamidis is approximately $13,000. *Id.* at 7a.

To assist lower-income Medicare Part D participants, the federal Low Income Subsidy (LIS) program provides copay support for any person with income less than 150% of the federal poverty level. App., *infra*, 6a. Petitioner also makes tafamidis available for free to ATTR-CM patients who are prescribed tafamidis and have an annual income up to 500% of the federal poverty level, if those patients are uninsured or underinsured—including those on Medicare. App., *infra*, 71a.

Medicare patients with incomes above the threshold for petitioner's free product program still face a substantial financial barrier to treatment: survey evidence indicates that at least 25% of new Part D enrollees will forego prescriptions or care if they are asked to pay more than $50, and that almost 50% would not fill their prescriptions if asked to pay more than $2,000. App., *infra*, 29a. Even if tafamidis's price were cut in half, Medicare patients would have an out-of-pocket cost of more than $8,000 per year, an amount that is unaffordable for a substantial number of middle-income patients. *Id.* at 30a.

Petitioner therefore proposed to create a copay assistance program, similar to one petitioner offers for commercially insured patients, for Medicare patients with household incomes between 500-800% of the federal poverty level who have been diagnosed with ATTR-CM and whose doctors have appropriately prescribed them tafamidis. App., *infra*, 71a. Specifically, petitioner proposed to provide copay assistance directly to qualifying Medicare patients and limit the patients' out-of-pocket costs to a maximum of $35 per month. *Id.* at 72a. Petitioner would not advertise the program to patients before their doctors have appropriately prescribed tafamidis for them. *Ibid.*

C. Proceedings Below

OIG Advisory Opinion. In June 2019, petitioner sought an advisory opinion from OIG that its copay as-

sistance program would not involve prohibited remuneration to induce the purchase of goods within the meaning of the AKS. App., *infra*, 9a.[2]

OIG issued its Advisory Opinion concluding that petitioner's program would implicate the AKS because it would generate "remuneration" that could "induce" patients to utilize tafamidis. App., *infra*, 106a. Referring to a lay dictionary instead of the well-developed meaning of "induce" in criminal law, OIG defined the term "induce" to mean "to lead or move by influence or persuasion." App., *infra*, 86a n.35 (quoting 56 Fed. Reg. 35,952, 35,958 (July 29, 1991)). By equating "induce" with "influence," OIG found that "where a Medicare beneficiary otherwise may be unwilling or unable to purchase [tafamidis] due to his or her cost-sharing obligations * * * [petitioner's program] would induce that beneficiary to purchase [tafamidis] by removing the financial impediment." App., *infra*, 87a. In other words, the AKS would criminalize petitioner's proposed program because "[i]f * * * the principal reason a beneficiary would not fill a prescription is inability to pay the out-of-pocket expenses, then remuneration that would address that inability to pay would, without question, influence the patient's purchasing decision." *Id.* at 87a n.36.

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[2] Petitioner further sought, in the alternative, an advisory opinion that it could provide funding to an independent charity that would provide financial assistance to patients suffering from ATTR-CM. App., *infra*, 30a-31a. Respondents rejected that request outright, citing the program's purported similarity to matters under investigation and subject to enforcement under the AKS. *Id.* at 34a. The proposed independent charity program is no longer part of this case.

Although OIG noted it could not opine on petitioner's intent because petitioner had not yet implemented its program, App., *infra*, 66a-67a, OIG's Advisory Opinion constituted the agency's final view that the program, as proposed, would provide remuneration that is prohibited by the AKS and that petitioner could be liable for sanctions were it to implement the program.

District Court. Petitioner filed suit in district court. As relevant here, petitioner sought an order vacating OIG's determination regarding the proposed copay assistance program as contrary to law under the Administrative Procedure Act (APA), 5 U.S.C. 702, 706. App., *infra*, 36a. On September 30, 2021, the district court issued an opinion and order granting the government's motion for summary judgment and endorsing OIG's interpretation of the AKS. See *id.* at 63a.

Court of Appeals. The Second Circuit affirmed. The court of appeals held that "remuneration" includes any form of "payment [or] compensation," App., *infra*, 16a, and that "to induce" involves "influence or persuasion," *id.* at 14a, rejecting petitioner's argument that the statutory text, structure, and history demonstrate that the AKS targets only payments made to corrupt decision-making. The court gave no weight to Congress's use of "kickback, bribe, or rebate"—words which this Court has recognized connote corrupt quid pro quo transactions—as specific examples of the conduct the AKS proscribes. *Id.* at 18a. Moreover, the court disagreed that Congress selected the word "induce" to imply a corrupting influence or ill motive, finding instead that it is "neutral with regard to intent." *Id.* at 15a. The court further stated that, even if a quid pro quo were necessary, such routine transactions as "commercial contract[s]" and "paying money" to purchase goods or services would

meet the literal meaning of "this for that," because no corruption is required. *Id.* at 14a.

The court of appeals declined to interpret the criminal AKS by reference to the civil Beneficiary Inducement Statute (BIS)—which is adjacent to the AKS in the U.S. Code and also references "remuneration," but omits the list of kickback, bribe, or rebate and uses the broader verb "influence," rather than "induce." App., *infra*, 20a-21a; 42 U.S.C. 1320a-7a(a)(5). The court recognized that the two statutes have "similar subject matter," but refused to consider the BIS because it "prohibit[s] different activities." *Id.* at 21a.

The court of appeals stated the statute's "willfully" *mens rea* requirement makes it "very unlikely" that generous family members or charitable organization would be prosecuted for violating the law. App., *infra*, 23a-24a. The court, however, found "willfully" is "not synonymous with a corrupt intent," but rather, means "a voluntary, intentional violation of a known legal duty," which the court equated with a "bad purpose." *Id.* at 19a. In the court's view, "willfully" only limits prosecution of those "who are unaware that such payments are prohibited by law and accidentally violate the statute"; it "goes no further." *Ibid.*

REASONS FOR GRANTING THE PETITION

Petitioner seeks this Court's intervention to correct the staggeringly overbroad construction of the AKS that was advanced by respondents and endorsed by the court of appeals. In their view, the AKS criminalizes not only patient assistance that causes improper utilization of medicines, but any assistance at all—even if, without such assistance, Medicare patients would be left with no

FDA-approved treatment. Neither the text nor the legislative history of the AKS supports this sweeping interpretation, which has far-reaching implications: it not only inhibits pharmaceutical companies from working with and helping the patients they serve, but also threatens to cut off charitable or family aid to help Medicare and Medicaid patients afford essential medical treatment and threatens other programs that seek to assist in the diagnosis, treatment, and care of patients who benefit from federal healthcare programs.

Although the court of appeals stated its belief that charities or family members would presumably lack an ill-defined "bad purpose" necessary for a "willful" AKS violation, that is not how respondents have interpreted the statute in enforcement and administrative proceedings. Respondents regularly target charities that assist federal beneficiaries for prosecution under the AKS, and rarely grant advance approval for independent charitable programs through OIG's advisory opinion process.

This Court has unequivocally and repeatedly stressed that a criminal statute should not be construed to reach benign conduct, and that overbreadth is not cured by government assurances of temperance. Unfortunately, the Court must clarify that point once again with regard to the AKS.

This case is an ideal vehicle in which to consider and decide this important issue. The case comes before the Court on an undisputed administrative record demonstrating that the program poses no risk of corrupting independent medical decision-making. Notwithstanding the AKS's broad impact on participants in the federal healthcare system, it is unlikely that many, if any, other cases presenting this critical issue will reach the Court.

The penalties for violating the AKS are too draconian to fight in most instances. Pharmaceutical manufacturers have acquiesced in billions of dollars in FCA settlements because of the threat of even greater jury verdicts and the ultimate threat of exclusion from Medicare. Even worse, because of this over-deterrence, manufacturers simply never initiate many socially desirable arrangements, such as those that would make it easier for physicians to diagnose conditions or for patients to comply with treatment regimens. Congress sought to mitigate such over-deterrence through the advisory opinion process, which respondents have instead turned into an exercise solely of case-specific prosecutorial discretion. Only this Court, in this case, can restore the AKS to the scope that Congress intended.

I. THE RULING BELOW VIOLATES THIS COURT'S CONSISTENT ADMONITION AGAINST OVERLY EXPANSIVE CONSTRUCTION OF CRIMINAL STATUTES, LIMITED ONLY BY GOVERNMENT DISCRETION

A. This Court Has Repeatedly Rejected Expansive Constructions of Criminal Statutes That Would Punish Routine, Even Desirable, Conduct, Subject Only to Government Permission

As construed by respondents and the court of appeals, the conduct criminalized by the AKS is nearly limitless. The court of appeals interpreted the phrase "any remuneration (including any kickback, bribe, or rebate) * * * to induce" to encompass nearly anything of value that merely influences access to federally reimbursed healthcare. Even indisputably beneficial programs that improve patient health and allow patients to afford essential medications that their physicians prescribed are

criminalized under this expansive interpretation of the AKS.

The AKS is a public corruption statute that prohibits corrupt payments in the nature of kickbacks and bribes—it is not a statute designed to broadly ration medical care on the backs of financially needy Medicare and Medicaid patients. Respondents and the court of appeals incorrectly ignored the AKS's textual features that limit its scope to payments that seek to corrupt the medical decision-making process. They assigned, for example, no significance to the AKS's express inclusion of examples of prohibited remuneration—"kickback, bribe, or rebate"—which are terms that classically evoke corrupt quid pro quo transactions. Respondents equate "induce" with "influence or persua[de]," even though Congress used the more innocuous term "influence" in the adjacent civil BIS provision but not in the AKS. Notably, in a recent petition to this Court, the Solicitor General explained that "induce," when used in a criminal statute, has an established, narrower meaning, *i.e.*, to entice or bring about the crime.[3] Applying the same logic, because a person cannot aid or abet innocent conduct, "induce" in the AKS suggests criminality in the *actus reus*.

The court of appeals' decision would turn laudable acts of charity into crimes punishable by up to ten years in prison. OIG itself recognizes that patient assistance

[3] Petition for Writ of Certiorari at 13-14, *United States* v. *Hansen*, petition for cert. pending, No. 17-10548 (filed Aug. 25, 2022) (noting that, in criminal law, "encourage" and "induce" historically connote complicity and that, in using those terms "to define the actus reus of the crime at issue [there], Congress carried forward the established criminal-law meaning of those terms").

programs have "long provided important safety net assistance to [patients who cannot afford their cost-sharing obligations]." Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120-01, 31,120 (May 30, 2014); see also 70 Fed. Reg. 70,623-03, 70,624 (Nov. 22, 2005) ("OIG is mindful of the importance of ensuring that financially needy beneficiaries who enroll in Part D receive medically necessary drugs, and OIG supports efforts of charitable organizations and others to assist financially needy beneficiaries."). Yet, by reading any element of corruption out of the AKS, these acts of charity—providing assistance to help Medicare patients access prescribed medicines—would meet the statute's *actus reus* elements. Under respondents' interpretation, only OIG's view of the actor's intent distinguishes innocent from criminal conduct, and OIG has often targeted charities for prosecution.

This case demonstrates that overbreadth. Because of Medicare's current benefit design, which does not cap the patient's out-of-pocket share of medical costs, patients can be faced with copay obligations that exceed their resources. That includes many Medicare patients who require the most cutting-edge care, such as breakthrough treatments for rare diseases like tafamidis. If the patient has sufficient resources, she will pay the copay, and the government will cover its share of the $225,000 annual cost. If the patient is poor enough, her copay will be waived under the LIS program, and Medicare will cover its share for that patient as well. But if the patient is middle income, and the $13,000 copay is beyond her means, the patient will not be able to access her Medicare insurance benefit—the government will pay

nothing, and the patient will die prematurely. If a generous family member, or perhaps that patient's church, provides the patient a share of the copay to help the patient pursue the treatment, that act of charity would satisfy the *actus reus* of the AKS, in the view of respondents and the court of appeals, because the money is remuneration being offered "to induce" the patient to obtain and medical professionals to provide the treatment.

By deterring third parties from helping Medicare patients cover their share of medical costs, the court of appeals' decision *frustrates* Congress's purposes. While respondents have, at points in this litigation, suggested that Congress intended the AKS as a mechanism to ration healthcare or to ensure that federal insurance benefits are provided only to those who are able and willing to pay their share, see, *e.g.*, Br. for Defs.-Appellees at 49, *Pfizer, Inc.* v. *HHS*, 42 F.4th 67 (Mar. 25, 2022) (No. 21-2764), Congress has not required that patients pay their own copays as a condition of receiving federal healthcare benefits.

By eliminating any element of corruption from the AKS, respondents and the court of appeals threaten to subject not only medical product manufacturers, but also doctors and even patients, to serious criminal liability. The AKS punishes not only the payor, but also the *recipient* of the "remuneration," making it a criminal felony to "solicit[] or *receive*[] any remuneration (including any kickback, bribe, or rebate) * * * in return for" purchasing or prescribing federally reimbursed medical goods or services. 42 U.S.C. 1320a-7b(b)(1) (emphasis added). Properly construed, this provision is limited to a doctor or patient who is party to a corrupt transaction. But the court of appeals' reading eliminates any element of corruption, and so would expose even a patient who merely

accepts financial assistance to access critical medical care.

This Court has repeatedly given criminal statutes narrowing constructions to avoid criminalizing conduct that Congress did not clearly intend to forbid. Just this past Term, in *Ruan* v. *United States*, the Court adopted a narrowing construction of the Controlled Substances Act (CSA), including "[a] strong scienter requirement," in order to "diminish the risk of 'overdeterrence,' *i.e.*, punishing acceptable and beneficial conduct." 142 S. Ct. 2370, 2378 (2022). The CSA prohibits doctors from distributing opioids "except as authorized," which includes distribution in accordance with ordinary medical practice. 21 U.S.C. 841(a). Addressing whether the statute's "knowingly or intentionally" scienter element applied to the "except as authorized" element, the Court observed that "[t]he conduct prohibited * * * (issuing invalid prescriptions) is * * * 'often difficult to distinguish from the gray zone of socially acceptable * * * conduct' (issuing valid prescriptions)." *Ruan*, 142 S. Ct. at 2377-2378. For this reason, the Court determined that the "knowing[] or intentional[]" element must apply to the question of authorization. *Id.* at 2379 (emphasis omitted).

The Court has likewise placed substantial limits on other fraud and corruption statutes. In *Skilling* v. *United States*, 561 U.S. 358 (2010), for example, the Court limited the honest services fraud statute, 18 U.S.C. 1346, to conduct constituting established forms of corruption—bribes or kickbacks—in order to prevent "proscrib[ing] a wider range of offensive conduct" than what Congress intended. *Id.* at 408. And in *McDonnell* v. *United States*, 579 U.S. 550 (2016), the Court declined

to construe a bribery theory of liability under that statute to reach commonplace acts of constituent service. *Id.* at 572-577.

In case after case, the Court has emphasized that criminal statutes cannot be interpreted broadly "on the assumption that the Government will 'use [them] responsibly.' " *McDonnell*, 579 U.S. at 576; see *Marinello* v. *United States*, 138 S. Ct. 1101, 1108-1109 (2018) (noting that the Court cannot "rely upon prosecutorial discretion to narrow [a tax obstruction statute's] scope"); *United States* v. *Sun-Diamond Growers of Cal.*, 526 U.S. 398, 408 (1999) (rejecting an interpretation of a statute where "nothing but the Government's discretion prevents [benign] examples from being prosecuted"). "[P]rosecutorial discretion is not a reason for courts to give improbable breadth to criminal statutes." *Abuelhawa* v. *United States*, 556 U.S. 816, 823 n.3 (2009). To the contrary, construing a criminal statute to cover routine and ordinary conduct "merely because the government promised to use it responsibly" would "leave us at the mercy of *noblesse oblige*." *United States* v. *Stevens*, 559 U.S. 460, 480 (2010). It is not enough that "Congress *could* have intended that th[e] broad range of conduct be made illegal, perhaps with the understanding that prosecutors would exercise their discretion to avoid such harsh results," especially in the face of a "paucity of material suggesting that Congress did so intend." *Liparota* v. *United States*, 471 U.S. 419, 427 (1985); see also *United States* v. *Taylor*, 142 S. Ct. 2015, 2023 (2022) (rejecting "the government's * * * interpretation [because, in relevant part, it] would vastly expand the statute's

reach by sweeping in conduct that poses an abstract risk").

Respondents and the court of appeals' interpretation of the AKS cannot be squared with this Court's precedents, would criminalize a broad swath of everyday, socially desirable conduct, and must be corrected.

B. Standard Principles of Statutory Construction, Applied to the Text, Structure, and History of the AKS, Confirm That Congress Intended Only to Reach Arrangements that Corrupt the Provision of Federally Funded Healthcare

Every available canon of statutory construction confirms that Congress never intended the AKS to have the nearly limitless scope attributed to it by respondents and the court of appeals.

1. The court of appeals broke from this Court's practice in its cursory dismissal of well-recognized canons of interpretation

Since its origin in 1972, the focus of the AKS has been on transactions that corrupt the provision of federally financed healthcare. The original statute expressly prohibited three types of conduct: "kickback," "bribe," or a particular kind of rebate—a return to the referring party "of any charge or fee for referring" a patient for Medicare or Medicaid services, 42 U.S.C. 1395nn(b), 1396h(b) (1976). As this Court observed in *Skilling*, the terms "kickback" and "bribe" have well-established meanings, each of which involves a corrupting influence on the recipient. 561 U.S. at 412-413 (citing statutes). And, in a leading case, the Second Circuit recog-

nized that "rebate" as used in the AKS as originally enacted similarly proscribed only a corrupt transaction. *Zacher*, 586 F.2d at 916-917.

When Congress revised the AKS in 1977, it retained the reference to these three exemplary corrupt transactions as the focus of the AKS. As amended, the AKS prohibits, under specified circumstances, "any remuneration (including any kickback, bribe, and rebate) * * * to induce" purchase or provision of a federally reimbursed good or service. 42 U.S.C. 1320a-7b(b)(2). While the new formulation may not be limited to conduct that precisely meets one of those three terms, the more general phrase "remuneration * * * to induce" cannot be read without reference to Congress's continuation of the specific examples from the pre-amendment statute. *Ibid.* "Where Congress employs a term of art obviously transplanted from another legal source, it brings the old soil with it." *George* v. *McDonough*, 142 S. Ct. 1953, 1959 (2022) (quoting *Taggart* v. *Lorenzen*, 139 S. Ct. 1795, 1801 (2019)).

Under the principles of *ejusdem generis* and *noscitur a sociis* the meaning of a general word in a list is limited by the list's more specific words. Here, the exemplary trio of "kickback, bribe, or rebate" within the phrase "remuneration (including any kickback, bribe, or rebate) * * * to induce" indicates that the "remuneration" involved must share the common characteristic of the offered examples—corruption. These doctrines "avoid ascribing to one word a meaning so broad that it is inconsistent with its accompanying words, thus giving unintended breadth to the Acts of Congress." *Yates* v. *United States*, 574 U.S. 528, 543 (2015) (plurality opinion) (quoting *Gustafson* v. *Alloyd Co.*, 513 U.S. 561, 575

(1995)) (explaining that the canon applies even when the list begins with "any").

By essentially ignoring the exemplary terms, the court of appeals also violated the rule against surplusage. See *Circuit City Stores, Inc.* v. *Adams*, 532 U.S. 105, 114 (2001) (applying *ejusdem generis* to "give independent effect to the statute's enumeration of * * * specific categories," which would otherwise be superfluous). Moreover, the fact that Congress included the same parenthetical in an analogous criminal statute, enacted forty years after the AKS was first amended, confirms that Congress's use of the examples was intentional and not a meaningless hangover from the pre-amendment AKS.[4]

Contrary to these principles of construction, the court of appeals held that the terms "kickback, bribe, or rebate" are "merely non-exhaustive examples" and not otherwise limiting. App., *infra*, 18a. The court of appeals insisted that *ejusdem generis* could only apply where the general word follows the specific, *ibid.*, but that is contrary to both this Court's and the Second Circuit's own precedent, see *Samantar* v. *Yousuf*, 560 U.S. 305, 317 (2010) (noting how illustrative examples following "includes" inform the understanding of the preceding text); *City of New York* v. *Beretta U.S.A. Corp.*, 524 F.3d 384, 401-402 (2d Cir. 2008) (applying *ejusdem generis* to 15 U.S.C. 7903(5)(A)(iii), in which more specific language follows a general category). The court of appeals also

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[4] See 18 U.S.C. 220(a)(2) (the Eliminating Kickbacks in Recovery Act) (making it a felony to offer "*any remuneration (including any kickback, bribe, or rebate)* * * * *to induce* a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or *in exchange for* an individual using the services of that recovery home, clinical treatment facility, or laboratory" (emphases added)).

dismissed *noscitur a sociis* with just two sentences, citing the purported lack of ambiguity in the statute. As a result, the court discounted as merely "illustrative" the statutory terms that provide crucial limits on the AKS and that demonstrate the corrupt conduct that Congress sought to prohibit.

Had the court of appeals applied these time-tested tools of statutory construction and given full effect to the specific examples that Congress included in the statute, it would have interpreted the AKS as criminalizing only remuneration—like a "kickback, bribe, or rebate"—that has a corrupting influence on the provision of federally insured healthcare.

2. The court of appeals' refusal to consider other, related statutory provisions in interpreting the AKS was also contrary to this Court's practice

If the AKS's reference to "kickback, bribe, or rebate" were not sufficient, the interplay of that statute with other statutes confirms that Congress meant the AKS to reach only genuinely corrupt conduct, and not to criminalize every entry into a "commercial contract" or "pay[ment of] money" to purchase goods or services. See App., *infra*, 14a. The AKS is one of several statutes that addresses fraud and abuse in federal healthcare programs. The commonalities and distinctions between these provisions make clear that the AKS has a narrower scope directed at corrupt transactions.

The court of appeals declined to engage in this essential method of statutory construction. See App., *infra*, 21a ("We find no reason to interpret the AKS by reference to the text of the BIS."). This Court, however, has repeatedly held that similarities and differences in

language among related statutes can provide valuable insight into their proper interpretation. See, *e.g.*, *Babb* v. *Wilkie*, 140 S. Ct. 1168, 1176 (2020); *McDonnell*, 579 U.S. at 580; see also *Sun-Diamond*, 526 U.S. at 406 (rejecting a construction of "gratuity" that would essentially be coterminous with "bribe").

Here, a comparison of the language Congress used in the criminal AKS with the text it chose for the civil BIS,[5] which addresses related subject matter, makes clear that Congress intended the AKS to have a narrower reach than its civil counterpart. Most significantly, the civil BIS, which addresses a subset of transactions covered by the AKS, references "remuneration * * * likely to influence" such purchases. The AKS's express reference to "kickback, bribe, or rebate" and the use of the more technical "to induce" distinguish the criminal AKS from the civil BIS. See Petition for Writ of Certiorari at 13-14, *United States* v. *Hansen*, petition for cert. pending, No. 17-10548 (filed Aug. 25, 2022) (Solicitor General noting that, in criminal law, "induce" historically connotes complicity and that its use in "defin[ing] the actus reus of the crime" reflects Congress's intent to connote that "established criminal-law meaning").

In addition, as noted, the AKS imposes criminal sanctions not only on the payor, but also the *recipient* of the "remuneration." 42 U.S.C. 1320a-7b(b)(1). By contrast, the BIS expressly "exclud[es] a beneficiary" from its scope. 42 U.S.C. 1320a-7a(a). It is incomprehensible

[5] 42 U.S.C. 1320a-7a(a)(5) (BIS) (providing civil penalties for offering "remuneration to" Medicare patients that "is likely to influence such individual to order or receive [goods or services] from a particular provider").

that Congress, having expressly excluded beneficiaries from lesser, civil liability under the BIS, would nonetheless subject them to criminal prosecution under the AKS, dependent solely on whether the recipient knew her conduct violated the AKS, making such violation "willful."

The foregoing is further confirmed by the interplay between the AKS and the False Claims Act (FCA), Pub. L. No. 111-148, § 6402(f)(1), 124 Stat. 119, 759 (2010). Congress amended the AKS in 2010 to specify that a claim for federal reimbursement resulting from violation of the AKS is *per se* a false or fraudulent claim subject to treble damages and statutory penalties under the FCA. That makes sense under a proper interpretation of the AKS, because a medical decision corrupted by an AKS violation deprives the government of the benefit of its bargain—the uncorrupted medical judgment of the prescribing physician. Indeed, even for conduct predating the 2010 amendment, federal prosecutors consistently argued that a claim for federal reimbursement resulting from an AKS violation was *per se* "false" under the FCA precisely because an AKS violation necessarily meant that the medical judgment had been corrupted. See, *e.g.*, U.S. Br. at 9, *United States ex rel. Kester* v. *Novartis Pharms. Corp.*, No. 11-cv-08196 23 (S.D.N.Y. June 27, 2014).

The court of appeals' refusal to consider the interplay between the AKS and these related provisions in construing the scope of the AKS's prohibitions effectively expanded the AKS far beyond the scope intended by Congress, subject only to the government's exercise of discretion.

3. The court of appeals has rendered superfluous the congressionally created advisory opinion process

In addition to creating inconsistencies with other statutory provisions, the court of appeals also rendered superfluous the statutory process by which entities may seek advisory opinions from OIG about whether an anticipated program would come within the AKS's scope. Specifically, Congress requires that the "Secretary * * * shall issue written advisory opinions as * * * [to w]hat constitutes prohibited remuneration within [the AKS]." 42 U.S.C. 1320a-7d(b)(2)(A). The statutory language is focused on the *actus reus* and clearly reflects Congress's understanding that there is remuneration that is *not* prohibited by the AKS. Recognizing that the AKS might deter beneficial conduct, Congress required OIG to advise requestors whether proposed activities are or are not illegal.

As construed by respondents and the court of appeals, that statutory directive is effectively meaningless. Under their view, *any* exchange of value relating to federally reimbursed medical care—from a "commercial contract" to "paying money for" a service to helping a person in need afford their medication—is conduct within the AKS's reach. App., *infra*, 14a. The *only* thing that separates routine, even laudable, behavior from a felony is whether the actor was "unaware that such payments are prohibited by law." *Ibid.* Thus, for an actor aware of the AKS—and, of course, anyone seeking an advisory opinion from OIG is aware of the AKS—any financial arrangement involving federal health care programs presumptively violates the AKS. The advisory opinion process thus devolves into an exercise of OIG's

enforcement discretion whether to permit such arrangements without sanctions, rather than the process Congress intended whereby OIG would delineate between legal and illegal conduct. *Ibid.* While Congress did instruct OIG in a separate provision to advise whether it would impose penalties, see 42 U.S.C. 1320a-7d(b)(2)(E), that only underscores that these are two distinct obligations. Making one of the two obligations "redundant or largely superfluous [is a] violation of the elementary canon of construction that a statute should be interpreted so as not to render one part inoperative." *Colautti* v. *Franklin*, 439 U.S. 379, 392 (1979). Moreover, construing the AKS's advisory opinion mechanism as a wholesale delegation of enforcement discretion to OIG is contrary to Congress's clear intent for that process to help avoid, not enable, overly broad enforcement of the statute.

4. If the AKS is ambiguous, the rule of lenity applies in favor of petitioner

Finally, after making this series of interpretive missteps, the court of appeals simply dismissed the rule of lenity in a footnote, based on the lack of ambiguity in the statute. For the reasons above, the statute, properly construed, *does* make clear that it is limited to transactions that corrupt medical decision-making about federally reimbursed care. But, if the AKS's text, structure, and history were not already clear on that point, the court of appeals should have applied the rule of lenity to circumscribe its scope, as this Court's precedent instructs. See, *e.g.*, *Yates*, 574 U.S. at 548 (plurality opinion) (applying the rule of lenity where "the Government urge[d] a reading of [42 U.S.C.] 1519 that exposes individuals to 20-year prison sentences for tampering with *any* physical object that *might* have evidentiary value in

any federal investigation into *any* offense") (citing *Liparota*, 471 U.S. at 427). This Court has consistently considered, and regularly applied, the rule of lenity when faced with overbroad government interpretations of criminal statutes. This case calls for the same prudent approach.

C. The Court of Appeals' Interpretation Depends on an Erroneous Understanding of the *Mens Rea* Requirement

Recognizing that its construction of the AKS would encompass everyday, unobjectionable arrangements, such as a "commercial contract" or "paying money for a" service, App., *infra*, 14a, the court of appeals turned to the AKS's *mens rea* element of "knowingly and willfully" as limiting the AKS's application to those who know about the AKS and intend specifically to induce the purchase of federally reimbursable drugs. At the same time, however, the court recognized that "willfully" provides minimal restriction on the statutory scope since it merely requires, in its view, "a voluntary, intentional violation of a known legal duty," which it equated with a "bad purpose," and thus only serves to prevent criminal liability for those "who are unaware that such payments are prohibited by law and accidentally violate the statute." *Id.* at 19a. Unlike the exemplary terms "kickback," "bribe," and "rebate," which have well-established meanings, see *Skilling*, 561 U.S. at 412-413, the phrase "bad purpose" lacks any defined content, and any person who is aware of the AKS would violate the statute by engaging in the routine and desirable conduct described above. The court was therefore incorrect in believing that "willfully" meaningfully constrains the AKS.

The court of appeals' interpretation of "willfully" also is inconsistent with Congress's understanding that the AKS proscribes conduct that is inherently wrongful, not merely prohibited by virtue of regulation. This Court has recognized that the meaning of "willfully" depends on the nature of the crime. For crimes that are *malum in se*, (*i.e.*, for which the conduct, or *actus reus*, is inherently wrongful), "willfully" requires that a defendant engage in conduct that he knows to be wrongful, even if he has no specific knowledge of the statute he is violating. *Bryan* v. *United States*, 524 U.S. 184, 191-192 (1998) (citing *Ratzlaf* v. *United States*, 510 U.S. 135, 137 (1994)). On the other hand, for crimes that are *malum prohibitum* (*i.e.*, regulate conduct that is not by its nature wrongful, but made so only by virtue of a statute), "willfully" requires that the defendant (1) knows the specific statutory provision prohibiting certain conduct (*i.e.*, "a known legal duty"), and (2) intentionally engages in that conduct despite knowledge of the known legal duty. *Cheek* v. *United States*, 498 U.S. 192, 201 (1991). For crimes that are *malum prohibitum*, the knowledge of the specific statute is required to prevent conviction based a bona fide misunderstanding. See *id.* at 199-200 (finding that a defendant must know about the legal duty in a tax law to be found criminally culpable because "it [is] difficult for the average citizen to know and comprehend the extent of the duties and obligations imposed by the tax laws").

Congress amended the AKS in 2010 to clarify that "a person need not have actual knowledge of [the AKS] or specific intent to commit a violation of this section" to be held criminally culpable. Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119, 759

(2010) (codified at 42 U.S.C. 1320a-7b(h)). That is because, unlike the crimes at issue in *Cheek* or *Ratzlaf*, "[the AKS] is not a highly technical tax or financial regulation that poses a danger of ensnaring persons engaged in apparently innocent conduct." *United States* v. *Starks*, 157 F.3d 833, 838 (11th Cir. 1998). As the Eleventh Circuit articulated, "the giving or taking of kickbacks for medical referrals is hardly the sort of activity a person might expect to be legal; compared to the licensing provisions that the *Bryan* Court considered, such kickbacks are more clearly *malum in se*, rather than *malum prohibitum*." *Ibid.*; see also *United States* v. *Ricard*, 922 F.3d 639, 648 (5th Cir. 2019) (upholding AKS conviction because the jury could have found the defendant "shuffled psychiatric patients among home health agencies, based on a desire for profit rather than their medical needs").[6] Any interpretation of the AKS that would cover conduct that is not inherently corrupt and wrongful is at odds with Congress's clear understanding of AKS as a *malum in se* offense.

[6] Further underscoring the point, when Congress amended the AKS in 1977, it did not yet incorporate the "knowing and willfully" *mens rea*. Congress thus must have viewed the limitation to wrongful behavior as inherent in the corrupt transactions described by the prohibited *actus reus*. The addition of "knowingly and willfully" in 1980 underscored this limitation but did not transform a crime that was *malum in se* to one that is *malum prohibitum*.

II. This Case Presents Issues of Profound Importance Severely Impacting Tens of Thousands of Americans, and This Is the Ideal Vehicle in Which to Rein in an Overbroad Construction of the AKS

If allowed to stand, the court of appeals' decision would inhibit a host of beneficial, charitable, and innovative efforts to improve patient access to treatment, not just the one proposed by petitioner. According to respondents and the court of appeals, the AKS is violated whenever anything of value might "influence" the purchase or recommendation (*i.e.*, prescribing) of a federally reimbursable healthcare product or service—even where, as here, there is no corruption or improper influence on independent medical decision-making. Shorn of the requirement that a payment be intended to corrupt decision-making, the AKS would make felons out of doctors, patients, hospitals, medical product manufacturers, and even charitable family members and friends who provide support that allows a patient to access vital medical care that the patient's doctor has already determined to be necessary.

The court of appeals' only response to these well-founded concerns was that "[i]t seems very unlikely to us that a charitable or concerned family member who is merely trying to help a loved one would meet th[e] mens rea element" of the AKS. App., *infra*, 23a-24a. The court seemed focused on the fact that the family member's intent was to get their loved one the medication, not the federal reimbursement. See *id.* at 24a. But that is a false dichotomy, as the family member would only offer the $13,000 because the government was providing its insurance benefit, such that the patient actually received the drug. At the very least, under the court of

appeals' interpretation, a family member who knows of the AKS's proscriptions—*e.g.*, a lawyer, judge, or many people involved in the healthcare industry—would be criminally liable under the AKS. Moreover, the court's supposition is belied by the aggressive history of government enforcement actions targeting charities for criminal and civil sanctions and OIG's advisory opinions denying requests for independent charity programs. Notably, OIG refused to even consider petitioner's advisory opinion request for an independent charity program to support ATTR-CM patient access to tafamidis because the proposed program was too similar to ongoing government enforcement actions. *Id.* at 34a.

Further, in September 2022, OIG issued an advisory opinion finding the AKS prohibits a 501(c)(3) charitable organization funded by a coalition of manufacturers from providing cost-sharing assistance to cancer patients for 90% of oncology medications and declining to exercise its discretion not to impose AKS sanctions for this proposed charitable program. See U.S. Dep't of Health and Human Servs., OIG Advisory Op. No. 22-19 (Sept. 30, 2022). Consistent with an OIG 2005 bulletin suggesting such a collaborative program would be acceptable, the program was designed to encompass some fifty different treatments from multiple manufacturers, so as to avoid improperly influencing the doctor or patient's choice among treatment options. *Id.* at 3. Contrary to its 2005 suggestion, however, OIG rejected the proposed collaborative program not because the program would lead to improper prescribing or use, but rather for the same reason that it rejected petitioner's proposed program: because OIG found that assisting financially needy cancer patients meet their copay obligations would "influence"

the patient's decision to fill their doctor's prescription. *Id.* at 13-14.

The court of appeals' decision, according to its terms, sweeps even more broadly. For example, under the court of appeals' construction, a company or medical association that provides educational materials to help physicians diagnose a condition more accurately and thus prescribe a treatment for that condition might be seen as violating the AKS. Indeed, even a patient's payment and a doctor's receipt of payment for an office visit—the purpose of which is for the doctor to "order[]" or "recommend[]" a specialist whose services will be reimbursed by Medicare—would implicate the AKS. Petitioner agrees that such payments *could* implicate the AKS if, for example, the doctor was merely acting as a pill mill or the patient paid extra to be prescribed a longer rehabilitation program than necessary, but that is because such payments *corrupt* the medical decision-making. Respondents and the court of appeals' construction requires no such corruption.

This Court need not speculate about the AKS's scope under respondents' construction, however, because respondents already have made clear that their interpretation reaches many beneficial business practices and activities designed to facilitate patient access to medical treatment. For example, OIG recently opined that a program that provides lodging to families when treatment is available only far from home would implicate the AKS. See U.S. Dep't of Health and Human Servs., OIG Advisory Op. No. 20-02, at 2 (Jan. 15, 2020). Although OIG exercised its discretion not to "impose administrative sanctions," it left no doubt that it believed

the program "could potentially generate a prohibited remuneration under the anti-kickback statute if the requisite intent * * * were present." *Ibid.*

Other recent OIG advisory opinions provide additional concrete examples of the types of beneficial activities that fall within the sweep of the AKS under respondents' construction and have been able to proceed only because OIG determined in its discretion to allow them. See, *e.g.*, U.S. Dep't of Health and Human Servs., OIG Advisory Op. No. 16-09 (Sept. 16, 2016) (concluding that installing refrigerator systems to stock manufacturers' sole-source vaccine "could potentially generate prohibited remuneration," but OIG in its discretion would not take enforcement action); U.S. Dep't of Health and Human Servs., OIG Advisory Op. No. 15-11 (Aug. 5, 2015) (concluding that providing a Breakthrough Therapy cancer medicine for free for a limited time to patients experiencing a delay in the insurance approval process "could potentially generate prohibited remuneration" under the AKS, but OIG in its discretion would not impose administrative sanctions). While OIG's agreement not to impose sanctions on such arrangements is welcome, this Court has repeatedly made clear that prosecutorial discretion is not a meaningful or enforceable limitation on criminal liability.

This case, moreover, is an excellent vehicle to decide these important questions because it presents a clean issue of statutory interpretation that is dispositive of the case. Petitioner's proposed program has been developed in a well-defined administrative record and was decided by the courts below on summary judgment. App., *infra*, 4a, 27a. This record makes clear—following the advisory opinion process that is mandated by statute—that petitioner's proposed program is not intended to and would

not cause improper prescribing or utilization. If the AKS requires an element of corruption—as its text, history, and structure demonstrate—then petitioner's program would not be prohibited under the AKS.

Furthermore, because petitioner brought this case against the government under the APA and Declaratory Judgment Act, it is one of the few vehicles, and perhaps the only clean vehicle, for the Court to consider the proper interpretation of the AKS in this context. Issues regarding the reach of the AKS historically have arisen in government enforcement actions but have evaded review because penalties for violating the AKS are so severe—*e.g.*, up to 10 years in prison, crushing fines and penalties for the AKS violation and resulting FCA violations where claims for federal payment resulted from the kickbacks, and potential exclusion from Medicare (42 U.S.C. 1320a-7(b)(7); *id.* at 1320a-7b(g)). Healthcare product companies and other healthcare stakeholders and charities cannot afford to fight an enforcement action through trial and appeal and risk severe monetary penalties and exclusion from federal healthcare programs. The Court is therefore unlikely to have another opportunity to address this important issue in the foreseeable future.

By ignoring the AKS's history and clear textual indicia of Congress's intent, the court of appeals read the element of corruption, which has been part of the AKS since its enactment, out of the statute. In so doing, it ignored this Court's frequent reminder that "Congress * * * does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes." *Whitman* v. *American Trucking Ass'ns*, 531 U.S. 457, 468 (2001). The court of appeals thereby subjects a wide

range of routine, even beneficial interactions to potential felony liability, subject only to the government's discretionary acts of grace. This Court's intervention is warranted, and this case is the proper vehicle in which to do so.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

DOUGLAS HALLWARD-DRIEMEIER
SAMANTHA BARRETT BADLAM
STEFAN P. SCHROPP
ROPES & GRAY LLP

ILANA H. EISENSTEIN
DLA PIPER LLP (US)

Counsel for Petitioner

OCTOBER 2022

APPENDIX

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 2021

Docket No. 21-2764-cv

PFIZER, INC.,
Plaintiff-Appellant,

v.

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES, XAVIER BECERRA, in his official capacity as Secretary of Health and Human Services, UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES OFFICE OF THE INSPECTOR GENERAL, CHRISTI A. GRIMM, in her official capacity as Principal Deputy Inspector General of and Senior Official in the United States Department of Health and Human Services Office of Inspector General,
Defendants-Appellees.

Argued: May 25, 2022

Decided: July 25, 2022

Before: POOLER, SACK, and NATHAN, *Circuit Judges*.

Plaintiff-appellant Pfizer, Inc. brought this action in the United States District Court for the Southern District of New York under the Administrative Procedure Act, 5 U.S.C. § 706(2), challenging an advisory opinion issued by the United States Department of Health and Human Services Office of Inspector General ("HHS OIG"). Pfizer produces and sells a drug called tafamidis

that treats a rare, progressive heart condition known as transthyretin amyloid cardiomyopathy. To make the expensive treatment more affordable, Pfizer proposed a Direct Copay Assistance Program, through which Pfizer would directly cover the cost of a patient's co-pay for tafamidis. HHS OIG issued an advisory opinion stating that the Direct Copay Assistance Program would violate the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b)(2)(B). The district court (Mary K. Vyskocil, *J.*) granted summary judgment to defendants, rejecting Pfizer's argument that liability under the Anti-Kickback Statute requires an element of "corrupt" intent. We agree with the district court that the agency's interpretation of the Anti-Kickback Statute is not contrary to law. We therefore

AFFIRM the judgment of the district court.

DOUGLAS HALLWARD-DRIEMEIER, Ropes & Gray LLP, Washington, DC (Samantha Barrett Badlam, Ropes & Gray LLP, Washington, DC; Joan McPhee, Ropes & Gray LLP, New York, NY; Ilana H. Eisenstein, DLA Piper LLP, Philadelphia, PA, *on the brief*), *for Plaintiff-Appellant*;

REBECCA S. TINIO (Benjamin H. Torrance, *on the brief*), *for Damian Williams, United States Attorney for the Southern District of New York, New York, NY, for Defendants-Appellees*.

SACK, *Circuit Judge*:

Pfizer, Inc. produces and sells a drug called tafamidis, which treats a rare, progressive heart condition known as transthyretin amyloid cardiomyopathy ("ATTR-CM"). Tafamidis is considered a breakthrough treatment – it is currently the only drug approved by the

United States Food and Drug Administration ("FDA") to treat ATTR-CM. It also carries an extremely high price tag: $225,000 per year.

Because ATTR-CM disproportionately affects older Americans, most ATTR-CM patients are covered by Medicare. Under Medicare's pricing formula, patients who use tafamidis are responsible for a co-pay of about $13,000 per year. Concerned that many patients cannot afford this price, Pfizer proposed a program, called the Direct Copay Assistance Program (the "Direct Program"), which would directly cover a patient's co-pay if the patient met specified eligibility criteria. Pfizer sought an advisory opinion from the United States Department of Health and Human Services Office of Inspector General ("HHS OIG") to ensure that its proposal did not run afoul of federal laws.

HHS OIG ultimately issued an unfavorable advisory opinion, concluding that the Direct Program would violate the federal Anti-Kickback Statute ("AKS"), 42 U.S.C. § 1320a-7b(b)(2)(B), if implemented with the intent specified in the statute. Pfizer then brought this action in the United States District Court for the Southern District of New York under the Administrative Procedure Act ("APA"), 5 U.S.C. § 706(2), challenging the agency's interpretation of the AKS as contrary to law. Following cross-motions for summary judgment, the district court (Mary K. Vyskocil, *Judge*) granted summary judgment to the government on the APA claim. *Pfizer, Inc. v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-4920, 2021 WL 4523676 (S.D.N.Y. Sept. 30, 2021). The court rejected Pfizer's narrower reading of the AKS, which would require an element of "corrupt" intent to impose liability. The district court concluded that the

agency's interpretation was not contrary to law. For the reasons set forth below, we AFFIRM the judgment of the district court.

BACKGROUND

Factual Background

The following facts, which are substantially undisputed by the parties, are drawn from Pfizer's complaint and the administrative record before HHS OIG.

A. Pfizer's Drug

ATTR-CM is a rare cardiac condition characterized by deposits of amyloid protein in the heart muscle, "causing the heart to stiffen and thereby limiting its ability to pump blood to the body." Compl. ¶ 3, at A.12. ATTR-CM patients "experience a progressive decline in function, beginning with fatigue and shortness of breath and ending with potential heart failure, inability to perform even the most basic daily activities, and eventually death." *Id.* Without treatment, patients have a median life expectancy of two to three-and-a-half years after diagnosis. An estimated 100,000 to 150,000 Americans, most of whom are elderly, suffer from the condition.

Through nearly two decades of research and testing, Pfizer developed a treatment for ATTR-CM called tafamidis, which it sells under the brand names Vyndaqel and Vyndamax. Tafamidis is not a cure, but it slows the decline in quality of life, reduces hospitalization rates, and typically helps patients live longer. In May 2019, the FDA approved tafamidis for the treatment of ATTR-CM, making it the first, and currently the only, FDA-approved pharmacological treatment for the disease. Other treatments exist, but they are "off-label," i.e., not

approved by the FDA to treat ATTR-CM. Some patients may also have non- pharmacological options, such as an organ transplant.

Pfizer charges $225,000 for a one-year course of tafamidis. According to Pfizer, the price of the drug reflects its "strong efficacy and safety profile, its slowing of the decline in functional status and quality of life, and the relatively small population of patients with ATTR-CM." Compl. ¶ 5, at A.13. The FDA designated tafamidis as an "orphan drug," which is a special classification that offers financial incentives, including potential market exclusivity, for the development of treatments for rare disease. Pfizer asserts that such drugs have nonetheless become increasingly expensive for pharmaceutical companies to develop. *Id.* ¶ 32, at A.21. Pfizer also contends that the "off-label" options for treating ATTR-CM are more expensive than tafamidis, as is a heart or liver transplant. *Id.* ¶ 5, at A.13; A.79-80. HHS, on the other hand, cites a 2020 study concluding that tafamidis is "the most expensive cardiovascular drug ever launched in the United States."[1]

B. The Direct Copay Assistance Program

Because ATTR-CM disproportionately affects older persons, most ATTR- CM patients are beneficiaries of Medicare.[2] Almost all Medicare plans provide coverage

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[1] OIG Advisory Op. No. 20-05, 12 (Dep't of Health & Human Servs. Sept. 18, 2020), at A.219 (citing Dhruv S. Kazi et al., *Cost-Effectiveness of Tafamidis Therapy for Transthyretin Amyloid Cardiomyopathy*, 141 CIRCULATION RES. 1214 (2020), https://ahajournals.org/doi/epub/10.1161/CIRCULATIONAHA.119.045093).

[2] *See Who is eligible for Medicare?*, U.S. Dep't of Health & Human Servs., https://hhs.gov/answers/medicare-and-medicaid/who-is-eligible-for-medicare/index.html ("Generally, Medicare is available for

for tafamidis, but under Medicare Part D – which covers outpatient prescription drugs – beneficiaries remain responsible for certain specified deductibles and co-pays. As relevant to this case, Part D beneficiaries are responsible for 100% of an initial deductible, which in 2020 was $435. After satisfying that deductible, beneficiaries enter various coverage phases, where they are responsible for a 25% coinsurance payment until they reach the "catastrophic coverage" threshold. Upon reaching "catastrophic coverage," which in 2020 was $2,652 out-of-pocket (including the prior deductible and coinsurance payments), beneficiaries continue to pay 5% of the cost for brand-name medications. There is no upper limit on that 5% contribution.

From the government's perspective, as explained by HHS OIG, this cost- sharing structure "expos[es] [Medicare] beneficiaries to the economic effects of drug pricing" and thereby acts as "a market safeguard that Congress included [in Medicare Part D] to protect against inflated drug prices." OIG Advisory Op. No. 20-05, 17-18 (Dep't of Health & Human Servs. Sept. 18, 2020), at A.224-25. The government provides a subsidy to assist lower-income Medicare beneficiaries, but only if they fall below 150% of the federal poverty level, or an annual income of $19,140. Survey data suggests that, in 2016, approximately 29% of Part D participants qualified for this subsidy.[3]

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people age 65 or older, younger people with disabilities[,] and people with End Stage Renal Disease (permanent kidney failure requiring dialysis or transplant).").

[3] Compl. ¶ 49 n.8, at A.27 (citing Jack Hoadley et al., *Medicare Part D in 2016 and Trends over Time*, Kaiser Family Foundation (Sept. 16, 2016), https://www.kff.org/report-section/medicare-part-d-in-

Under the payment structure outlined above, Medicare beneficiaries who use tafamidis are responsible for a co-pay of approximately $13,000 per year. Pfizer's concern is that many "middle-income" Medicare patients, who do not otherwise qualify for co-pay assistance options, will be unable to afford that price. Compl. ¶ 7, at A.13-14. Even if the company cut the price of tafamidis in half, Pfizer contends, the Medicare co-pay would be approximately $8,000, which remains a significant financial barrier for many patients. *Id.* ¶ 53, at A.28. Pfizer pointed to one study indicating that 49% of cancer patients failed to refill their prescriptions when the out-of-pocket costs exceeded $2,000.[4]

To address this concern, Pfizer proposed the Direct Copay Assistance Program. Through this program, Pfizer would cover almost the entirety of a Medicare beneficiary's co-pay for tafamidis so long as: (1) the patient was prescribed tafamidis to treat ATTR-CM, (2) the patient is a U.S. resident, and (3) the patient meets program criteria for financial need, which are tailored to address the burden that "middle-income" patients face in acquiring tafamidis. Patients who are eligible for the Direct Program would be responsible for only $35 per month, with Pfizer covering the remainder of the approximately $13,000 annual co-pay. The federal government, through Medicare, would pick up the rest of the $225,000 tab.

2016-and-trends-over-time-section-4-the-low-income-subsidy-program).

[4] Compl. ¶ 51 n.10, at A.27 (citing Jalpa A. Doshi et al., *Association of Patient Out- of-Pocket Costs with Prescription Abandonment and Delay in Fills of Novel Oral Anticancer Agents*, 36 J. OF CLINICAL ONCOLOGY 476 (2018)).

Pfizer emphasized, both in its submissions to HHS and in its complaint in the district court, that it would not use the Direct Program to solicit new patients for tafamidis – a patient would only become eligible for the Direct Program after a physician prescribes the treatment. Compl. ¶ 63, at A.30; A.81. Pfizer also stated that the Direct Program provides no financial incentive to physicians to favor a tafamidis prescription. Compl. ¶ 65, at A.31; A.84.

C. The Anti-Kickback Statute

The statutory scheme at issue is the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b. Congress first enacted the AKS in 1972 to combat fraud and abuse in connection with Medicare and Medicaid. The AKS prohibits, in relevant part, "knowingly and willfully offer[ing] or pay[ing] any remuneration" to "induce" an individual to purchase a federally reimbursable healthcare product. *Id.* § 1320a-7b(b)(2)(B). Liability under the AKS includes both civil and criminal penalties, including the possibility of a pharmaceutical company's complete exclusion from federal reimbursement for its drugs. *See id.* § 1320a-7(b)(7). At least in part because the sanctions under the AKS are severe, Congress created a process by which parties may seek advisory opinions from HHS OIG as to whether a proposed course of action would violate the AKS. *Id.* § 1320a-7d(b). Advisory opinions are binding on both the government and the requesting parties, unless set aside by a reviewing court. *Id.* § 1320a-7d(b)(4).

Procedural History

A. HHS OIG Advisory Opinion

On June 27, 2019, Pfizer submitted a request to HHS OIG for an advisory opinion on the legality of the Direct Program. On December 9, 2019, HHS OIG informed Pfizer that it had reached an unfavorable opinion and would issue an advisory opinion to that effect if Pfizer did not voluntarily withdraw the request. In response, Pfizer sought further consultation with the agency to explain "why there was little risk of fraud or abuse" with the Direct Program, and how the program would be limited to patients who "had been prescribed tafamidis by their physician[] and were only unable to access their medication due to financial need." Compl. ¶¶ 106-07, at A.43. Nevertheless, on May 26, 2020, HHS OIG informed Pfizer that its position remained unchanged. Pfizer did not withdraw its request, and the agency issued its advisory opinion on September 18, 2020.

In the advisory opinion, HHS OIG explained that the Direct Program "plainly would" involve prohibited conduct under the AKS: Pfizer proposes to "provide remuneration in the form of a valuable Subsidy Card to eligible Medicare beneficiaries," which would in turn "induce that beneficiary to purchase [tafamidis] by removing the financial impediment" of the cost-sharing obligation. OIG Advisory Op. No. 20-05, 14-16, at A.221-23. The agency concluded that the Direct Program "would present more than a minimal risk of fraud and abuse under the Federal anti-kickback statute," and is indeed "highly suspect . . . because one purpose of the [Direct Program]—perhaps the primary purpose—would be to induce Medicare beneficiaries to purchase [Pfizer's] federally reimbursable Medications." *Id.* at 16, at A.223.

The agency "[did] not express any opinion as to the appropriateness of [tafamidis's] list price," but noted that the Direct Program "would effectively abrogate statutory cost-sharing requirements under the Medicare Part D program," and consequently "drive up costs to the Medicare program."[5] *Id.* at 17-18, at A.224-25.

B. Federal Court Action

Meanwhile, on June 26, 2020, Pfizer filed this action in the United States District Court for the Southern District of New York challenging, in relevant part, HHS OIG's advisory opinion on the Direct Program as contrary to law under the Administrative Procedure Act, 5 U.S.C. § 706(2). The parties filed cross-motions for summary judgment, and the government filed for dismissal of certain claims that are not on appeal.

On September 30, 2021, the district court granted summary judgment to the government on the APA claim. *Pfizer, Inc. v. U.S. Dep't of Health & Human Servs.*, No. 1:20-cv-4920, 2021 WL 4523676 (S.D.N.Y. Sept. 30, 2021). Pfizer's primary argument is that the

[5] In 2005, HHS OIG published guidance that elaborated on the risks of co-pay assistance programs from drug manufacturers: "[C]ost-sharing subsidies can be very profitable for manufacturers, providing additional incentives for abuse. So long as the manufacturer's sales price for the product exceeds its marginal variable costs plus the amount of the cost-sharing assistance, the manufacturer makes a profit. These profits can be considerable, especially for expensive drugs for chronic conditions." 70 Fed. Reg. 70,623, 70,626 (Nov. 22, 2005). The agency reiterated this concern in 2014, explaining that "the ability to subsidize copayments for their own products may encourage manufacturers to increase prices, potentially at additional cost to Federal health care programs and beneficiaries who are unable to obtain copayment support." 79 Fed. Reg. 31,120, 31,122 (May 30, 2014).

Direct Program must be administered with a "corrupt" intent in order to violate the AKS, and Pfizer defines "corrupt" intent as a quid pro quo that "improperly or corruptly" skews the patient's decision- making. *See* Appellant's Br. 10, 20. The district court disagreed, finding nothing in the text of the AKS that is "amenable to a reading that there be corruption involved." *Id.* at *11. Rather, the district court reasoned, the plain meaning of the terms "remuneration" and "induce" describe a payment that persuades another to take a certain course of action. *Id.* at *11-13. The district court concluded: "Because the stated intent of the payments Pfizer proposes here [is] to increase the number of Medicare beneficiaries who purchase the drug, the Court is unable to . . . issue judgment in [Pfizer's] favor on the APA claim, since the AKS prohibits all remuneration that induces purchases of drugs like tafamidis . . . ." *Id.* at *15.

Pfizer appeals.

DISCUSSION

I. Standard of Review

"On appeal from a grant of summary judgment in a challenge to agency action under the APA, we review the administrative record and the district court's decision *de novo*."[6] *Yale-New Haven Hosp. v. Leavitt*, 470

[6] Where the plaintiff challenges an agency's interpretation of a statute that Congress has designated for administration by that agency, this Court also applies the analytical framework described in *Chevron U.S.A., Inc. v. National Resources Defense Council, Inc.*, 467 U.S. 837 (1984), to determine if the agency's interpretation is owed any deference. *Chevron* first requires that we determine whether the statute "is silent or ambiguous with respect to the specific issue." *Id.* at 843. Neither the district court nor Pfizer raises the issue of *Chevron* deference, presumably because they find no ambiguity

F.3d 71, 77 (2d Cir. 2006) (internal quotation marks omitted). Under the APA, agency actions – including advisory opinions – must be set aside if they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A).

II. APA Claim

A. Textual Arguments

When interpreting a statute, "[w]e begin with the text." *Facebook, Inc. v. Duguid*, 141 S. Ct. 1163, 1169 (2021); *see also Katz v. Focus Forward, LLC*, 22 F.4th 368, 372 (2d Cir. 2022) ("If the statutory language is unambiguous, we construe the statute according to the plain meaning of its words." (internal quotation marks omitted)).

The AKS provides, in relevant part:

> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> . . . .
>
> (B) to purchase . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than

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in the AKS on this question. Because we find no ambiguity and agree with the district court's interpretation of the statute, we too do not rely on *Chevron* deference in reaching our conclusion.

> $100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b)(2)(B). Pfizer argues that three phrases in the statute's text suggest an element of "corrupt" intent: (1) "any remuneration . . . to induce," (2) "(including any kickback, bribe, or rebate)," and (3) "willfully." We disagree.

a. "[A]ny remuneration . . . to induce"

Pfizer first contends that the phrase "any remuneration . . . to induce" necessarily connotes a quid pro quo, and that quid pro quos are "designed to corrupt the recipient's behavior." Appellant's Br. 26. The district court disagreed that a quid pro quo is required for AKS liability, reasoning that "the plain meaning of the word 'inducement' implies a 'one-way' transaction, where the requestor simply gets someone to take an action." *Pfizer*, 2021 WL 4523676, at *13. For the purposes of this appeal, we do not need to decide whether the AKS contains a quid pro quo element. HHS OIG expressly stated in the advisory opinion that the Direct Program would "operate as a *quid pro quo*," in that Pfizer "would offer remuneration . . . to the beneficiary in return for the beneficiary purchasing [tafamidis]." OIG Advisory Op. No. 20-05, 14, at A.221. "Quid pro quo" translates literally to "something for something." *See* BLACK'S LAW DICTIONARY (11th ed. 2019) (defining "quid pro quo" as "[a]n action or thing that is exchanged for another action or thing of more or less equal value; a substitute"). We have no doubt that at least some kind of quid pro quo, direct or indirect, exists here. *See* Appellees' Br. 25 n.5 ("[W]hether there was a quid pro quo in

this case—in the sense of an exchange of one thing for another—is not at issue.").

However, we do not think it is the case, as Pfizer suggests, that every quid pro quo is inherently corrupt. There are, of course, many such transactions made without corrupt intent. A commercial contract, for example, is literally a quid pro quo – a "this for that." Arguing that "quid pro quo" necessarily implies corruption, Pfizer points to a case in the bribery context where we explained that "[t]he 'corrupt' intent necessary to a bribery conviction is in the nature of a quid pro quo requirement." *United States v. Alfisi*, 308 F.3d 144, 149 (2d Cir. 2002). But the question in *Alfisi* was how "bribery" should be defined for the purposes of criminal liability under 18 U.S.C. § 201(b)(1)(A). We concluded that to be a bribe, which is by definition corrupt, a payment must involve a quid pro quo element. *Id.* So be it – but that does not mean the inverse is true, i.e., that all quid pro quo transactions are necessarily corrupt. Otherwise, any number of commonplace transactions – paying money for a meal, for example – would, according to Pfizer's theory, be made with corrupt intent.

Pfizer further argues that the word "induce," even on its own, implies a corrupting influence or ill motive, but we find no support for this proposition. The plain meaning of "induce" is to "entic[e] or persuad[e] another person to take a certain course of action." BLACK'S LAW DICTIONARY (11th ed. 2019); *see also* AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE (5th ed. 2022) (defining "induce" as "[t]o lead or move, as to a course of action, by influence or persuasion," or "[t]o bring about or stimulate the occurrence of; cause," as in "a drug used to induce labor"). The word

is thus neutral with regard to intent – one can persuade another to take an action with good or bad motives.

Pfizer relies heavily on two cases to argue that the word "induce" implies corruption. Neither supports its position.

In *United States v. Zacher*, 586 F.2d 912 (2d Cir. 1978), this Court considered a case in which a nursing home administrator accepted supplemental payments from families of Medicaid patients equal to the difference between the Medicaid reimbursement rate and the private pay the nursing home ordinarily charged. We concluded that the defendant was not liable for accepting bribes under the AKS because the payments merely "influenc[e]d [the defendant] to admit the patient," rather than "induc[ing] him to act dishonestly." *Id.* at 916. We further noted that "[k]ickbacks, rebates and bribes," as prohibited under the AKS, "each involve a corrupt payment." *Id.* But the appeal in *Zacher* "turn[ed] on the question of whether the payments received by [the defendant] *can be considered bribes* within the meaning of th[e] [AKS]," not whether *any* payment prohibited by the AKS must involve dishonesty. *Id.* at 914 (emphasis added). Moreover, in *Zacher* we interpreted the original 1972 version of the AKS, which prohibited only kickbacks, bribes, or rebates. Congress did not expand the statute to cover "any remuneration" until the statute was amended in 1977. *See* Pub. L. No. 95- 142, § 4(a), 91 Stat. 1175, 1180 (1977). *Zacher*'s reading of the 1972 statute thus gives us little guidance on resolving the current appeal.

Pfizer argues that the 1977 amendment is immaterial to our consideration of *Zacher*, because it did not alter the statute's original focus on corrupt payments. But

the plain meaning of "remuneration" is clearly broader than a kickback, bribe, or rebate: "Remuneration" means "[p]ayment; compensation, esp[ecially] for a service that someone has performed," and the modifier "any" further broadens the scope of the phrase. BLACK'S LAW DICTIONARY (11th ed. 2019).[7]

Pfizer's second case, *United States v. Krikheli*, 461 F. App'x 7 (2d Cir. 2012), was an unpublished summary order affirming the jury instructions for an AKS charge. The district court instructed the jury that "[t]o induce a person means to attempt to gain influence over the reason or judgment of that person," and the government needed to prove "that the remuneration was offered or paid as a quid pro quo in return for the referring of the patient." *Id.* at 11. A panel of this Court concluded that those instructions "accurately described the law." *Id.* Even treating this non-precedential case as though it were authoritative, nothing in *Krikheli*'s instructions required an element of corruption to find an inducement. As discussed above, a quid pro quo transaction is not necessarily corrupt. And "to gain influence over the reason or judgment" of a person is simply the definition of

[7] Our sister circuits have also noted Congress's broadening of the AKS through the 1977 amendment. *See, e.g.*, *Hanlester Network v. Shalala*, 51 F.3d 1390, 1398 (9th Cir. 1995) ("The phrase 'any remuneration' was intended to broaden the reach of the [AKS] which previously referred only to kickbacks, bribes, and rebates."); *United States v. Greber*, 760 F.2d 68, 72 (3d Cir. 1985) ("By adding 'remuneration' to the [AKS] in the 1977 amendment, Congress sought to make it clear that even if the transaction was not considered to be a 'kickback' for which no service has been rendered, payment nevertheless violated the Act.").

"persuade," which is neutral in connotation. Pfizer's attempt to read a more sinister intent into the phrase "any remuneration . . . to induce" fails.

b. "([I]ncluding any kickback, bribe, or rebate)"

Pfizer next argues that the parenthetical following "any remuneration" – "(including any kickback, bribe, or rebate)" – limits the statute to corrupt payments. As an initial matter, the district court disagreed with Pfizer as to whether the term "rebate" implies corrupt intent: The court reasoned that the plain meaning of "rebate" is neutral, *Pfizer*, 2021 WL 4523676, at *12 (quoting BLACK'S LAW DICTIONARY (11th ed. 2019), which defines "rebate" as "[a] return of part of a payment, serving as a discount or reduction"), whereas Pfizer insists that the term "rebate" in the AKS refers to a particular kind of corrupt payment for Medicare and Medicaid services.

Even if Pfizer were correct on that score, the Supreme Court has made clear that the word "includes," when used in a statute, "is usually a term of enlargement, and not of limitation." *Burgess v. United States*, 553 U.S. 124, 131 n.3 (2008) (internal quotation marks omitted); *see also Google LLC v. Oracle Am., Inc.*, 141 S. Ct. 1183, 1197 (2021) (explaining that, for a statutory provision involving the fair use doctrine, the "provision's list of factors is not exhaustive" because it uses "the words 'include' and 'including'"); *Christopher v. SmithKline Beecham Corp.*, 567 U.S. 142, 162 (2012) ("[T]he definition [of a 'sale' in a section of the Fair Labor Standards Act of 1938] is introduced with the verb 'includes' instead of 'means.' This word choice is significant because it makes clear that the examples enumerated in

the text are intended to be illustrative, not exhaustive."). Therefore, the listed examples of "kickback, bribe, or rebate" in the AKS do not limit the meaning of "any remuneration"; they are merely non-exhaustive examples.

Pfizer counters with two canons of statutory interpretation, *ejusdem generis* and *noscitur a sociis*. We do not think either is applicable. *Ejusdem generis* refers to the understanding that "[w]here general words follow specific words in a statutory enumeration, the general words are construed to embrace only objects similar in nature to those objects enumerated by the preceding specific words." *Circuit City Stores, Inc. v. Adams*, 532 U.S. 105, 114-15 (2001) (internal quotation marks omitted). This canon applies only where the general phrase *follows* the specific list of items, making it a "residual" phrase. *See id.* (applying *ejusdem generis* to a statute listing "seamen, railroad employees, or any other class of workers engaged in foreign or interstate commerce"). Here, by contrast, the term "any remuneration" comes *before* the specific list of items and cannot fairly be characterized as a "residual" phrase. Rather, as noted above, the parenthetical – "(including any kickback, bribe, or rebate)" – is better read as a list of non- exhaustive examples.

Noscitur a sociis refers to the rule that "an ambiguous term may be 'given more precise content by the neighboring words with which it is associated.'" *United States v. Stevens*, 559 U.S. 460, 474 (2010) (quoting *United States v. Williams*, 553 U.S. 285, 294 (2008)). "Any remuneration," however, is not ambiguous, at least in this context, and it therefore must be read according to its plain meaning.

c. "[W]illfully"

Pfizer's final textual argument is that the "willful" mens rea required by the AKS suggests "an element of corruption or improper influence," because a "willful" act is one taken with a "bad purpose." Appellant's Br. 34 (quoting *Bryan v. United States*, 524 U.S. 184, 191 (1998)). But a "bad purpose" is not synonymous with a corrupt intent – it is more accurately understood as "a voluntary, intentional violation of a known legal duty." *United States v. Bishop*, 412 U.S. 346, 360 (1973); *see also Cheek v. United States*, 498 U.S. 192, 200-01 (1991) (explaining that "willfully," as defined by a "bad purpose," does not require "proof of any motive other than an intentional violation of a known legal duty" (quoting *United States v. Pomponio*, 429 U.S. 10, 12 (1976))). According to a contemporaneous House Budget Committee report, Congress added the willfulness element to the AKS to avoid punishing "an individual whose conduct, while improper, was inadvertent." H.R. Rep. 96-1167, at 59 (1980). In other words, the AKS does not apply to those who are unaware that such payments are prohibited by law and accidentally violate the statute.[8] Contrary to Pfizer's assertion, the mens rea element goes no further.

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[8] The AKS specifies that "a person need not have actual knowledge of this section or specific intent to commit a violation of this section" in order to be held liable, 42 U.S.C. § 1320a-7b(h), but that does not override the willfulness element. In the context of certain "highly technical" statutory schemes, the Supreme Court has required "that the jury . . . find that the defendant was aware of the *specific* provision of the [law] that he was charged with violating." *Bryan*, 524 U.S. at 194 (emphasis added). Through § 1320a-7b(h), Congress simply ensured that the AKS would avoid that heightened mens rea requirement.

B. Other Arguments

Pfizer makes several additional arguments, beyond the text of the AKS, as to why the statute should be read with an element of "corrupt" intent. We find none to be persuasive.

a. Relationship with Other Statutes

Pfizer argues that the AKS, with its criminal penalties, should be read more narrowly than the Beneficiary Inducement Statute ("BIS"), 42 U.S.C. § 1320a-7a, a civil statute enacted in 1996 that also seeks to combat fraud against government healthcare programs. The BIS imposes liability on any person or entity who

> offers to [transfer] or transfers remuneration to any individual eligible for benefits under [a federal or state healthcare program] that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under [a federal or state healthcare program].

Assuming the heightened requirement does not apply, a person can "willfully" violate a statute as long as he knows that his conduct is illegal, even if he is not aware of the exact statutory provision that his conduct violates. *See, e.g.*, *id.* at 190 (affirming the trial court's instruction that "[a] person acts willfully if he acts intentionally and purposefully with the intent to do something the law forbids, that is, with the bad purpose to disobey or disregard the law. . . [T]he person need not be aware of the specific law or rule that his conduct may be violating" (internal quotation marks omitted)).

42 U.S.C. § 1320a-7a(a)(5). According to Pfizer, Congress intended the BIS to be a broader, civil counterpart to the AKS, which means that we should interpret the term "induce" in the AKS more narrowly than the term "influence" in the BIS.

We find no reason to interpret the AKS by reference to the text of the BIS. The AKS is not simply a narrower version or criminal counterpart of the BIS – although the two statutes have similar subject matter, they prohibit different activities. The AKS focuses on induced purchases of federally reimbursable goods or services, whereas the BIS prohibits improperly influencing a beneficiary's choice of the "particular provider, practitioner, or supplier" from whom they purchase such goods or services. *Id.* Accordingly, HHS OIG concluded that the Direct Program would implicate the AKS but *not* the BIS: The Direct Program might seek to induce purchases of tafamidis, but it does not attempt to influence the beneficiary's choice of provider from whom they would obtain the medication. OIG Advisory Op. No. 20-05, 24-27, at A.231-34.[9]

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[9] HHS OIG explained that, "[f]or purposes of the [BIS], pharmaceutical manufacturers are not 'providers, practitioners, or suppliers' unless they also own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs." OIG Advisory Op. No. 20-05, 24, at A231 (citing OIG, Special Advisory Bulletin, *Offering Gifts and Other Inducements to Beneficiaries* (Aug. 2002), https://oig.hhs.gov/fraud/docs/alerts Andbulletins/SABGiftsandInducements.pdf). Because Pfizer is a pharmaceutical manufacturer that "does not own or operate, directly or indirectly, any pharmacies that dispense [tafamidis,] . . . [Pfizer] is not a 'provider, practitioner, or supplier' for purposes of the [BIS]." *Id.* at 24-25, at A231-32. Thus, the agency concluded, the Direct Pro-

Furthermore, unlike the statutory provisions at issue in *United States v. Sun-Diamond Growers of California*, 526 U.S. 398 (1999), upon which Pfizer heavily relies, the BIS and AKS were not enacted through the same bill, or even close in time. *See id.* at 404. The Supreme Court has cautioned against finding "[n]egative implications raised by disparate provisions" when "the two relevant provisions were not considered or enacted together." *Gomez-Perez v. Potter*, 553 U.S. 474, 486 (2008); *see also Lindh v. Murphy*, 521 U.S. 320, 330 (1997) ("[N]egative implications raised by disparate provisions are strongest when the portions of a statute treated differently had already been joined together and were being considered simultaneously when the language raising the implication was inserted."). Thus, there is little utility in comparing the language of the BIS to that of the AKS.

Pfizer also urges us to read a corruption element into the AKS's relationship with the False Claims Act ("FCA"), 31 U.S.C. § 3729. In 2010, Congress added a provision to the AKS that states: "[A] claim that includes items or services resulting from a violation of [the AKS] constitutes a false or fraudulent claim for the purposes of [the FCA]." 42 U.S.C. § 1320a-7b(g). This provision allows the government to recover losses from claims submitted in violation of the AKS, using the procedural mechanisms established by the FCA. It does not, as Pfizer contends, mean that all AKS violations are inherently "corrupt." FCA liability can be premised on "specific representations about the goods or services

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gram "would not implicate the [BIS] with respect to [Pfizer], notwithstanding the fact that this same remuneration stream would implicate the Federal anti-kickback statute." *Id.* at 25, at A.232.

provided" which, while not expressly false, "fail[] to disclose noncompliance with material statutory, regulatory, or contractual requirements." *Universal Health Servs., Inc. v. United States ex rel. Escobar*, 579 U.S. 176, 190 (2016). In other words, if a company submits a claim for federal reimbursement that is based on goods or services rendered in violation of the AKS, then the claim may be "false" for the purposes of the FCA simply because it is the product of a material statutory violation.

b. Overcriminalization

Pfizer next contends that the agency's interpretation of the AKS "criminalizes a range of 'beneficial activities'" and leads to an "absurd and unjust result." Appellant's Br. 38 (quoting *Clinton v. City of New York*, 524 U.S. 417, 429 (1998)), 46.[10] Pfizer raises several hypothetical parties who it claims are at risk of liability under the agency's reading of the AKS, such as a generous family member who helps to cover the cost of medical treatment. Although the AKS is broad, however, it is not limitless. As discussed, a person must "knowingly and willfully" provide prohibited remuneration to be liable, which means she must have offered the payment with the intent to violate a known legal duty. It seems very

[10] We note that much of Pfizer's overbreadth argument is made within the context of the rule of lenity, which, as Pfizer concedes, only requires a criminal statute to be construed in the defendant's favor when the statute is ambiguous. Appellant's Br. 44; *see United States v. Santos*, 553 U.S. 507, 514 (2008). As discussed above, we find no ambiguity in the contested provision of the AKS. *See supra* Section II.A.b. The rule of lenity is thus inapplicable to this case.

unlikely to us that a charitable or concerned family member who is merely trying to help a loved one would meet that mens rea element.

In addition, to violate the AKS, one must intend to induce the purchase of a *federally reimbursable* healthcare product. *See* 42 U.S.C. § 1320a-7b(b)(2)(B). The Direct Program is specifically designed to induce Medicare beneficiaries to purchase Pfizer's tafamidis, a federally reimbursable drug. As such, the Direct Program falls squarely within the AKS's prohibitions. The concerned family member, on the other hand, does not have the same interest in whether the federal government reimburses the pharmaceutical company for the medication – she just wants to ensure that her relative receives medical treatment. In that sense, it is difficult to imagine the circumstances under which a family member's financial support would carry the specific purpose of inducing the purchase of a federally reimbursable drug. We are thus unpersuaded that the agency's reading of the AKS "would produce an absurd and unjust result which Congress could not have intended." *Clinton*, 524 U.S. at 429 (quoting *Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 574 (1982)).

c. Advisory Opinion Process

Finally, Pfizer argues that the HHS OIG advisory opinion process is rendered superfluous by the district court's "far-reaching interpretation of the AKS as prohibiting any conceivable influence on a prescribing decision[, which] essentially means that the offer of anything of value is inevitably within the statute's reach." Appellant's Br. 40. If the statute has no discernible bounds, Pfizer reasons, then there is no need for an administrative process to clarify which programs are prohibited.

We think Pfizer's characterization of the district court's opinion is mistaken. The court never suggested that the AKS "prohibit[s] any conceivable influence on a prescribing decision." *Id.* Rather, the court concluded based on the plain meaning of the text that the AKS "prohibits knowingly and willfully providing remuneration which is intended to induce a purchase of [certain] medical treatments or services." *Pfizer*, 2021 WL 4523676, at *14. The advisory opinion process is thus helpful for determining when a proposed program is designed to "induce" the purchase of a federally reimbursable medical treatment, just as the agency did here. *See* A.221-23 (explaining how the Direct Program "operate[s] as a *quid pro quo*" that would induce purchases of tafamidis).

CONCLUSION

We have considered the plaintiff's remaining arguments on appeal and conclude that they are without merit. We therefore AFFIRM the judgment of the district court.

APPENDIX B

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

1:20-cv-4920 (MKV)

PFIZER INC., *Plaintiff*,

-against-

UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES et al., *Defendants*

OPINION AND ORDER GRANTING DEFENDANTS MOTION TO DISMISS AND FOR SUMMARY JUDGMENT AND DENY PLAINTIFFS MOTION FOR SUMMARY JUDGMENT

MARY KAY VYSKOCIL, United States District Judge:

In this case, Plaintiff Pfizer Inc. seeks declarations that one or both of two potential co- pay assistance programs, if implemented, would not violate the federal Anti-Kickback Statute ("AKS"), and Beneficiary Inducement Statute ("BIS"). Before this case was filed, the federal government, acting through the Office of the Inspector General ("OIG") of the Department of Health and Human Services ("HHS"), reviewed the programs and notified Pfizer that at least one of the of them could violate the statutes if implemented as Pfizer intended. The consequences of a violation could be dire for Pfizer, potentially including civil or criminal monetary penalties and exclusion of all Pfizer products from eligibility for coverage under Medicare and Medicaid. *See* 42 U.S.C. §§ 1320a-7, 1320a-7a, 1320a-7b.

Before the Court are cross-motions from the parties, both seeking judgment in their favor.[1] Following careful review of the parties' submissions and having heard oral argument on the motions, Defendants' motion is GRANTED, and Plaintiff's motion is DENIED.

FACTUAL BACKGROUND AND PROCEDURAL HISTORY

A. Pfizer's Drug and Proposed Programs

The Parties substantially agree on the facts relevant to this dispute. In light of that, the Court cites to the Complaint [ECF No. 1] ('Cpl."). For facts not contained in the complaint, the Court cites the administrative record of proceedings before the Department of Health and Human Services [ECF No. 46] ("AR").

Pfizer produces and markets a drug called tafamidis[2] to treat Transthyretin Amyloid Cardiomyopa-

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[1] The filings relevant to the parties' motions are 1) Pfizer's Memorandum of Law in Support of the Motion for Summary Judgment [ECF No. 34] ("Pfizer Br."), 2) Defendants' Memorandum of Law in Opposition to Pfizer's Motion and in Support of the Motion to Dismiss and for Summary Judgment [ECF No. 45] ("HHS Br."); 3) Pfizer's Reply Memorandum of Law and Opposition to Defendants' Motion [ECF No. 53] ("Pfizer Reply"), and 4) Defendants' Reply Memorandum of Law [ECF No. 57] ("HHS Reply"). Since briefing was complete, the parties filed several letters bringing supplemental authority to the Court's attention and addressing other issues [ECF Nos. 58-59, 66, 75-76, 83]. The Court also granted leave to the National Minority Quality Forum and the Pharmaceutical Research and Manufacturers of America to file briefs in the case as amicus curiae [ECF No. 65] ("NMQF Br."); [ECF No. 62] ("PhRMA Br.").

[2] As explained in the complaint, tafamidis actually refers to two drugs sold under the brand names Vyndaqel and Vyndamax. See

thy ("ATTR-CM"). Cpl. ¶ 1. ATTR-CM is a rare, progressive condition that causes deposits of amyloid protein to be deposited in the heart muscle. Cpl. ¶ 25. As a result, the afflicted person may experience progressive heart failure, culminating in being unable to perform even basic life tasks. Cpl. ¶ 25. Patients with diagnosed ATTR-CM have a life expectancy of 2-3.5 years after diagnosis. Cpl. ¶ 25. There are estimated to be approximately 100,000-150,000 people afflicted with ATTR-CM in the United States, with higher concentrations among the elderly and among African American males. Cpl. ¶ 3, 27. Tafamidis is currently the only FDA-approved drug to treat ATTR-CM. Cpl. ¶¶ 42-43. The drug was developed through extensive testing and trials over the course of nearly 20 years and benefitted from "orphan drug" classification from the FDA.[3] Cpl. ¶¶ 28-41.

Because ATTR-CM disproportionately affects older Americans, a large proportion of the population eligible for treatment with tafamidis receives Medicare. Cpl. ¶¶ 45, 55. Medicare Part D is the portion of Medicare concerned with outpatient prescription drugs like tafamidis. Cpl. ¶ 45. An integral part of Medicare Part D is the cost-sharing baked into the scheme. Through a complicated scheme, and as relevant to the drugs in this case, Medicare Part D participants are responsible for certain deductibles and co-pays based on the cost of the drugs

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Cpl. ¶ 1. They are the same for the purposes of this case and are referred to collectively as "tafamidis."

[3] Orphan drug classification is a special status that the FDA may grant a proposed/developing drug to treat a rare disease and qualifies the developer for incentives related to the drug development. Cpl. ¶ 33 (citing 21 U.S.C. § 360bb, and then citing 21 C.F.R. Part 316).

doctors prescribe them. In 2020, for example, Medicare Part D participants were responsible for a $435 deductible before they received any assistance. Cpl. ¶ 46. Then, a participant has to contribute 25% of all costs until the total costs of his or her medications reached the "catastrophic coverage" threshold (in 2020, $9,303). Cpl. ¶ 46. In real numbers, this means that a Medicare Part D enrollee who took only brand-name drugs was responsible for $2,652 before receiving "catastrophic coverage." Upon reaching that threshold, the participant is responsible for 5% of all remaining costs, with no upper limit. Cpl. ¶ 46.

In order to assist lower income Medicare Part D participants, and to dissuade patients from foregoing coverage, the federal government provides co-pay support for any person whose income is less than 150% of the federal poverty level. Cpl. ¶ 49. Surveys of Medicare Part D participants suggest that approximately 29% of all Part D participants fall in this range. Cpl. ¶ 49. However, Pfizer suggests that the upper limit for this additional support is too low, and fails to include all Medicare recipients who otherwise cannot afford the Part D cost-sharing.[4] The company offers survey evidence that at least 25% of new Part D enrollees will forego prescriptions or care if they are asked to pay more than $50 and that almost 50% of cancer patients asked to pay more than $2,000 out of pocket did not fill prescriptions. Cpl. ¶ 51.

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[4] The median annual income for Medicare beneficiaries is approximately $29,650. See Pfizer Br. at 12. However, 150% of the federal poverty level only reaches beneficiaries making up to approximately $19,140 (for an individual). Cpl. ¶ 49.

Tafamidis costs $225,000 per year. AR 2, 12, 125. As a result of the payment scheme outlined above, Medicare Part D participants would pay approximately $13,000 per year in cost- sharing, absent assistance, for the medication. Cpl. ¶ 52. Pfizer suggests that while affluent patients may be able to afford that amount, there is a substantial number of "middle-income" patients who cannot pay these prices. Cpl. ¶¶ 53-55. Indeed, Pfizer states that even if tafamidis's price was cut in half, patients would still be required to pay more than $8,000 per year. Cpl. ¶ 53. In light of this substantial barrier to treatment, Pfizer sought to create its own co-pay assistance programs. Cpl. ¶ 7.

Pfizer has proposed two programs in which it would provide additional assistance to patients in order to limit their costs to a maximum of $35 a month. First, it proposes a "Direct Copay Assistance Program" (the "Direct Program") under which Pfizer would provide funds directly to the patient. Cpl. ¶ 61. Pfizer proposes that to be eligible for assistance in the Direct Program, "patients must: (1) be prescribed tafamidis for an on-label (approved) indication, that is, ATTR-CM; (2) be United States residents; and (3) meet program criteria for financial need tailored to address the burden otherwise faced by middle-income patients who are unable to access other available resources." Cpl. ¶ 62. Pfizer states that it would not advertise the program or use it to solicit patients before the drug is prescribed. Cpl. ¶ 63. Second, Pfizer proposes an assistance program involving a Pfizer-supported charity (the "Charity Program"). For this, Pfizer would fund an existing independent charity to develop its own guidelines and programs to assist Part D participants with payments for tafamidis. Cpl. ¶ 70. While Pfizer would communicate with the charity

about funding needs, the charity would otherwise operate independently and develop its own guidelines for aid programs. Cpl. ¶ 72.

Relevant to this case and these programs, Pfizer is currently subject to a "Corporate Integrity Agreement" signed as a part of a $23.9 million settlement of earlier AKS claims related to a purportedly independent charity Pfizer attempted to use as a part of a different co-pay assistance program. *See* AR 480, 483. The agreement, signed in 2018, provides that for five years, Pfizer will contribute to an independent charity co-pay assistance program only if:

> a. . . . Pfizer has not made and shall not make . . . suggestions or requests to the Independent Charity PAP about the identification, delineation, establishment, or modification of disease state funds;
>
> b. Pfizer does not and shall not exert any direct or indirect influence or control over the Independent Charity PAP's process or criteria for determining eligibility of patients who qualify for its assistance program;
>
> [. . .]
>
> d. Pfizer does not and shall not provide donations for a disease state fund that covers only a single product or that covers only Pfizer's products.

AR at 501-02.

B. The Administrative Review

To combat fraud and abuse in connection with Medicare and Medicaid, Congress enacted the federal Anti-Kickback Statute, 42 U.S.C. § 1320a-7b ("AKS"). In relevant part, that statute prohibits:

> knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce [a] person . . . to purchase . . . or arrange for or recommend purchasing . . . any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program [defined elsewhere as Medicare and Medicaid]. 42 U.S.C. § 1320a-7b(b)(2)(B).

Violations of the AKS include criminal and civil sanctions, up to and including a pharmaceutical company's exclusion entirely from federal reimbursement for any of its medications. Cpl. ¶ 122; *see also* 42 U.S.C. § 1320a-7(b)(7) (permitting the Secretary of Health and Human Services to "exclude . . . from participation in any Federal health care program" any person or entity that violates the AKS).

A similar regime is contained within the Beneficiary Inducement Statute ("BIS"), 42 U.S.C. § 1320a-7a. In relevant part, this statute subjects to a civil penalty any entity that: "offers to or transfers remuneration to any individual eligible for benefits under [a federal or state healthcare program] . . . that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner,

or supplier any item or service for which payment may be made, in whole or in part, under [a federal or state healthcare program]." 42 U.S.C. § 1320a-7a(a)(5). Certain definitions and exceptions apply only to the BIS and not to the AKS, including specifically a definition of "remuneration" that specifically excludes "waiver of coinsurance and deductible amounts" except in limited circumstances. 42 U.S.C. § 1320a-7a(i)(6).

Because the threat of sanctions and criminal charges for violations of the AKS and BIS are severe, Congress enacted a process by which entities can seek advisory opinions from the HHS OIG about whether an anticipated program or course of action would violate either or both of the statutes. 42 U.S.C. 1320a-7d(b). Any resulting advisory opinion is a binding administrative action on both the Government and the requesting party. 42 U.S.C. § 1320a-7d(b)(4)(A).

In 2005 and 2014, the HHS OIG published guidance documents about what kinds of assistance programs violate the AKS or BIS and how companies can ensure compliance with the law. Cpl. ¶ 94. In the first guidance document, HHS OIG stated that assistance programs like the Direct Program and Charity Program that Pfizer proposes, "pose a heightened risk of fraud and abuse" under the AKS, particularly because they "shield [Medicare Part D] beneficiaries from the economic effects of drug pricing, thus eliminating a market safeguard against inflated prices." 70 Fed. Reg. 70,623, 70,626 (Nov. 22, 2005). This concern was reiterated in 2014, when the HHS OIG noted that assistance programs provide pharmaceutical companies like Pfizer with "the ability to subsidize copayments for their own products [and] may encourage manufacturers to increase prices, potentially at additional cost to Federal

health care programs and beneficiaries who are unable to obtain copayment support." 79 Fed. Reg. 31,122 (May 30, 2014). In both the 2005 and 2014 guidance however, the agency noted that an assistance fund that "[targets] only one drug or drugs made by one manufacturer would not, standing alone, be determinative of an anti-kickback statute violation." Cpl. ¶ 94 (first citing 70 Fed. Reg. 70,623- 03, 70,627 n.19 (Nov. 22, 2005); and then citing 79 Fed. Reg. 31,120, 31,122 (May 30, 2014)).

In light of this previous guidance, Pfizer sought an advisory opinion about its anticipated tafamidis programs in June 2019. Cpl. ¶ 103. Less than two months later, OIG rejected the request, stating that it was "not able to issue an advisory opinion" as to the Charity Program "because 'the same or substantially the same course of action is under investigation, or has been the subject of a[n] [enforcement] proceeding involving [HHS] or another governmental agency.'" Cpl. ¶ 104. After further consultation with OIG, Pfizer resubmitted the request, seeking an opinion only as to the Direct Program and excluding the Charity Program. Cpl. ¶ 104. In December 2019, OIG informed Pfizer that it had reached "an unfavorable opinion" of the Direct Program (*i.e.* that it would violate the AKS), and that OIG would issue a binding advisory opinion to that effect if Pfizer did not voluntarily withdraw the request. Cpl. ¶ 105. Pfizer sought a second meeting with OIG following this notification and submitted additional clarifying information about the Direct Program. Cpl. ¶¶ 106-07. Nonetheless, OIG again informed Pfizer in May 2020 that it had reached an unfavorable view of the Direct Program and that a binding advisory opinion would issue if Pfizer did not withdraw the request. Cpl. ¶ 108. Pfizer filed this

case shortly thereafter. After the case was filed, OIG issued a binding Advisory Opinion regarding the Direct Program. *See* AR 141-68.

The Advisory Opinion issued by the HHS OIG concluded that the Direct Program would not violate the BIS, but that it could violate the AKS "if the requisite intent to induce or reward referrals for, or purchases of, items and services reimbursable by a Federal health care program were present."[5] AR 142. The opinion largely focused on the intent of the program as the hallmark for an AKS violation, noting that the Direct Program might "operate as a *quid pro quo*—[Pfizer] would offer remuneration . . . to the beneficiary in return for the beneficiary purchasing" tafamidis. AR 154. Significantly, the OIG observed that the program appeared designed to induce "a Medicare beneficiary [who] otherwise may be unwilling or unable to purchase [tafamidis] due to his or her cost-sharing obligations, which are driven by the list price, . . . to purchase" the drug. AR 155. The HHS OIG further noted that the Direct Program presented "more than a minimal risk of fraud and abuse," as a result of Pfizer's elimination of patient cost-sharing, "one of the key pricing controls" inherent in Medicare Part D. AR 156, 158. The claims in Plaintiff's complaint, in part, seek a declaration eliminating the potential that the Direct Program ever could violate the AKS.

[5] Because of this conclusion, the Court's review of the issues related to the Direct Program do not consider the BIS, as all parties agree that it would not be violated by the program.

C. Procedural History of This Case

The complaint in this case contains four causes of action concerning both the Direct Program and the Charity Program. First, Pfizer seeks a declaration that the Direct Program and the Charity Program do not violate the AKS or the BIS. Cpl. ¶¶ 137-143 (Count I). Second, Pfizer seeks a declaration that OIG's guidance regarding the Charity Program would infringe on Pfizer's First Amendment rights. Cpl. ¶¶ 144-150 (Count II). Third, Pfizer seeks a declaration that OIG's guidance regarding the Charity Program would violate the Fifth Amendment Due Process Clause. Cpl. ¶¶ 151-57 (Count III). Finally, Pfizer seeks an order vacating HHS's guidance and advisory opinion as contrary to law under the Administrative Procedure Act ("APA"). Cpl. ¶¶ 158-168 (Count IV).

The parties filed cross-motions for judgment on the claims, and Defendants, alternatively, filed for dismissal of certain of the claims. In support of dismissal of the complaint, Defendants argue that the Court lacks jurisdiction to hear the case as related to the Charity Program because there is no claim, other than those for a declaratory judgment, related to it. Since the Declaratory Judgment Act does not provide an independent basis for jurisdiction, HHS argues that the claims should be dismissed as to the Charity Program. *See* HHS Br. at 22-23. Both Pfizer and HHS then seek summary judgment on the declaratory judgment and substantive APA claims related to the Direct Program and, to the extent they are not dismissed, those related to the Charity Program. The Court has heard oral argument on the cross-motions. *See* Transcript of Summary Judgment Hearing [ECF No. 80] ("Tr.").

After the Court held oral argument on the cross-motions, Plaintiff filed a letter seeking leave to file a motion pursuant to Federal Rule of Civil Procedure 41(a)(2) to dismiss Counts I, II, and III of its complaint, which would eliminate all claims related to the Charity Program and would limit the case only to Pfizer's claim that the HHS OIG advisory opinion was issued in violation of the APA as not in accordance with law. *See* Letter to Court [ECF No. 78]; Cpl. ¶¶ 158-68. The Government does not object to the request. *See* Letter to Court [ECF No. 79]. However, Rule 41(a)(2) is not absolute and permits voluntary dismissal by order of the Court "upon such terms and conditions as the court deems proper." Fed. R. Civ. P. 41(a)(2).

The Second Circuit has explained that relevant factors to consider in connection with a Rule 41(a)(2) motion include "the plaintiff's diligence in bringing the motion; any 'undue vexatiousness' on plaintiff's part; the extent to which the suit has progressed, including the defendant's effort and expense in preparation for trial; the duplicative expense of relitigation; and the adequacy of plaintiff's explanation for the need to dismiss." *Zagano v. Fordham Univ.*, 900 F.2d 12, 14 (2d Cir. 1990). Pfizer has not explained any "need" to dismiss the claims other than the avoidance of legal issues that otherwise could be fatal to Plaintiff's claims [ECF No. 78 at 1]. Given that the parties already had briefed and argued the issues related to the claims and that the Court already had devoted significant resources to preparing for argument and to resolving all of the issues in the parties' motions, Plaintiff's request for dismissal under Rule 41(a)(2) is denied and the Court proceeds to consideration of all the parties' arguments.

LEGAL STANDARD

A. Rule 12(b) Motion

Defendants first move under Rules 12(b)(1) and 12(b)(6) of the Federal Rules of Civil Procedure for dismissal of Plaintiff's claims related to the Charity Program because the Court lacks subject matter jurisdiction over the claims. A court must dismiss a claim if it "lacks the statutory or constitutional power to adjudicate it." *Morrison v. National Australia Bank Ltd.*, 547 F.3d 167, 170 (2d Cir. 2008) (internal quotation marks omitted), *aff'd*, 561 U.S. 247 (2010). "The plaintiff bears the burden of proving subject matter jurisdiction by a preponderance of the evidence." *Aurecchione v. Schoolman Transp. Sys., Inc.*, 426 F.3d 635, 638 (2d Cir. 2005). In deciding the motion to dismiss, the Court "must take all facts alleged in the complaint as true and draw all reasonable inferences in favor of plaintiff." *Morrison*, 547 F.3d at 170 (quoting *Natural Resources Defense Council v. Johnson*, 461 F.3d 164, 171 (2d Cir. 2006)).

B. Rule 56 Motion

Both Plaintiff and Defendants move for summary judgment on any claims that survive the motion to dismiss. "Summary judgment is appropriate only when, 'the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.'" *Ya-Chen Chen v. City Univ. of N.Y.*, 805 F.3d 59, 69 (2d Cir. 2015) (quoting Fed. R. Civ. P. 56(a)). In this case, because the parties are limited to the facts in the administrative record, Plaintiff and Defendants agree that there are no questions of fact in this case. *See* Pfizer Br. at 8, HHS Br. at 11.

In a case challenging administrative agency action, courts must "review *de novo* 'all relevant questions of law' and 'interpret[ations] [of] constitutional and statutory provisions' made by an agency." *Aleutian Cap. Partners, LLC v. Scalia*, 975 F.3d 220, 229 (2d Cir. 2020) (quoting 5 U.S.C. § 706) (alterations in original). Summary judgment is appropriate to finally resolve Plaintiff's claims here. *Aleutian Cap. Partners*, 975 F.3d at 229 ("Where, as here, an APA-based challenge to an agency's action presents a pure question of law, a district court's procedural decision to award summary judgment is generally appropriate." (citing *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1083-84 (D.C. Cir. 2001))).

C. The Court's Review of the HHS OIG Actions

The parties disagree about the appropriate deference the Court must give the administrative guidance documents and the advisory opinion here. Defendants note that the Court should defer entirely to the administrative actions. *See* HHS Br. at 11. Pfizer urges that no deference to the advisory opinion is appropriate and that the HHS guidance on which it is based is entitled only to deference "to the extent the agency's rationale has the power to persuade." Pfizer Br. at 8-9.

Formal deference either to the HHS OIG Advisory Opinion or to other HHS guidance is not appropriate here. Interpretations of law contained in guidance and advisory documents are "entitled to respect" to the extent that those interpretations have the "power to persuade." *Christensen v Harris Cnty.*, 529 U.S. 576, 587 (2000). This deference, stemming from *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944), only means that the Court must consider the administrative decision for its "per-

suasive" value, and not necessarily with any more respect than the Court considers non-binding precedent. *See Georgia v. Public.Resource.Org, Inc.*, U.S. , 140 S. Ct. 1498, 1510 (2020) ("But, as Georgia concedes, the Compendium is a non-binding administrative manual that at most merits deference under *Skidmore v. Swift & Co.* That means we must follow it only to the extent it has the 'power to persuade.' Because our precedents answer the question before us, we find any competing guidance in the Compendium unpersuasive." (internal citations omitted)). Thus, the Court considers the advisory opinion issued by the HHS OIG alongside the parties' arguments but does not weigh it any more heavily than its persuasive value.

DISCUSSION

I. DEFENDANTS ARE ENTITLED TO DISMSSAL OF THE CLAIMS RELATED TO PFIZER'S PROPOSED CHARITY PROGRAM

A. Subject-Matter Jurisdiction

Defendants first argue, in support of dismissal of Pfizer's claims related to the Charity Program, all brought pursuant to the Declaratory Judgment Act, that the Court is without jurisdiction to hear those claims. Pfizer's first three causes of action seek declarations that the Charity Program does not violate the AKS or BIS (Count I), that application of HHS OIG guidance to the Charity Program would violate Pfizer's First Amendment rights (Count II), and that application of the guidance to the Charity Program would violate the Fifth Amendment right to equal protection held by third parties (Count III). Cpl. ¶¶ 137-57. Because the Declaratory Judgment Act does not independently provide subject matter jurisdiction, absent a substantive claim

related to the Charity Program, Pfizer must establish that any declaration related to that program would resolve an actual controversy between the parties. Moreover, even if jurisdiction is proper, Pfizer must satisfy prudential ripeness concerns. While the Court disagrees that it lacks jurisdiction to hear the claims, the Court agrees with Defendants that Pfizer's Charity Program claims do not satisfy the standard for prudential ripeness and must be dismissed.

The Declaratory Judgment Act gives federal courts discretion to "declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." 28 U.S.C. § 2201(a). But, it does not operate as an independent grant of jurisdiction, or create a cause of action. *Chevron Corp. v. Naranjo*, 667 F.3d 232, 244 (2d Cir. 2012); *In re Joint E. & S. Dist. Asbestos Litig.*, 14 F.3d 726, 731 (2d Cir. 1993). Rather, the Act's "operation is procedural only—to provide a form of relief previously unavailable." *In re Joint E. & S. Dist. Asbestos Litig.*, 14 F.3d at 731. Absent a substantive claim related to the same dispute, in order to sustain a claim for a declaratory judgment, plaintiffs must provide facts to establish that there is a dispute between the parties that is "'definite and concrete, touching the legal relations of parties having adverse legal interests[]' and that it [is] 'real and substantial' and 'admi[ts] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 277, 240-41, 257 (1937)). Otherwise, the Court does not have jurisdiction to consider a claim that

simply seeks a declaratory judgment. *Holder v. Humanitarian L. Project*, 561 U.S. 1, 12 (2010).

In connection with the Declaratory Judgment Act, courts also have developed a set of "prudential ripeness" standards that judges must apply when considering whether a claim for a declaratory judgment that might technically satisfy other requirements otherwise nonetheless is not appropriate for review. Specifically, the Court considers: (1) the fitness of the issues for judicial decision; and (2) the hardship to the parties of withholding court consideration. *See Vullo v. Off. of the Comptroller of the Currency*, 378 F. Supp. 3d 271, 283 (S.D.N.Y. 2019). An issue is not fit for adjudication if, on balance, the Court's analysis is contingent on future events that may or may not occur. *In re Combustion Equip. Ass'n Inc. v. EPA*, 838 F.2d 35, 39 (2d. Cir. 1988). The Second Circuit also has set out a more extensive set of factors to review in connection with prudential ripeness:

> (1) whether the judgment will serve a useful purpose in clarifying or settling the legal issues involved; . . . (2) whether a judgment would finalize the controversy and offer relief from uncertainty . . . [3] whether the proposed remedy is being used merely for procedural fencing or a race to res judicata; [4] whether the use of a declaratory judgment would increase friction between sovereign legal systems or improperly encroach on the domain of a state or foreign court; and [5] whether there is a better or more effective remedy."

Dow Jones & Co., Inc. v. Harrods Ltd., 346 F.3d 357, 359-60 (2d Cir. 2003).

1. The Court Has Jurisdiction to Consider the Declaratory Judgment Claims Even in the Absence of Another Substantive Claim about the Charity Program

Whether the Court has jurisdiction to consider a claim under the Declaratory Judgment Act turns in part on whether there is a substantive claim related to the same subject matter. Here, while Pfizer's APA claim seeks "a judgment setting aside OIG's determination that the Proposed Copay Assistance Programs [defined as both the Direct and Charity Programs] implicate the AKS or BIS," Cpl ¶ 168, there is no possible claim related to the Charity Program. The HHS OIG never decided that the Charity Program violated the AKS and the BIS. As noted above, because another investigation into a substantially similar course of action was pending, OIG declined Pfizer's request for an opinion on the Charity Program.

The APA claim does not challenge that decision, nor could it. As an initial matter, the HHS OIG took no final agency action with respect to the Charity Program, precluding this Court's review. *See* 5 U.S.C. § 704. More importantly, the HHS OIG decision to refuse to consider Pfizer's initial advisory opinion request appears to be substantively correct. HHS regulations prohibit the OIG from issuing an advisory opinion where "[t]he same, or substantially the same, course of action is under investigation, or is or has been the subject of a proceeding involving the Department of Health and Human Services or another governmental agency." 42 C.F.R. § 1008.15(c)(2). Defendants cite this regulation and other

non-Pfizer-related investigations (and Pfizer's still-in-effect 2018 Corporate Integrity Agreement) as prohibiting any action with respect to the Pfizer Charity Program. HHS Br. at 29-30. Defendants also point to the Corporate Integrity Agreement as independently barring Pfizer's attempt to seek approval for a second similar program, including because it waived some of the rights it seeks to assert here. *See* HHS Br. 26-27, 30-31. Absent a challenge to the regulation barring the HHS OIG from considering requests for advisory opinions in this circumstance or the application of that regulation to Pfizer here, which Pfizer does not allege, there is not a standalone APA claim about the Charity Program. Ordinarily, this would mean that Pfizer's declaratory judgment claim also fails for failure to allege a concrete case or controversy.

But, Pfizer argues that a concrete dispute between the parties exists in connection with the claims for declaratory judgments concerning the Charity Program. Pfizer Reply at 23. In support of that argument, the company points to cases where courts issued declaratory judgments in connection with "pre-enforcement" review of possible prosecutions or legal actions. Most of the cases Pfizer cites arise in the context of First Amendment, *i.e.* where a speaker was threatened with arrest or prosecution before they spoke. *See, e.g.*, *Susan B. Anthony List v. Driehaus*, ___U.S.___, 134 S. Ct. 2334 (2014) (permitting pre-enforcement review of a potential election spending prosecution where state election commission had received a referral for prosecution, but no case was filed); *Holder*, 561 U.S. at 12 (2010) (permitting pre-enforcement review of statute criminalizing donations to organizations alleged to be connected to terrorism where court found a "genuine threat of imminent

prosecution"). In short, these cases present concrete actual controversies because of the real, stated threat of the legal action against the plaintiff.

Pfizer frames its injury, as it relates to the Charity Program, at least in part as an issue of speech. *See* Cpl. ¶¶ 132-34. Pfizer claims that its spending on the Charity Program would fall within the "speech incident to charitable giving" recognized by the Supreme Court. Cpl. ¶ 132 (citing *McCutcheon v. Fed. Election Comm'n*, 572 U.S. 185, 203 (2014)). The potential of AKS sanctions for that speech, Pfizer asserts, chills its ability to engage in the speech and presents a choice of either "relinquish[ing] its right to initiate and administer the proposed programs" or "go[ing] ahead with the programs and risk[ing] an enforcement action and the serious consequence of possible exclusion from federal health care programs." Pfizer Reply at 24.

Pfizer also cites a case outside the speech context: *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007). In that case, the Court permitted the plaintiff company to seek a declaratory judgment that a contract and patent were unenforceable and invalid respectively. *Id.* at 137. Analogizing the case to those involving potential prosecutions, the Court emphasized the "coercion" present between the parties, *i.e.*, that the threat of an action for breach of contract was preventing the plaintiff from taking other actions. *Id.* at 129-131.

Pfizer raises at least some threat of coercion here. While the HHS OIG took no position on the Charity Program that Pfizer proposed, the Department of Justice allegedly is currently involved in cases against three other pharmaceutical companies for AKS violations stemming from donations to independent charitable foundations.

See Pfizer Reply at 24, n.17. And AKS charges have resulted in more than $850 million in settlements from pharmaceutical companies and independent charities. *Id.* Thus, while Pfizer cannot point to any facts which specifically indicate HHS will prosecute it for AKS violations in connection with the Charity Program, it has raised a real prospect that its actions are shaped and coerced by the threat of prosecution, and the potential draconian civil penalties.

Between the allegations of coercion and the potential chilling effect on speech incident to charitable giving, Pfizer has alleged an actual case or controversy between the parties sufficient to maintain a standalone declaratory judgment claim. *See Holder*, 561 U.S. at 15-16 (actual case or controversy is present where plaintiffs stated they would begin charitable giving after the threat of prosecution was eliminated, where the government has filed prosecutions against others for the threatened violations, and where the government has not argued that these particular plaintiffs will not be prosecuted if they do what they say they wish to do.). In the circumstance present here, the Court has jurisdiction to review Pfizer's declaratory judgment claims with respect to the Charity Program.

2. Pfizer's Declaratory Judgment Claims Related to the Charity Program Do Not Satisfy the Standard for Prudential Ripeness

As noted above, a court reviews a declaratory judgment action for prudential ripeness by considering (1) the fitness of the issues for judicial decision; and (2) the hardship to the parties of withholding court consideration. *Vullo*, 378 F. Supp. 3d at 283. While the Court has jurisdiction to consider Pfizer's declaratory judgment

claim, the claim is far too remote and the facts of the underlying program are far too undeveloped to satisfy the prudential ripeness criteria. Moreover, there is no hardship alleged here that overcomes these barriers to review. As a result, the Charity Program claims are dismissed.

This is not a close case. Of course, Pfizer's claim is a purely legal question and "may be decided without further factual development." *Gary D. Peake Excavating Inc. v. Town Bd. of Town of Hancock*, 93 F.3d 68, 71-72 (2d Cir. 1996). However, HHS correctly argues that Pfizer "has only vaguely defined" the Charity Program and that the "legality of the [p]rograms depends on future facts." HHS Br. at 25; HHS Reply at 10. The record before the Court contains no details of the program other than Pfizer's unilateral description in its first unfulfilled and unreviewed request for an HHS OIG advisory opinion. *See* HHS Br. at 25 (citing AR 746, 757). OIG did not have any discussions with Pfizer regarding the program and did not request any information in connection with the Charity Program from Pfizer. And, the HHS OIG never actually gave its own views on the Charity Program. It is unclear, for example, that the HHS OIG would find that this specific program would violate the AKS or BIS or whether, after consultation with Pfizer and any resulting revisions, the program could proceed without objection from either party. While Pfizer has offered some facts here that may permit the Court to consider some of these questions, the record is still sparse as it relates to the Charity Program. Such an undeveloped record still is not "fit" for resolution by the Court. *Simmonds v. INS*, 326 F.3d 351, 359 (2d Cir. 2003) ("[I]ssues have been deemed ripe when

they would not benefit from any further factual development and when the court would be in no better position to adjudicate the issues in the future than it is now." (first citing *Whitman v. Am. Trucking Ass'ns*, 531 U.S. 457, 479 (2001); and then citing *Duke Power Co. v. Carolina Env't Study Grp.*, 438 U.S. 59, 81-82 (1978))). Rather, the prudent approach is the one envisioned by the law, permitting Pfizer and the HHS OIG first to review the program and reach definitive conclusions.

The Court is cognizant that the Supreme Court specifically has cautioned against finding that claims related to pharmaceutical products are not ripe. *See Abbott Labs. v. Gardner*, 387 U.S. 136, 153 (1967) ("[P]etitioners deal in a sensitive industry, in which public confidence in their drug products is especially important. . . . [A]ccess to the courts under the Administrative Procedure Act and the Declaratory Judgment Act must be permitted, absent a statutory bar or some other unusual circumstance . . . ."). However, in that case, the Court noted that the agency's action "purport[ed] to give an authoritative interpretation of a statutory provision that has a direct effect on the day-to-day business of all prescription drug companies; its promulgation puts petitioners in a dilemma that it was the very purpose of the Declaratory Judgment Act to ameliorate." *Id.* at 152. None of these factors weigh in Pfizer's favor here.

The details of the proposed program are ill-defined and vague. The HHS OIG has not purported to authoritatively determine any rights that are relevant to all companies nor even to authoritatively determine any of Pfizer's rights. Instead, the exact attributes of the Charity Program, and whether it (or the regulation of it) violates the law is "contingent on future events that may or may not occur," including Pfizer's own actions. HHS Br.

at 25 (citing *In re Combustion*, 838 F.2d at 37-39). This is not a "definite and concrete" dispute, and, as a result, the Charity Program claims are unripe. In light of that, Defendants' motion to dismiss is granted as to Counts II and III of the complaint and Count I to the extent it relates to the Charity Program.

B. Pfizer's Fifth Amendment Claim Independently Fails for Lack of Standing

Pfizer's claim in Count III of the complaint that application of HHS OIG's guidance to the both the Direct Program and the Charity Program would violate the Fifth Amendment also fails because Pfizer lacks standing to assert it.

"A plaintiff has standing only if he can 'allege personal injury fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief.'" *California v. Texas*, ___ U.S.___, 141 S. Ct. 2104, 2114 (2021) (quoting *DaimlerChrysler Corp. v. Cuno*, 547 U.S. 332, 342 (2006)). In connection with the Fifth Amendment claim, Pfizer seeks to represent not its own interests, but those of ATTR-CM patients who may lack access to tafamidis because of what it believes to be irrational economic classifications in the Medicare system. *See* Cpl. ¶¶ 135, 157. As Defendants note, a party cannot ordinarily "rest his claim to relief on the legal rights or interests of third parties." *Kowalski v. Tesmer*, 543 U.S. 125, 129 (2004) (cited at HHS Br. at 34). Because Pfizer's claim is primarily concerned with the equal protection rights of middle-income Medicare beneficiaries, and because Pfizer is not such a person, the claim is not Pfizer's to bring.

In response, Pfizer argues that this case is similar to *Eisenstadt v. Baird*, 405 U.S. 438 (1972), where a company was allowed to bring claims on behalf of its patients using contraceptives. *Id.* at 445. However, the only law involved in that case was a statute criminalizing contraceptive production, the enforcement of which uniquely fell on the company. *Id.* Here, while framed as unique to tafamidis and the AKS, Pfizer's objection relates to the alleged impact on middle-income Medicare recipients, not on Pfizer. That impact may be common to all drugs eligible under Medicare Part D, which imposes the same co-pay requirements on all beneficiaries (*i.e.* a percentage of the cost of the drugs they are prescribed). Pfizer is not uniquely positioned to assert those rights.

Relatedly, any injury is traceable not to Pfizer's ability to organize their co-pay assistance programs, or lack of it, but instead to the Medicare Part D scheme. In order to establish standing to sue, a plaintiff must allege an injury that is "fairly traceable to the defendant's allegedly unlawful conduct and likely to be redressed by the requested relief." *California*, 141 S. Ct. at 2113 (quoting *DaimlerChrysler Corp.*, 547 U.S. at 342). The injury Pfizer raises in connection with the Fifth Amendment claim, that prohibition of the co-pay assistance programs "would discriminate on the basis of wealth without being rationally related to a legitimate government interest," Cpl. ¶ 153, is traceable not to the HHS OIG determination about Pfizer's intended co- pay programs, but is instead traceable to the statutory scheme of Medicare Part D itself. The Supreme Court directs judges to consider the precise statutory scheme from which an alleged harm arises, and to find that a plaintiff has standing to sue where the proposed remedy targets the statute responsible for it. *California*, 141 S. Ct. at 2114-16.

Because Pfizer's alleged harm does not emerge from the HHS OIG guidance related to the AKS it seeks to challenge, but instead from the structure of the Medicare Part D scheme, it has not established standing to sue here.

II. DEFENDANTS' MOTION FOR SUMMARY JUDGMENT ON PLAINTIFFS' DIRECT PROGRAM CLAIMS IS GRANTED

The Court now turns to the Plaintiff's claims regarding the Direct Program. As recounted above, the HHS OIG issued an advisory opinion finding that the Direct Program could violate the AKS "if the requisite intent to induce or reward referrals for, or purchases of, items and services reimbursable by a Federal health care program were present." AR 142. The OIG found that the Direct Program appeared designed to induce "a Medicare beneficiary [who] otherwise may be unwilling or unable to purchase [tafamidis] due to his or her cost-sharing obligations, which are driven by the list price, . . . to purchase" tafamidis, leaving Medicare to "bear the costs." AR 155. Pfizer now seeks both a declaratory judgment that the Direct Program does not violate the AKS or the BIS (Count I) and an order vacating the HHS OIG guidance and advisory opinion related to the Direct Program as contrary to law under the APA (Count IV).

Pfizer does not contend that the Direct Program would not "induce" purchases of tafamidis that otherwise might not occur. Instead, its primary argument is that, even if Pfizer's intent were to induce purchases, that intent would be insufficient to constitute a violation of the AKS. Rather, Pfizer suggests that AKS liability requires that the Direct Program be administered with

a "corrupt" intent or that the payments made through the Direct Program otherwise must constitute an improper *quid pro quo* where Pfizer directly influences a doctor's or patient's decision to prescribe or purchase tafamidis. Pfizer Br. at 9-15. Pfizer then argues that because it lacks such an intent and because there is no such monetary benefit, the argument goes, the Direct Program cannot violate the AKS. Pfizer Br. at 15-16. Pfizer seeks a declaration to that effect and an order setting aside the advisory opinion as contrary to law, urging that the Direct Program never could implicate the AKS. Defendants also move for summary judgment on Pfizer's claims. For the reasons that follow, Pfizer's motion is denied, and Defendants' motion is granted.

A. The Plain Text AKS Does Not Require A Corrupt Intent or a Direct Quid Pro Quo

The Court begins with the text of the AKS. *Facebook, Inc. v. Duguid*, ___ U.S. ___, 141 S. Ct. 1163, 1170 (2021) ("We begin with the text"). "It is axiomatic that the plain meaning of a statute controls its interpretation, and that judicial review must end at the statute's unambiguous terms. Legislative history and other tools of interpretation may be relied upon only if the terms of the statute are ambiguous." *Lee v. Bankers Trust Co.*, 166 F.3d 540, 544 (2d Cir. 1999) (citations omitted).

> The AKS provides in relevant part:
>
> Whoever ***knowingly and willfully*** offers or pays ***any remuneration (including any kickback, bribe, or rebate)*** directly or indirectly, overtly or covertly, in cash or in kind to any person ***to induce*** such person . . . to purchase,

> lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b)(2)(B) (emphasis added). As that text makes clear, the mental state elements of the AKS do not include a "corrupt" intent. Instead, the statute is implicated where a defendant 1) knowingly and willfully provides remuneration 2) to induce (*inter alia*) a purchase. *Id.*

1. Remuneration

Pfizer argues that "remuneration," especially read in light of the examples provided in the statute, must be narrowly construed only to include payments made with a corrupt intent. *See* Pfizer Br. at 9-12. This argument is unpersuasive. First, the plain meaning of "remuneration" includes any "payment" or "compensation, esp[ecially] for a service that someone has performed." Remuneration, BLACK'S LAW DICTIONARY (11th ed. 2019).[6] The word is not amenable to a reading that there be corruption involved.

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[6] Black's Law Dictionary is routinely used to determine the "plain meaning" of statutory or contractual language. See *Sullivan v. Hudson*, 490 U.S. 877, 894 (1989) (citing Black's Law Dictionary for the plain meaning of the phrase "civil action"); *United States v. Davis*, 648 F.3d 84, 89 (2d Cir. 2011) (citing Black's Law Dictionary for the plain meaning of the phrase "contrary to law"); *DeMoura v. Cont'l Cas. Co.*, ___ F. Supp. 3d ___, 2021 WL 848840, at *5

This construction is reinforced when one considers the other words in the statute. The AKS provides in a parenthetical that "any remuneration" can "includ[e] any kickback, bribe, or rebate." 42 U.S.C. § 1320a-7b(b)(2)(B). Pfizer argues that "remuneration must be construed closely to "kickback" and "bribe," which imply corrupt intention. Pfizer Br. at 11-12. Pfizer is correct about the definitions of "kickback" and "bribe," both of which imply or require an illegal or immoral action. *See* Bribe, BLACK'S LAW DICTIONARY (11th ed. 2019) ("A price, reward, gift or favor given or promised *with a view to pervert the judgment of or influence the action of a person in a position of trust.*" (emphasis added)); Kickback, BLACK'S LAW DICTIONARY (11th ed. 2019) ("A sum of money *illegally paid* to someone in authority") (emphasis added). To strengthen this argument, Pfizer also cites the constructive canon of *ejusdem generis*, which provides that "[w]here general words follow an enumeration of two or more things, they apply only to persons or things of the same general kind or class specifically mentioned." Antonin Scalia & Bryan Garner, READING LAW: THE INTERPRETATION OF LEGAL TEXT 199 (1st ed. 2012); Pfizer Br. at 11-12.

This argument fails. To start, Pfizer ignores that the AKS also mandates that "remuneration" includes "rebates," the plain meaning of which implies no corrupt intention. *See* Rebate, BLACK'S LAW DICTIONARY (11th ed. 2019) ("A return of part of a payment, serving as a

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(E.D.N.Y. 2021) (citing Black's Law Dictionary for the plain meaning of the words "direct" and "physical"); *Nasdaq, Inc. v. Exch. Traded Managers Grp., LLC*, 431 F. Supp. 3d 176, 232 (S.D.N.Y. 2019) (citing Black's Law Dictionary for the plain meaning of the phrase "royalty-bearing").

discount or reduction. 2. An amount of money that is paid back when someone has overpaid."). Just as Pfizer argues that "bribe" and "kickback" must inform the meaning of "remuneration," so too must "rebate." And the three example words do not share a common element of "corrupt" intent which can then be read into "remuneration."

Moreover, Pfizer's citation to the *ejusdem generis* canon is misplaced. That canon serves as a means to inform the meaning of a "general" word that *follows* more specific words. *See* Scalia & Garner, READING LAW at 199. Instead, the appropriate constructive canon here, to the extent one is necessary, is the "presumption of [a] nonexclusive 'include.'" Scalia & Garner, READING LAW at 132. This canon provides that "the verb *to include* introduces examples, not an exhaustive list," and indicates an intention "to defeat the negative-implication canon" (*i.e.* the rule that inclusion of certain things necessarily excludes others). *Id.* at 132-33. Applying this maxim, the proper reading of the AKS text is that the parenthetical "including any kickback, bribe, or rebate" provides some, but not all of the examples of "remuneration" within the meaning of the statute. Giving the term "remuneration" its plain meaning, coupled with the non- exhaustive nature of the parenthetical and the fact that "rebate" does not imply any corrupt intention, the Court concludes that word "remuneration" should not be limited to reach only those instances that include corrupt acts.

This construction is consistent with relevant law. The Seventh Circuit, in *United States v. Borrasi*, 639 F.3d 774 (7th Cir. 2011), rejected an argument similar to the one Pfizer makes here: that a AKS defendant's "primary motivation" is what matters for liability. *Id.* at 782.

In particular, the Seventh Circuit embraced the unanimous view of other Circuits at the time that "corrupt intent" is not necessary for liability under the AKS. *Id.* (citing *United States v. Greber*, 760 F.2d 68, 71 (3d Cir. 1985); and then citing *United States v. Davis*, 132 F.3d 1092, 1094 (5th Cir. 1998); and then citing *United States v. Kats*, 871 F.2d 105, 108 (9th Cir. 1989); and then citing *United States v. McClatchey*, 217 F.3d 823, 835 (10th Cir. 2000)). In *Borassi*, employees at a medical center were convicted of AKS violations for paying kickbacks for referrals of Medicare patients. *Id.* at 777. The bribes were structured as the employees' salaries. *Id.* While the individuals were employees and performed work, at least some portion of their salary was paid in connection with referrals. *Id.* at 782. The Court rejected that the Government must prove that the "primary purpose" of the payments was corrupt and unlawful and instead affirmed the Defendants' convictions. *Id.* 782, 786. It was sufficient that the payments were made to affect decisions about medical services, and did not need to be motivated by a corrupt, unlawful, or immoral aim. While the AKS certainly includes such acts within its ambit, the plain text of the statute is broader, encompassing any "remuneration" "to induce" a person to make a healthcare purchase or decision.

2. Inducement

Pfizer also argues that the "to induce" element in the AKS, itself implies that a corrupt intent is required or that a *quid pro quo* transaction exists. *See* Pfizer Br. at 10-13. Pfizer principally relies on an non-precedential Second Circuit summary order noting that in an AKS case "the government [i]s required to prove that any payments to middlemen were made to induce referrals in a *quid pro quo* transaction." *United States v. Krikheli*,

461 F. App'x 7, 10-11 (2d Cir. 2012). While this view may find some minimal support in other cases, it is belied by the text of the statute and other cases that examine the issue closely.

First, there is no language in the AKS proximate to or modifying "induce" that premises liability on a corrupt *quid pro quo* transaction where a benefit must flow to the requestor. The plain meaning of the word "inducement" implies a "one-way" transaction, where the requestor simply gets someone to take an action. *See* Inducement, BLACK'S LAW DICTIONARY (11th ed. 2019) ("The act or process of enticing or persuading another person to take a certain course of action."); Inducement, GARNER'S DICTIONARY OF LEGAL USAGE (3d ed. 2011) ("ordinarily means 'that which influences or persuades'"). In other words, the AKS requires only that payments are made with an intent to influence a decision about medical care or purchases, and does not require any further proof of intent or purpose. *United States v. TEVA Pharm. USA, Inc.*, No. 13 Civ. 3702 (CM), 2016 WL 750720, at *17 (S.D.N.Y. Feb. 22, 2016) ("[T]he [Government] need only prove that 'one purpose' of [the] remuneration is to induce a person to use a service for which payment is made under a federal health care program.").

Lacking support in the text of the statute, Pfizer points to the *Krikheli* summary order, in which the Second Circuit stated that a court "accurately described the law" by requiring the Government to prove "prove that the remuneration was offered or paid as a quid pro quo in return" in an AKS prosecution. *Krikheli*, 461 F. App'x at 11. Pfizer then argues that "quid pro quo," according to precedential Circuit decisions, necessarily implies a "corrupt" intent. Pfizer Br. at 10 (citing *United States v.*

Alfisi, 308 F.3d 144, 149 (2d Cir. 2002)). It first deserves mention that the case to which Pfizer points for this definition arose in the context of a bribery prosecution. The federal bribery statute specifically states that a defendant must act "corruptly." 18 U.S.C. § 201(b). Thus, it is of no importance that a case analyzing whether a *quid pro quo* bribe determined that it must have been "corruptly" made. Of more importance to this case, the AKS has no such statutory requirement.

To the extent *Krikheli* did propose such a rule of law though, it clearly is an outlier case, as no other Circuit has endorsed the narrow definition Pfizer urges here and *Krikheli* is not a precedential decision. The closest to which Pfizer points are cases emphasizing the purposes of the AKS, but not necessarily the legal requirements for liability. *See*, *e.g.*, *United States ex rel. Banigan v. PharMerica Inc.*, 950 F.3d 134, 137 (1st Cir. 2020) ("The AKS was designed to prevent medical providers from making decisions based on improper financial initiatives rather than medical necessity."); *United States ex rel. Young v. Suburban Homes Physicians*, 2017 WL 6625940, *4 (N.D. Ill. Dec. 28, 2017) (characterizing remuneration as "some unjustified, illegitimate value . . . conferred on the recipient," to conform to Congress's purpose in the AKS to prevent "provider decisions clouded by improper financial considerations").

The law is clear, however, that "[v]ague notions of a statute's 'basic purpose' are inadequate to overcome the words of its text regarding the specific issue under consideration." *Montanile v. Board of Trustees of Nat. Elevator Indus. Health Benefit Plan*, 577 U.S. 136, 150 (2016) (citing *Mertens v. Hewitt Assocs.*, 508 U.S. 248, 261 (1993)) (alterations in original omitted). Because the text of the statute is clear that the only showing of intent

necessary for a person to be liable under the AKS is that remuneration be given "to induce" a beneficiary to purchase or receive medical services, the Court will not consider these other notions of "purpose." This approach is wholly consistent with other cases where courts have determined that the text of the AKS clearly only requires a payment intended to induce a purchase or provision of medicine or medical services. As Judge McMahon of this Court noted several years ago, judges in this District largely "follow the rule of the Third, Fifth, Seven, Ninth, and Tenth Circuits: that the [Government] need only prove that 'one purpose' of [the] remuneration is to induce a person to use a service for which payment is made under a federal health care program." *TEVA Pharm. USA, Inc.*, No. 13 Civ. 3702 (CM), 2016 WL 750720, at *17 (S.D.N.Y. Feb. 22, 2016).

The only other Circuit case to which Pfizer points in support of its position is *Guilfoile v. Shields*, 913 F.3d 178 (1st Cir. 2019). That case, however, does not support Pfizer's reading of the AKS. Instead, Pfizer's view may be endorsed by one judge on the panel concurring in part and dissenting in part from the Court's decision. The *Guilfoile* court reversed a district court's determination that consulting payments for a *bona fide* medical consultant did not implicate the AKS. *Id.* at 182-84. Specifically, the consultant worked for a medical device company, establishing relationships between the company and hospitals, which would then purchase products from the company. *Id.* The First Circuit held that the consulting payments could be illegal kickbacks in violation of the AKS, despite that the consulting fees otherwise were a valid form of compensation. *Id.* at 183-84, 194. One judge wrote separately, however, dissenting from the Court's finding of a potential AKS violation, to note

that these kinds of payments were not within the "heartland" of the AKS. *Id.* at 199. That judge noted that the payments made by the company to its consultant fell outside the core of the AKS because there was too significant attenuation between the consulting fees to the ultimate purchases by hospitals to make out inducement. *Id.* at 198. Pfizer similarly argues here that a payment falls outside this core, and therefore does not violate the AKS, absent a direct link or improper direct influence. Pfizer Br. at 11; Pfizer Reply at 3, 9. That view was not the holding of the court in *Guilfoile*, and, in any event, the concurring judge recognized that criminal statutes often expand beyond the "heartland" of their purpose. *Id* at 199 ("Of course, statutes that have cores also have peripheries. And conduct that falls within the periphery of a statute's scope is no less unlawful than conduct that falls within its core."). In sum, *Guilfoile* does not support Pfizer's contention that a "corrupt" intent or other improper direct influence on a purchasing decision is required for liability under the AKS.

In other words, the AKS means what it says. It prohibits knowingly and willfully providing remuneration which is intended to induce a purchase of medical treatments or services. While the statute is broad, that alone does not mandate that the Court must endorse a narrower reading.[7] Because its support for its position is

[7] Pfizer also argues that the AKS should be limited by application of the rule of lenity. Pfizer Br. at 13-14. That is inappropriate here. The Rule of Lenity requires ambiguity in the statute. See *Yates v. United States*, 574 U.S. 528, 547-48 (2015) ("[I]f our recourse to traditional tools of statutory construction leaves any doubt about the meaning of 'tangible object,' as that term is used in § 1519, we would invoke the rule that 'ambiguity concerning the ambit of criminal statutes should be resolved in favor of lenity.'" (quoting *Cleveland v. United States*, 531 U.S. 12, 25 (2000))). The Supreme Court also

unavailing, the Court declines Pfizer's invitation to do so here.

B. The HHS OIG Advisory Opinion Is Not Contrary to Law

Based on the plain reading of the AKS text and the relevant law, the Court now turns to the HHS OIG determination that the Direct Program could violate the AKS "if the requisite intent to induce or reward referrals for, or purchases of, items and services reimbursable by a Federal health care program were present." AR 142. This conclusion is not contrary to law, and, thus, judgment will be entered for Defendants.

As Pfizer describes the Direct Program, it is aimed to allow individuals who otherwise may not purchase tafamidis (through economic hardship, personal choice, or both) to purchase it. Pfizer Br. at 1. Because the stated intent of the payments Pfizer proposes here are to increase the number of Medicare beneficiaries who purchase the drug, the Court is unable to issue the declaratory judgment Pfizer seeks or to issue judgment in its favor on the APA claim, since the AKS prohibits all remuneration that induces purchases of drugs like tafamdis (unless the payments fall into one of the safe harbors).

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has emphasized that the rule of lenity is appropriate only where "[n]either the statute's language nor its structure provides any definitive guidance." *United States v. Thompson/Center Arms Co.*, 504 U.S. 505, 513 (1992). Breadth is not the same thing as ambiguity. *Nat'l Org. for Women, Inc. v. Scheidler*, 510 U.S. 249, 262 (1994). The Court has determined a clear plain meaning of the text of the AKS, which is not ambiguous. As a result, the rule of lenity is inapplicable here.

The Court is not unmindful of the potential consequences of this conclusion. Pfizer makes the point that tafamidis is the only drug approved to treat ATTR-CM and made strenuous arguments to that end during argument in this case. Pfizer Br. at 1; Tr. at 60:20-62:13, 72:13-16. In theory, the AKS exists to permit doctors to prescribe the correct medication among alternatives and not because of an economic interest in prescribing one medication or another. *Cf. United States v. Patel*, 778 F.3d 607, 612 (7th Cir. 2015) ("The Statute was enacted to protect the Medicare and Medicaid programs from increased costs and abusive practices resulting from provider decisions that are based on self-interest rather than cost, quality of care or necessity of services."). Where tafamidis is the only approved option for patients, economic hardship may result in patients with a debilitating illness foregoing treatment that otherwise might assist them.

The Government responds that an available alternative would be to lower the cost of tafamidis, which is set by Pfizer. However, as the parties discussed at length during the argument in this case, because Medicare Part D imposes cost-sharing as a percentage of a drug's price, it is impossible entirely to eliminate the financial impact of tafamidis. *See* Tr. at 45:25-47:2. And, Pfizer produces unrebutted statistics that Medicare Part D recipients sometimes forego treatment when asked to pay more than $50 due to economic hardships. Cpl. ¶ 51; Pfizer Br. at 17 n.19. It should also be noted that the Defendants' cost-saving argument is of even less persuasive value, since the off-label alternative treatments to which it points are as or more expensive than tafamidis and, in at least some circumstances, the costs would be entirely borne by the Government. Pfizer Br. at 16-17.

Still, this Court must apply the law as it currently is written and is bound by precedent and legal authority that interprets the AKS broadly and as potentially encompassing the kinds of payments Pfizer would make as part of the Direct Program. While there may be an administrative or legislative remedy to the problems Pfizer seeks to correct here, the remedy does not lie with the Court.

CONCLUSION

For the reasons stated herein, Pfizer's motion for summary judgment [ECF No. 33] is DENIED. Defendants' motion to dismiss or, in the alternative, for summary judgment [ECF No. 44] is GRANTED. With regard to the Charity Program that Pfizer intends to operate, the company's claims in Counts I, II, and III are not ripe for adjudication here and are dismissed. With regard to the Direct Program, the law is clear that absent an express carve-out, the Anti- Kickback Statute prohibits any remuneration intended to induce someone to purchase or receive a drug or medical service. No independent corrupt intent or direct *quid pro quo* is necessary. Because that is all the HHS OIG concluded when it issued an advisory opinion to Pfizer about the Direct Program, the agency's action is not contrary to law and the Court cannot declare that the Direct Program will not violate the Anti-Kickback Statute as Pfizer requests.

The Clerk of Court respectfully is directed to close the motions at ECF Nos. 33 and 44, to enter judgment for Defendants, and to close the case.

SO ORDERED.

Date: September 30, 2021
New York, NY

/s/ Mary Kay Vyskocil
MARY KAY VYSKOCIL
United States District Judge

APPENDIX C

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL
Washington, DC 20201

September 18, 2020

Nick Lagunowich
Regional President North America, Rare Disease
Pfizer Inc.
235 East 42nd Street
New York, NY 10017

Re: OIG Advisory Opinion No. 20-05

Dear Mr. Lagunowich:

We are writing in response to your request for an advisory opinion regarding a pharmaceutical manufacturer's proposal to provide cost-sharing assistance directly to Medicare beneficiaries who arc prescribed either of two formulations of its drug (the "Proposed Arrangement"). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the "Act"), or under the exclusion authority at section 1128(b)(7) of the Act, or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act, the Federal anti-kickback statute.

You have certified that all of the information provided in your request, including all supplemental submissions, is

true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied on the facts and information presented to us and, in accordance with 42 C.F.R. § 1008.39(d), other publicly available information. We have not undertaken an independent investigation of the certified facts and information presented to us by Pfizer Inc., the requestor of this opinion. This opinion is limited to the facts presented to us by Pfizer Inc. and other publicly available information found in the course of our independent inquiry in connection with our assessment of the Proposed Arrangement.

Based on the facts certified in your request for an advisory opinion, supplemental submissions, and other publicly available information, we conclude that: (i) the Proposed Arrangement, as structured, would not generate prohibited remuneration under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act; and (ii) the Proposed Arrangement would generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals for, or purchases of, items and services reimbursable by a Federal health care program were present and that the Office of Inspector General ("OIG") could potentially impose administrative sanctions on Pfizer Inc. under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. Any definitive conclusion regarding the existence of an anti-kickback statute violation requires consideration of all of the facts and circumstances of the arrangement as

implemented, including a party's intent.[1] Where, as is the case here, the arrangement is proposed but has not yet been implemented, we cannot reach a definitive conclusion regarding the existence of an anti-kickback statute violation.

This opinion may not be relied on by any persons other than Pfizer Inc., the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. The Disease and Available Treatment Options

Transthyretin amyloid cardiomyopathy ("ATTR-CM" or the "Disease") is a progressive, rare disease caused by deposition of transthyretin amyloid fibrils in the heart that can lead to heart failure and death.[2] The Disease can be an inherited condition, known as the hereditary form, or it can occur spontaneously, known as the wild-type form. Pfizer Inc. ("Requestor"), a pharmaceutical

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[1] See accord OIG, Medicare and State Health Care Programs: Fraud and Abuse; Issuance of Advisory Opinions by the OIG, 62 Fed. Reg. 7,351-52 (Feb. 19, 1997), available at https://oig.hhs.gov/authorities/docs/interim.pdf.

[2] National Institutes of Health, Transthyretin Amyloidosis (2020), available at https://ghr.nlm.nih.gov/condition/transthyretin-amyloidosis#genes: see also Ronald M. Witteles et al., Screening for Transthyretin Amyloid Cardiomyopathy in Everyday Practice, JACC: Heart Failure, vol. 7 (Aug. 2019), available at https://heartfailure.onlinejacc.org/content/7/8/709.

manufacturer, estimated that approximately 100,000 to 150,000 Americans are affected by the Disease.[3]

Requestor manufactures and markets two forms of tafamidis, Vyndaqel® and Vyndamax® (each, a "Medication" and collectively, the "Medications"). In 2019, the U.S. Food and Drug Administration ("FDA") approved the Medications for the treatment of both the wild-type and the hereditary forms of the Disease in adults to reduce cardiovascular mortality and cardiovascular-related hospitalization.[4] Requestor certified that the majority of patients with the Disease are Medicare beneficiaries, and the majority of patients who may be prescribed the Medications will be Medicare beneficiaries.

According to Requestor, the Medications are not curative. However, a multicenter, international, double-blind, placebo-controlled phase 3 trial found that one form of the Medications reduced all-cause mortality and the frequency of cardiovascular-related hospitalizations

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[3] Requestor certified that its prevalence estimate of the Disease is based on information available to Requestor and that such estimate may change over time as knowledge of the Disease improves.

[4] Prior to its approval of the Medications, the FDA had not approved a pharmacological therapy to treat the Disease. According to Requestor, it does not expect FDA approval for a competitor therapy until 2021 or later. Requestor further certified that some patients who could not afford their cost-sharing obligations for the Medications elected to enroll in a phase 3, placebo-controlled, clinical trial for a drug of another manufacturer that is being studied for the treatment of the Disease. Requestor asserted that, even if the FDA were to approve another therapy for the treatment of the Disease, "if the Medications demonstrate superior efficacy and safety" then that superior efficacy and safety would be relevant to the fraud and abuse analysis of the Proposed Arrangement in the same way that the lack of FDA-approved alternatives is now.

and also reduced decline in functional capacity and quality of life.[5]

With respect to alternative treatments for the Disease, Requestor certified that there may be non-pharmacological treatments (e.g., a heart transplant or dual heart and liver transplant); while such transplants have had some success, Requestor certified that they have limited application because most patients with the Disease are too sick and have too many comorbidities to meet transplant criteria. In addition, according to Requestor, some physicians prescribe Onpattro® and Tegsedi® off-label for treatment of the Disease.[6]

Requestor set the list price at $225,000 for each one-year course of treatment with the Medications. According to Requestor, at this price and based on cost-sharing requirements in the phases of the standard Medicare Part D benefit (i.e., deductible, initial coverage, coverage gap, catastrophic), a Medicare beneficiary enrolled in the standard benefit must pay annually approximately $13,000 in out-of-pocket expenditures for the Medications. According to Requestor, a significant portion of Medicare beneficiaries cannot afford to purchase the

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[5] Mathew S. Maurer et al., Tafamidis Treatment for Patients with Transthyretin Amyloid Cardiomyopathy, N Engl J. Med. 2018; 379:1007-16 (Sept. 13, 2018), available at https://www.nejm.org/doi/pdf/10.1056/NEJMoa1805689?articleTools=true.

[6] According to Requestor, "some physicians have prescribed off-label a drug that is not approved to treat [the Disease] ... because that other drug is covered under Medicare Part B, for which Medigap insurance is available to reduce the patient's out-of-pocket expenses." Requestor further certified that, "[t]here is no question that some physicians may consider drug costs and a patient's out-of-pocket burden when making prescribing judgments."

Medications because of these annual out-of- pocket expenses; stated another way by Requestor, these out-of-pocket costs operate as a financial impediment for a substantial portion of the Medicare population, preventing them from purchasing the Medications. Requestor certified that, in 2019, many Medicare beneficiaries filling their first order for the Medications would face $5,100 in true out-of- pocket ("TrOOP") spending, and therefore would reach the catastrophic phase (which had a threshold of $5,100 in 2019) with their first prescription.[7] Requestor also certified that, once beneficiaries are in the catastrophic coverage phase, the coinsurance requirement in that phase would be prohibitive for many beneficiaries.[8]

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[7] In the catastrophic phase of the Part D benefit, the Medicare program pays 80 percent of the costs for pharmacological therapies through reinsurance; the plan pays 15 percent of these costs; and the beneficiary is responsible for coinsurance equal to the greater of (i) 5 percent of the costs of therapies such as the Medications or (ii) $3.60 for generic drugs and $8.95 for brand-name drugs in 2020. See Medicare Payment Advisory Commission, Report to the Congress: Medicare and the Health Care Delivery System (June 2020), available at http://www.medpac.gov/docs/default-source/reports/jun20_reporttocongress_sec.pdf?sfvrsn=0; see also Kaiser Family Foundation, An Overview of the Medicare Part D Prescription Drug Benefit (Nov. 2019), available at https:// www.kff.org/medicare/fact-sheet/an-ovenview-of-the-medicare-part-d-prescription-drug-benefit/.

[8] Underscoring the significance of ability-to-pay as an impediment to purchasing the Medications, Requestor stated, "offering co-payment assistance to help eligible patients afford a clinically-appropriate medication, when such medication is the only approved medication for the disease and the principal reason that patients would not fill their prescriptions is the inability to pay their out-of-pocket costs, does not improperly induce the underlying prescribing decisions" (emphasis added).

B. The Proposed Arrangement

1. The Subsidy Program

Requestor certified that it has designed an assistance program to address the financial impediment of the out-of-pocket costs for the Medications. Specifically, under the Proposed Arrangement, Requestor would institute a cost-sharing assistance program specific to Medicare beneficiaries who are prescribed the Medications (the "Subsidy Program"). To be eligible for financial assistance under the Subsidy Program, the applicant must: (i) be a Medicare beneficiary enrolled in either a Part D plan or a Medicare Advantage – Part D ("MA-PD") plan that covers the Medications; (ii) be a United States resident; (iii) meet the Subsidy Program's criteria for financial need, which Requestor would set as a household income between 500 percent and 800 percent of the Federal Poverty Level ("FPL"); and (iv) have been prescribed one of the Medications on- label for the treatment of the Disease. Requestor certified that Medicare beneficiaries with household incomes up to 500 percent of the FPL would continue to be eligible for Requestor's existing free drug program for the Medications, except that Requestor has required, and would continue to require, that patients not be able to receive assistance from other funding sources, including the Medicare Low-Income Subsidy,[9] in order to be eligible for Requestor's free drug program.

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[9] The Medicare Low-Income Subsidy provides premium and cost-sharing assistance for beneficiaries with household incomes up to 150 percent of the FPL. According to publicly available data, as of March 2020, approximately 27.2 percent of Medicare beneficiaries enrolled in Medicare Part D receive a full or partial subsidy from

Requestor certified that it would not offer assistance under the Subsidy Program as part of any advertisement or solicitation for the Medications. According to Requestor, if a beneficiary qualifies for the Subsidy Program, Requestor, through a third-party Subsidy Program administration vendor,[10] would complete enrollment by activating a physical card, issuing a personal identification number to the beneficiary, or both (collectively, the "Subsidy Card") that the beneficiary would use at the point of sale to receive cost-sharing assistance when purchasing the Medications. Under the Subsidy Program, a beneficiary would be responsible for a monthly copayment of up to $35 at the point of sale each time he or she fills a prescription for one of the Medications. Requestor, through its vendor, would pay 100 percent of the beneficiary's remaining cost-sharing obligations for the Medications, including any deductible and required cost sharing owed during the initial coverage phase, the coverage gap phase, and the catastrophic coverage phase.[11]

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the Federal government as part of the Medicare Low-Income Subsidy. See Centers for Medicare and Medicaid Services, LIS Enrollment by Plan (Mar. 2020), available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/LIS-Enrollment-by-Plan. Counts and percentages are calculated based on plan enrollments greater than 10.

[10] We have not been asked to opine on, and express no opinion regarding, the arrangement between Requestor and the third-party vendor.

[11] Requestor certified that the purpose of the Subsidy Program is "to provide copay assistance directly to eligible Medicare Part D beneficiaries to help them pay the TrOOP costs required to matriculate through the Part D deductible, initial coverage phase and coverage gap and then to assist patients with affording the 5% coinsurance required during the catastrophic phase."

Requestor certified that a beneficiary would be eligible to obtain a Subsidy Card regardless of which provider or practitioner prescribes the Medications.

Requestor certified that the Subsidy Program would provide assistance only for the Medications and would not provide financial support for other FDA-approved pharmacological therapies to treat the Disease or other medical needs of beneficiaries diagnosed with the Disease (e.g., prescription drugs used by the patient in connection with managing the Disease, treating symptoms of the Disease, or treating pain and other side effects of the Disease). Requestor also certified that certain foundations operating patient assistance programs presently have funds covering amyloidosis (of which the Disease is a type).

Based on publicly available data maintained by the Centers for Medicare and Medicaid Services, approximately 91 percent of Medicare beneficiaries have a household income below 800 percent of the FPL.[12] Of the beneficiaries comprising that 91 percent, based on facts certified by Requestor, those with incomes at or below 500 percent of the FPL would be eligible to receive assistance through either the Medicare Low-Income Subsidy or Requestor's free drug program, and the balance (with household incomes between 500 percent and 800 percent of the FPL) would be eligible to receive cost-sharing assistance through the Subsidy Program. The remaining 9 percent of Medicare beneficiaries would not be eligible

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[12] Centers for Medicare and Medicaid Services, Medicare Current Beneficiary Survey, Survey File data. Baltimore, MD: U.S. Department of Health and Human Services, 2018, available at https://www.cms.gov/research-statistics-data-and-systemsresearchmcbscodebooks/2018-mcbs-survey-file.

for assistance through the Subsidy Program, Requestor's free drug program, or the Medicare Low-Income Subsidy.

2. The Hub

Requestor has developed a patient support hub, VyndaLink (the "Hub"), that is operated by a third-party vendor pursuant to a written services agreement.[13] The Hub would administer the Subsidy Program. Requestor certified that prescribing physicians would be able to contact the Hub to learn about the Subsidy Program.

Requestor certified that the Hub, which is already in place, currently uses the following enrollment process and would employ the process in the same manner for purposes of enrolling patients in the Subsidy Program. First, Requestor certified that, to enroll a patient in the Hub, both the prescriber and the patient must complete and sign a patient enrollment form. According to Requestor, the prescriber must provide prescription information and must confirm that he or she has prescribed the Medication for the treatment of the Disease. The prescriber also must certify that he or she has made an independent judgment that the Medication is medically necessary for the patient and that all information provided on the form is accurate. If the patient seeks financial assistance, the patient also must provide certain financial information and documentation of annual household income.

For purposes of the Subsidy Program, Requestor certified that, once a beneficiary is enrolled in the Hub, the

[13] We have not been asked to opine on, and express no opinion regarding, the services arrangement between Requestor and the Hub.

Hub would conduct a benefits investigation to determine coverage for the Medication under the applicant's Part D or MA-PD plan, including out-of-pocket costs and payor coverage requirements. If the beneficiary seeks financial assistance, the Hub first would conduct alternative funding research to determine if other options (e.g., the Medicare Low-Income Subsidy) are available to provide financial assistance to the beneficiary.

Requestor certified that the Hub would conduct an individualized, case-by-case income determination based on a uniform measure of financial need and would determine a beneficiary's eligibility for the Subsidy Program in a verifiable, uniform, and consistent manner. Once the Hub verifies that a beneficiary is eligible for the Subsidy Program, it would enroll the beneficiary and would communicate such enrollment to the beneficiary, the prescriber (upon the prescriber's request), and the applicable specialty pharmacy, as described in more detail below.

3. Dispensing Pharmacies

Requestor certified that eligible beneficiaries would be able to use the Subsidy Card at any specialty pharmacy that Requestor authorizes to dispense the Medications (a "Dispensing Pharmacy"), and the Subsidy Card would not be conditioned on a beneficiary using a particular Dispensing Pharmacy.[14] Likewise, according to Requestor, the Subsidy Program would not give preference to any particular Dispensing Pharmacy and is structured such that the beneficiary would have the same limited cost-sharing obligation ($35 per monthly fill) regardless

[14] Requestor certified that it does not own or operate, directly or indirectly, any pharmacies that dispense the Medications.

of the Dispensing Pharmacy he or she selects to fill the prescription for the Medications.

According to Requestor, Dispensing Pharmacies are the only pharmacies authorized by Requestor to dispense the Medications to any patient who wishes to purchase the Medications, regardless of whether the patient is eligible for the Subsidy Program. Prior to the commercial launch of the Medications, Requestor conducted a request for proposal ("RFP") process inviting specialty pharmacies to submit information describing their qualifications to be a Dispensing Pharmacy. To be eligible to serve as a Dispensing Pharmacy, the specialty pharmacy must have met several criteria set forth by Requestor.

At the conclusion of the RFP process, Requestor selected a number of pharmacies that met its criteria. Requestor certified that no other specialty pharmacies have since requested to be a Dispensing Pharmacy. According to Requestor, if other specialty pharmacies were to ask Requestor to participate as a Dispensing Pharmacy, Requestor would evaluate their qualifications under the same criteria referenced above and would base its decision on whether to include the specialty pharmacy on: (i) the ability of the specialty pharmacy to meet the criteria and (ii) whether it is in the best interests of patients to include the additional specialty pharmacy.

Requestor further certified that regional specialty pharmacies that are owned or affiliated with institutions (i.e., hospitals and integrated delivery networks) that: (i) have experience with the Disease, including diagnosing and managing patients diagnosed with the Disease, (ii) agree to contract with Requestor or Requestor's agent and comply with all contract terms, and (iii) are able to

meet certain basic data reporting requirements, are eligible to be a Dispensing Pharmacy. Requestor identified specialty pharmacies owned by or affiliated with institutions that met these requirements, and some of these specialty pharmacies chose to participate as a Dispensing Pharmacy.

Requestor certified that, to its knowledge, there has not been any instance where there were no Dispensing Pharmacies included among the preferred pharmacies in a beneficiary's Medicare Part D or MA-PD plan. Requestor certified that if a beneficiary's plan were to require the beneficiary to use a particular specialty pharmacy ("Plan Pharmacy") and that Plan Pharmacy is a Dispensing Pharmacy, then the beneficiary would be able to use the Subsidy Card at that Plan Pharmacy. If a beneficiary's plan were to allow the beneficiary to obtain the Medications at more than one Dispensing Pharmacy, the Hub would ask the beneficiary and the prescribing physician whether they have a preference. If neither the beneficiary nor the prescribing physician has a preference, the Hub would transfer the prescription to a Plan Pharmacy that is a Dispensing Pharmacy using an objective "round robin" process.

Notwithstanding the foregoing, Requestor certified that, if a Part D or MA-PD plan would otherwise require a beneficiary to use a Plan Pharmacy that is not a Dispensing Pharmacy, the Hub would send the prescription to the beneficiary's or the prescribing physician's preferred Dispensing Pharmacy. If neither the patient nor the prescribing physician expresses a preference, the Hub would send the prescription to the Dispensing Pharmacy with the lowest patient out-of-pocket costs (as determined by the Part D or MA-PD plan). If more than one Dispensing Pharmacy offers the patient lowest out-

of- pocket costs or if the out-of-pocket costs are the same across all or many Dispensing Pharmacies, the Hub would send the prescription to one of the Dispensing Pharmacies offering the lowest out-of-pocket costs using an objective, "round robin" process. The recipient pharmacy would then address coverage and reimbursement issues with the beneficiary's plan.

II. LEGAL ANALYSIS

A. Law

1. Federal Anti-Kickback Statute

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward, among other things, referrals for, or purchases of, items or services reimbursable by a Federal health care program.[15] Where remuneration is paid purposefully to induce or reward referrals or purchases of items or services payable by a Federal health care program, the anti- kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible transaction. For purposes of the anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.[16]

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[15] See section 1128B(b) of the Act.

[16] As we have stated previously, "Congress's intent in placing the term 'remuneration' in the statute in 1977 was to cover the transferring of anything of value in any form or manner whatsoever. The statute's language makes clear that illegal payments arc prohibited beyond merely 'bribes,' 'kickbacks,' and 'rebates,' which were the three terms used in the original 1972 statute." OIG, Medicare and

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to induce or reward referrals for items and services reimbursable by a Federal health care program.[17] Violation of the statute constitutes a felony punishable by a maximum fine of $100,000, imprisonment up to ten years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 11283(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

Congress has developed several statutory exceptions to the Federal anti-kickback statute.[18] In addition, the U.S. Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to sanctions under the anti-kickback statute, even though they potentially may be capable of inducing referrals of federally reimbursable business.[19] The safe harbors set forth specific conditions that, if met,

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State Health Care Programs: Fraud and Abuse; OIG Anti-Kickback Provisions, 56 Fed. Reg. 35,952 (July 29, 1991), available at https://oig.hhs.gov/fraud/docs/safeharborregulations/072991.htm.

[17] See, e.g., United States v. Nagelvoort, 856 F.3d 1117 (7th Cir. 2017); United States v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985).

[18] Section 1128B(b)(3) of the Act.

[19] See 42 C.F.R. § 1001.952.

assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor.

2. Beneficiary Inducements CMP

A separate section of the Act, section 1128A(a)(5) (the "Beneficiary Inducements CMP"), provides for the imposition of civil monetary penalties against any person who offers or transfers remuneration to a Medicare or State health care program (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program (including Medicaid). The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. The Beneficiary Inducements CMP "is a separate and distinct authority, completely independent of the [Federal] anti-kickback statute."[20]

A distinct definition of "remuneration" applies exclusively to section 1128A of the Act, which includes the Beneficiary Inducements CMP. Specifically, section 1128A(i)(6) of the Act defines "remuneration" to include "the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for

[20] OIG, Health Care Programs: Fraud and Abuse; Revised OIG Civil Money Penalties Resulting From the Health Insurance Portability and Accountability Act of 1996, 63 Fed. Reg. 14,393, 14,395 (Mar. 25, 1998), available at https://www.govinfo.gov/content/pkg/FR-1998-03-25/pdf/FR-1998-03-25.pdf.

free or for other than fair market value."[21] Section 1128A(i)(6) of the Act also sets forth a number of exceptions to the definition of "remuneration" that apply for purposes of section 1128A of the Act. These exceptions protect certain remuneration from violating the Beneficiary Inducements CMP. These exceptions[22] apply only for the purposes of the definition of "remuneration" applicable to section 1128A of the Act (the CMP statute); they do not apply for purposes of section 1128B(b) of the Act (the Federal anti-kickback statute).

B. Analysis

Under the Proposed Arrangement, Requestor seeks to provide cost-sharing subsidies directly to Medicare beneficiaries who purchase its Medications. As an initial matter, the OIG has been and continues to be extremely mindful of the importance of ensuring that beneficiaries who enroll in Medicare Part D have access to medically necessary drugs. We also recognize that, presently, there are no other FDA-approved pharmacological therapies for treatment of the Disease. Our prior guidance has contemplated this scenario; specifically, we have stated that we believe lawful avenues exist for pharmaceutical manufacturers and others to help ensure that all Part D beneficiaries can afford medically necessary

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[21] See also 42 C.F.R. § 1003.110 (defining "remuneration," for purposes of the regulations implementing the Beneficiary Inducements CMP, to be consistent with the definition of "remuneration" set forth at section 1128A(i)(6) of the Act).

[22] See, e.g., section 1128A(i)(6)(E) of the Act (setting forth the exception for waivers of coinsurance and deductible amounts); section 1128A(i)(6)(F) of the Act (setting forth the exception for remuneration that promotes access to care and poses a low risk of harm to patients and Federal health care programs).

drugs, including in those instances where there may be only one drug to treat a disease.[23] However, the Subsidy Program proposed by Requestor differs materially from the lawful avenues described in our prior guidance.

In the course of reviewing this request, we found certain publicly available information that relates to the subject of this request for an advisory opinion that was not provided by Requestor but informs our conclusion about the fraud and abuse risks posed by the Proposed Arrangement.[24] Therefore, we first provide additional context—otherwise available to the public—in this analysis.

1. Additional Publicly Available Background Information

According to a study published in 2020, Requestor's Medications constitute the most expensive cardiovascular drug ever launched in the United States.[25] The study

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[23] OIG, Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70,623, 70,626 (Nov. 22, 2005), available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2005/2005PAPSpecialAdvisoryBulletin.pdf (hereinafter the "2005 Bulletin"); see also OIG, Supplemental Special Advisory Bulletin: Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31,120 (May 30, 2014), available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/2014/independent-charity-bulletin.pdf (hereinafter the "2014 Bulletin").

[24] We conducted an appropriate independent inquiry to better inform our understanding of the Medications and the Disease as it relates to our assessment of the Proposed Arrangement. See 42 C.F.R. § 1008.39(d).

[25] Dhruv S. Kazi et al., Cost-Effectiveness of Tafamidis Therapy for Transthyretin Amyloid Cardiomyopathy, Circulation. 2020; 141:1,214-24 (originally published Apr. 14, 2020), available at https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.119.045093.

concluded that treating all eligible patients with the Disease with the Medications (n~120,000) would increase health care spending in the United States by $32.3 billion a year, with nearly all of the budget impact resulting from the cost of the Medications.[26] With respect to the annual increase in spending of $32.3 billion, the study explained that:

> [t]his includes a $31.9 billion increase in annual prescription drug expenditures, which would increase the total US spending for all prescription drugs by 9.3% (from $344 billion in 2018 to $375.9 billion).[] As diagnosis rates increase, as a result of greater awareness about ATTR-CM, increased use of nuclear scintigraphy for accurate diagnosis, and more widespread uptake of genetic tests to screen family members of individuals with variant ATTR-CM, the budget impact of tafamidis is expected to increase as well.[27]

A recent commentary in *JAMA Cardiology* co-authored by an investigator on the Medications' pivotal phase 3 clinical trial also raised concerns regarding pricing of the Medications.[28] Further, according to these authors, current estimates that the prevalence of the Disease is approximately 100,000 people in the United States "may be

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[26] Id. at 1,220.

[27] Id. (internal citations omitted).

[28] Gurwitz JH, Maurer MS. Tafamidis—A Pricey Therapy for a Not-So-Rare Condition. JAMA Cardiol. 2020;5(3):247-248, 248 doi:10.1001/jamacardio.2019.5233, available at https://jamanetwork. com/journals/jamacardiology/article-abstract/2758314?resultClick=l ("[T]he very high prices for [the Medications] are not justified and appear to be a particularly egregious example of price gouging.").

a substantial underestimate of the number of patients eligible for" the Medications.[29]

We likewise take into consideration our recent enforcement history involving conduct by pharmaceutical manufacturers–vis-à-vis foundations that operate assistance programs– that the United States alleged was illegal. To date, the United States has settled enforcement actions totaling more than $900 million against ten pharmaceutical manufacturers, including Requestor,[30] and four foundations, for conduct solely involving the allegedly illegal use of foundations that operate patient assistance programs as conduits for improper payments to patients.[31] Central to these allegations is a concern that

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[29] Id. at 247.

[30] See DOJ, Press Release, Pfizer Agrees to Pay $23.85 Million to Resolve Allegations that it Paid Kickbacks Through a Co-Pay Assistance Foundation (May 24, 2018), available at https://www.justice.gov/usao-ma/pr/pfizer-agrees-pay-2385-million-resolve-allegations-it-paid-kickbacks-through-co-pay; OIG, Corporate Integrity Agreement between the Office of Inspector General of the Department of Health and Human Services and Pfizer Inc. (May 23, 2018), available at https://oig.hhs.gov/fraud/cia/agreements/Pfizer_Inc_05232018.pdf.

[31] See, e.g., DOJ, Press Release, Novartis Agrees to Pay Over $51 Million to Resolve Allegations that It Paid Kickbacks Through Co-Pay Foundations (July 1, 2020), available at https://www.justice.gov/usao-ma/pr/novartis-agrees-pay-over-51-million-resolve-allegations-it-paid-kickbacks-through-co-pay (noting that the United States has collected over $900 million from ten pharmaceutical companies relating to similar conduct); DOJ, Press Release, Fourth Foundation Resolves Allegations that it Conspired with Pharmaceutical Companies to Pay Kickbacks to Medicare Patients (Jan. 21, 2020), available at https://www.justice.gov/usao-ma/pr/fourth-foundation-resolves-allegations-it-conspired-pharmaceutical-companies-pay (explaining that four foundations have paid a total of $13 million to settle similar allegations).

pharmaceutical manufacturers blunt the impact of patient cost sharing to induce patients to fill prescriptions for costly medications. This, in turn, removes a potential downward pressure on the price of the drugs. Most of these settlements involved concurrent execution of integrity agreements with the OIG.[32]

2. Federal Anti-Kickback Statute

In evaluating the Proposed Arrangement under the Federal anti-kickback statute, we look to whether it would involve remuneration to an individual to induce that individual to purchase an item or service for which payment may be made under a Federal health care program. The Proposed Arrangement plainly would. Specifically, under the Subsidy Program, Requestor would provide remuneration in the form of a valuable Subsidy Card to eligible Medicare beneficiaries. To be eligible, a Medicare beneficiary must, among other criteria, be prescribed one of the Medications for treatment of the Disease, meet certain financial need criteria, and be enrolled in a Part D or MA-PD plan that provides coverage for the Medications. These beneficiaries would, in turn, use the Subsidy Card at the point of sale to pay virtually all of the cost-sharing obligations that would other-wise apply for the Medications. In this respect, the Subsidy Program would operate as a quid pro quo—Requestor would offer remuneration (the Subsidy Card) to the beneficiary in return for the beneficiary purchasing one of

[32] None of these settlement agreements with the Department of Justice or associated integrity agreements with the OIG involve any admission of wrongdoing by any pharmaceutical manufacturer or foundation.

the Medications.[33] We note also that the Subsidy Card can only be used to pay for Medicare cost-sharing obligations specific to the Medications; it has no value outside of these cost-sharing obligations, and it cannot be used to assist with expenses related to the other medical needs of beneficiaries diagnosed with the Disease (e.g., prescription drugs used by the patient in connection with managing the Disease, treating symptoms of the Disease, or treating pain and other side effects of the Disease).[34]

Requestor certified that beneficiary cost-sharing obligations for the Medications are approximately $13,000 per year, and Requestor identified inability to pay these cost- sharing obligations as an impediment to a significant portion of Medicare beneficiaries purchasing the Medications. Requestor designed the Subsidy Program to address this impediment. Thus, the Subsidy Card would be offered to beneficiaries to induce them to purchase a covered item by removing what would otherwise be an impediment that would deter such purchase.[35]

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[33] Any definitive conclusion regarding a prohibited quid pro quo would require consideration of a party's intent when implementing the Proposed Arrangement, which has not yet occurred.

[34] We also note that Requestor has identified foundations that operate patient assistance programs that presently have funds covering amyloidosis. The Disease is a type of amyloidosis.

[35] As we have stated previously, "[t]he meaning of the term 'to induce,' which describes the intent of those who offer or pay remuneration in paragraph (2) of the [anti-kickback] statute, is found in the ordinary dictionary definition: 'to lhead or move by influence or persuasion,'" which reflects the "congressional intent to create a very broadly worded prohibition." 56 Fed. Reg. 35,952 (July 29, 1991), available at https://oig.hhs.gov/fraud/docs/safeharborregulations/072991.htm.

Based on Requestor's certifications, a beneficiary would know about the availability of the Subsidy Program at the time he or she purchases the Medications. Accordingly, where a Medicare beneficiary otherwise may be unwilling or unable to purchase the Medications due to his or her cost-sharing obligations, which are driven by the list price of the Medications, the Subsidy Program would induce that beneficiary to purchase the Medications by removing the financial impediment, and the Medicare program would bear the costs for the Medications.[36] Using the language of the Federal anti-kickback statute, Requestor proposes to provide remuneration (the Subsidy Card) to a person (the Medicare beneficiary) to induce that person to purchase an item (the Medications) reimbursable under a Federal health care program (Medicare).[37]

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[36] Among the arguments advanced by Requestor in its request for this advisory opinion is that "offering co-pay assistance to help eligible patients afford a clinically-appropriate medication, when such medication is the only approved medication for the disease and the principal reason that patients would not fill their prescriptions is their inability to pay their out-of-pocket costs, does not improperly induce the underlying prescribing decisions." We disagree with Requestor's formulation of the legal standard. The central inquiry here is whether one purpose of the remuneration offered and provided by Requestor is to induce the beneficiary to purchase the Medications. If, as Requestor's formulation indicates, the principal reason a beneficiary would not fill a prescription is inability to pay the out-of-pocket expenses, then remuneration that would address that inability to pay would, without question, influence the patient's purchasing decision.

[37] Any definitive conclusion regarding a violation of the anti-kickback statute would require consideration of a party's intent when implementing the Proposed Arrangement, which has not yet occurred.

There is no statutory exception or regulatory safe harbor to the Federal anti-kickback statute that would apply to protect the remuneration offered under the Proposed Arrangement.[38] Absent any protection under a statutory exception or regulatory safe harbor, we examine whether the Proposed Arrangement would pose more than a minimal risk of fraud and abuse under the anti-kickback statute. While the Proposed Arrangement could help individual beneficiaries access the Medications, this potential benefit neither: (i) changes the fact that the Proposed Arrangement plainly would involve remuneration to an individual to induce that individual to purchase an item for which payment may be made under a Federal health care program; nor (ii) sufficiently mitigates the risks of fraud and abuse present in the Proposed Arrangement. In particular, where, as here, a manufacturer offers remuneration (the Subsidy Card) contingent on the purchase of its products, the remuneration presents many of the traditional risks of fraud and abuse that the anti-kickback statute is designed to prevent, including increased costs to Federal health care programs (e.g., through elimination of beneficiary sensitivity towards the price of the Medications);

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[38] There is a statutory exception to the Federal anti-kickback statute that protects certain non-routine waivers by pharmacies of cost-sharing obligations. Section 1128B(b)(3)(G) of the Act (42 U.S.C. § 1320a-7b(b)(3)(G)); see also 42 C.F.R. § 1001.952(k)(3) (implementing the statutory exception for a pharmacy's waiver of beneficiary copayment, coinsurance, and deductible amounts). This statutory exception and regulatory safe harbor do not apply to the Subsidy Program because Requestor is not a pharmacy. Moreover, insofar as Requestor would reimburse the pharmacy on behalf of the Medicare beneficiary, the Proposed Arrangement would operate as a subsidy, rather than a waiver, of the beneficiary's cost-sharing obligations.

beneficiary steering and anti-competitive effects; and interference with or skewing of clinical decision making.

In light of these risks, and for the combination of the following reasons, we conclude that the Proposed Arrangement would present more than a minimal risk of fraud and abuse under the Federal anti-kickback statute; indeed, we find the Proposed Arrangement highly suspect under the Federal anti-kickback statute because one purpose of the Subsidy Program—perhaps the primary purpose—would be to induce Medicare beneficiaries to purchase Requestor's federally reimbursable Medications.

a. Risk of Improper Increased Costs to the Medicare Program

The Proposed Arrangement could improperly increase overall costs to the Medicare program by insulating Medicare beneficiaries from the economic effects of the cost of the Medications, thereby abrogating a market safeguard that Congress included to protect against inflated drug prices.

i. Requestor's List Price

In evaluating the risk of increased costs, we cannot ignore that the initial list price for the Medications—which Requestor set—has been characterized as the most expensive cardiovascular drug ever launched in history', and the facts and circumstances here suggest that the implementation of the Proposed Arrangement, in conjunction with other assistance available to patients, is critical to Requestor's ability' to maintain the price at

this level.[39] The fact that a new treatment will generate costs to the Federal health care programs in absolute terms is not relevant to our analysis. All treatments generate costs to the Federal health care programs. However, where the projected costs are derived from pricing terms that necessitate the subsidization of cost-sharing obligations for beneficiaries, information about the projected costs is directly relevant to our analysis.

While we do not express any opinion as to the appropriateness of the Medications' list price, we cannot ignore how the Proposed Arrangement would operate to drive up costs to the Medicare program by providing remuneration to beneficiaries to shield them from the economic impacts of the list price and, in so doing, influence their decision to purchase the Medications.[40] We cautioned against this specific concern in our 2005 Bulletin, where we observed:

> [C]ost-sharing subsidies can be very profitable for manufacturers, providing additional incentives for abuse. So long as the manufacturer's sales price for the product exceeds its marginal variable costs plus the amount of the cost-sharing assistance, the manufacturer makes a profit.

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[39] As noted above, Requestor's Medications alone could "increase the total US spending for all prescription drugs by 9.3%" if all patients with the Disease were prescribed—and purchased—the Medications. Dhruv S. Kazi et al., Cost-Effectiveness of Tafamidis Therapy for Transthyretin Amyloid Cardiomyopathy, Circulation. 2020;141:1214-24, (originally published Feb. 12, 2020), available at https://www.ahajournals.org/doi/10.1161/CIRCULATIONAHA.119.045093.

[40] Id.

> These profits can be considerable, especially for expensive drugs for chronic conditions.[41]

Moreover, we believe there is a significant risk that the Proposed Arrangement could be used to support future increases in the list price, further driving up costs to Federal health care programs and resulting in additional harm to the Medicare fisc.

ii. Abrogation of Part D Program Safeguard

There is a significant risk that the Proposed Arrangement would effectively abrogate statutory cost-sharing requirements under the Medicare Part D program. Specifically, the design of the Proposed Arrangement appears to be calibrated to circumvent one of the key pricing controls (exposing beneficiaries to the economic effects of drug pricing)[42] that Congress instituted in its design of the standard Medicare Part D prescription drug

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[41] 2005 Bulletin, 70 Fed. Reg. at 70,626.

[42] See Congress of the United States, Congressional Budget Office, A Detailed Description of CBO's Cost Estimate for the Medicare Prescription Drug Benefit (July 2004), available at https://www.cbo.gov/sites/default/files/108th-congress-2003-2004/reports/07-21-medicare.pdf. Specifically, with respect to its estimate for the Medicare prescription drug benefit, the Congressional Budget Office stated:

> CBO assumed that even the most aggressive use of cost-management tools by drug plans would be unlikely to keep prices for some drugs from rising as a result of a Medicare drug benefit. By reducing the cost to consumers of obtaining covered drugs, the new Medicare drug benefit would correspondingly make Medicare enrollees . . . less sensitive to drug prices. For instance, if a drug's target population consisted mainly of Medicare beneficiaries

benefit and would lay bare the dangers of removing this market safeguard.[43]

> and close substitutes for that drug did not exist, the manufacturer could raise the drug's price—or, in the case of a new drug, could enter the market with a higher launch price. The loss in sales resulting from that price hike would not be large enough to reduce the manufacturer's profit, however, because beneficiaries would pay only a portion of that higher price. Preventing such price hikes would be difficult without imposing direct price controls or threatening to deny or delay coverage of the drug. Most drugs, however, face competition from close substitutes, and the most likely effect of a Medicare drug benefit would be modest price increases for the subset of drugs that had patent protection or exclusive marketing rights. CBO modeled that 'price effect' as a function of drug spending by enrollees who previously did not have prescription drug coverage . . . . CBO estimated that the cost-sharing requirements of the [Medicare Prescription Drug, Improvement, and Modernization Act of 2003] would limit the extent of that price effect. Beneficiaries . . . would still face the full negotiated price of the drugs they purchased before they reached their deductible and when their spending fell between their initial coverage limit and the catastrophic threshold. Even after they reached the catastrophic threshold, beneficiaries would generally face some coinsurance and thus would not be completely insulated from price increases.

Id.

[43] See generally section 1860D-2(b) of the Act; see also 2005 Bulletin, 70 Fed. Reg. at 70,626 ("Inflated prices could have a 'spillover' effect on the size of direct subsidies, reinsurance payments, and risk corridor payments paid by Medicare to Part D plans in future years, potentially resulting in higher costs to the Medicare program.") (internal citations omitted).

Simply put, the Proposed Arrangement would leave Requestor's price for the Medications unbridled by a key market constraint inherent to the Medicare Part D drug benefit design, while the Medicare program and taxpayers bear the financial brunt of an unchecked drug price. It is not appropriate for pharmaceutical manufacturers to use remuneration that would be prohibited by the Federal anti-kickback statute as a backdoor way to sidestep the cost-sharing requirements that Congress included in the standard Part D benefit.

iii. Elimination of Cost-Sharing Obligations for Almost All Medicare Beneficiaries

We view the Subsidy Program holistically with other assistance that would be available to Medicare beneficiaries who are prescribed the Medications to demonstrate the potentially improper impact on costs to the Federal health care programs. Requestor certified that the majority of patients who may be prescribed the Medications will be Medicare beneficiaries. Requestor further certified that the cost-sharing obligations present a prohibitive financial barrier for a significant proportion of these Medicare patients. The Subsidy Program would eliminate any meaningful cost-sharing obligations and, operating in conjunction with Requestor's free drug program and the Medicare Low- Income Subsidy, would mean all but approximately 9 percent of Medicare beneficiaries who are prescribed one of the Medications

would be able to purchase it without incurring any significant out-of-pocket costs.[44] Nonetheless, under the Proposed Arrangement, Requestor would continue to be paid for, and the Medicare program would continue to bear the cost of, the Medications purchased by all beneficiaries who do not qualify for Requestor's free drug program (including beneficiaries who qualify for the Subsidy Program and beneficiaries who qualify for the Medicare Low-Income Subsidy).

We also note that, in our guidance related to patient assistance programs operated by foundations, we explained that funds that have generous financial need criteria, particularly when a fund is limited to a subset of available drugs or the drugs of a major donor, could be evidence of intent to fund a substantial part of the cost sharing for a particular drug for the purpose of inducing the use of that drug.[45] The same concern holds true for purposes of the Subsidy Program, which establishes financial need thresholds that, operating in conjunction with Requestor's free drug program and the Medicare

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[44] As discussed in section 1(B)(1), supra, approximately 91 percent of Medicare beneficiaries have a household income below 800 percent of the FPL, which is the upper income threshold of the Subsidy Program. Those beneficiaries falling between 500 percent and 800 percent of the FPL would be eligible for the Subsidy Program. Those with household incomes below 500 percent of the FPL, which is the lower income threshold of the Subsidy Program, would be eligible for either the Medicare Low-Income Subsidy or Requestor's free drug program. This leaves only approximately nine percent of Medicare beneficiaries (i.e., those with incomes above 800 percent of the FPL) responsible for paying the full cost-sharing amounts when purchasing these Medications.

[45] 2014 Bulletin, 79 Fed. Reg. at 31,122.

Low-Income Subsidy, ensure that approximately 91 percent of Medicare beneficiaries would not have any significant out-of-pocket costs associated with the Medications.

Requestor also certified that, based on 2019 thresholds, many Medicare beneficiaries would reach the catastrophic phase with their first purchase of the Medications and that the Subsidy Program is designed to move these beneficiaries into the catastrophic phase of the Part D benefit. Our concern regarding increased costs to the Medicare program is magnified where, as here, the Proposed Arrangement would hasten Medicare beneficiaries' progression to the catastrophic phase, where the Medicare program pays 80 percent of the costs for pharmacological therapies through reinsurance, in addition to the money the Medicare program has already paid plans to deliver the Part D drug benefit.[46]

b. Risk of Patient Steering and Anti-Competitive Effects

We have longstanding concerns that cost-sharing subsidies provided by a pharmaceutical manufacturer can: (i) have the practical effect of steering beneficiaries to, and locking them into, the manufacturer's product; and (ii) lead to anti-competitive effects.[47] We believe it would be ill-advised to draw a conclusion with respect to the Proposed Arrangement without considering the facts certified by Requestor surrounding existing treatments for, and potential future advances in treating, the Disease. In addition, the patient's decision to purchase the Medications does not occur in a vacuum; a critical prerequisite

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[46] See 2005 Bulletin, 70 Fed. Reg. at 70,625-26.

[47] Id. at 70,626.

to such decision is the treating physician's decision to order (or not to order) a prescription for the Medications, hi this respect, Requestor acknowledged that "[t]here is no question that some physicians may consider drug costs and a patient's out-of-pocket burden when making prescribing judgments." We agree, and we anticipate that the treating physician will consider the costs and the availability of the Subsidy Program when determining the preferred treatment option for a patient. Likewise, because Requestor has set the list price at $225,000 for each annual course of treatment, we fully expect patients to consider the cost of the Medications—as well as the availability of the Subsidy Program—in evaluating the Medications over an alternative option. In light of these circumstances, we conclude that Requestor's Subsidy Program would present more than a minimal risk of steering beneficiaries to, and locking them into, the Medications.

The fact that the Medications are the only FDA-approved pharmacological therapy for the Disease as of today does not alleviate our concerns regarding patient steering and anti-competitive effects. By Requestor's own certifications, patients and their health care providers presently have a choice when selecting a treatment for the Disease and may have additional treatment options in the future. More specifically, Requestor described two medications that physicians have prescribed off-label to treat patients with the Disease and indicated that they are aware of physicians opting to prescribe one of these medications because it is covered under Medicare Part B, for which a beneficiary may have Medigap

coverage to defray cost-sharing obligations.[48] We understand that physicians may also consider non-pharmacological treatments (e.g., organ transplants) as an option for at least some patients with the Disease, but we recognize the complexity and severity of these treatments means they may not be a feasible option for many beneficiaries. We take no position on the effectiveness of one treatment over another; we only highlight that where a patient may have a choice in treatment, and the Subsidy Program is designed to influence that choice, there is more than a minimal risk that the remuneration (the Subsidy Card) would steer patients to the Medications.

In addition, the fact that there is no other FDA-approved pharmacological therapy for the Disease available today does not foreclose the possibility that new treatments will emerge, nor that new treatments could be less expensive or equally (or more) effective. Indeed,

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[48] Requestor certified that the list price for these alternative pharmacological treatments is higher than the list price for the Medications. We note, however, that our concerns regarding patient steering derive from the relative costs of treatment options to the beneficiary, rather than the relative costs to the Medicare program. In addition, even if the alternative treatments are more expensive to the Medicare program, that fact does not alleviate our concern that the Subsidy Program would inappropriately increase overall costs to the Medicare program by insulating Medicare beneficiaries from the economic effects of the price of the Medications. In other words, the increased costs to the Medicare program would be a direct result of the improper remuneration in the Subsidy Program. Finally, we note that, standing alone, the fact that the list price of an alternative pharmacological treatment may be higher than the list price of the Medications is not determinative of overall costs to Federal health care programs for the various pharmacological treatment alternatives; any comparison of total costs would likely require a complex economic analysis, the results of which would not address our concerns about the patient-steering risks of the Subsidy Program.

Requestor's certifications indicate that FDA approval of a competitor therapy in 2021 is a possibility. Even so, Requestor asserted its view that, even if the FDA were to approve another therapy for the treatment of the Disease, "if the Medications demonstrate superior efficacy and safety" then that superior efficacy and safety would be relevant to the fraud and abuse analysis of the Proposed Arrangement in the same way the lack of FDA-approved alternatives is now. We disagree. The Subsidy Program would virtually eliminate cost-sharing obligations for the Medications, which could inappropriately divert many beneficiaries with the Disease from any other treatment option—now or in the future—to the Medications because of the minimal out-of-pocket expenses when compared to those for other treatment options. In fact, we believe the Subsidy Program shares many of the risky features of problematic seeding programs insofar as it would steer patients to the Medications now so that these beneficiaries would continue to purchase the Medications in the future, even if other FDA-approved therapies emerge. Further, we believe that the Subsidy Program could negatively affect competition for as long as it remains in existence because it would give a financial advantage to the Medications over competing treatments, regardless of whether such other treatments are equally as effective.[49]

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[49] "Ensuring fair competition in the health care marketplace is one of the goals of the anti-kickback statute." OIG, Medicare and State Health Care Programs: Fraud and Abuse; Clarification of the Initial OIG Safe Harbor Provisions and Establishment of Additional Safe Harbor Provisions Under the Anti-Kickback Statute, 64 Fed. Reg. 63,518, 63533 (Nov. 19, 1999), available at https://oig.hhs.gov/fraud/docs/safeharborregulations/getdoc1.pdf.

c. Potential Effects on Clinical Decision-Making

While remuneration that would induce a beneficiary to purchase the Medications, standing alone, would implicate the Federal anti-kickback statute, we also believe the remuneration offered under the Subsidy Program could affect a physician's clinical decision-making, which is relevant to our assessment of the overall risk of the Proposed Arrangement. We recognize that the Proposed Arrangement would not involve remuneration to prescribers; rather, Requestor would offer remuneration to a Medicare beneficiary to induce the beneficiary to purchase the Medications. As discussed above, a critical prerequisite to such decision is the treating physician's decision to order (or not to order) a prescription for the Medications, and Requestor acknowledged that "[t]here is no question that some physicians may consider drug costs and a patient's out-of-pocket burden when making prescribing judgments." In addition, as described above, Requestor certified that some physicians presently prescribe another pharmacological therapy instead of the Medications because the other treatment is a Part B drug, and some beneficiaries have purchased Medigap insurance policies that cover some or all of their Part B cost-sharing obligations.[50] Much like our conclusion that patients would consider the costs of the

[50] Unlike Medigap insurance policies, which beneficiaries may choose to purchase to cover a variety of health care costs and which are a long-standing feature in the Medicare program that must follow requirements and standards set forth by Congress, the Subsidy Program is designed by Requestor in a way that would support the list price for its Medications while undermining the Pail D benefit constructed by Congress.

Medications in deciding their preferred treatment option with their physician, we likewise anticipate that some—if not most—physicians would consider a patient's out-of-pocket costs for the Medications when deciding whether to prescribe them.

Requestor further certified that a physician must work with a beneficiary to enroll him or her in the Hub and may contact the Hub to find out about the Subsidy Program. The Hub also would communicate patient enrollment in the Subsidy Program to the patient's prescribing physician (upon the prescriber's request). Based on these facts, it is reasonable to anticipate that physicians would learn of the Subsidy Program soon after its implementation (e.g., through their first communication with the Hub) and, once a physician is aware of the program, every subsequent prescribing decision would be made with the knowledge that the Subsidy Program is available to minimize out-of-pocket costs for Medicare beneficiaries.

With this knowledge, we believe the Subsidy Program could affect the prescriber's decision as to whether to order the Medications. To be clear, we are not suggesting that it is inappropriate for a physician to consider costs to patients; however, in these circumstances where Requestor has certified that cost-sharing obligations are the impediment to a significant portion of Medicare beneficiaries purchasing the Medications, we believe that the availability of the Subsidy Card may impact the treating physician's clinical decision-making, i.e., whether to prescribe the Medications for those beneficiaries. Moreover, both presently and if any new treatments emerge in the future—which Requestor certified could be as early as 2021—we believe there is a risk that the availability of the Subsidy Program could sway a

physician to prescribe the Medications over any other treatment, even if such treatments are equally (or more) effective or have a lower overall cost.

3. Beneficiary Inducements CMP

In evaluating the Proposed Arrangement under the Beneficiary Inducements CMP, we consider whether Requestor would know or have reason to know that the remuneration it would offer to beneficiaries is likely to influence their selection of a particular provider, practitioner, or supplier for the order or receipt of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program. Here, we conclude that, although the Subsidy Card is clearly remuneration to a beneficiary, tire Proposed Arrangement would not implicate the Beneficiary Inducements CMP.

a. Scope of Beneficiary Inducements CMP

As a threshold matter, we note that the Beneficiary Inducements CMP (section 1128A(a)(5) of the Act) contains a different, narrower prohibition than the Federal anti-kickback statute (section 1128B(b) of the Act) and uses a definition of "remuneration" that does not apply for purposes of the Federal anti-kickback statute. The Federal anti-kickback statute prohibits the knowing and willful offer, payment, solicitation, or receipt of any remuneration to induce or reward, among other things, referrals for, or purchases of, any item or service payable by a Federal health care program. In contrast, the Beneficiary Inducements CMP is focused on remuneration that the offeror knows or should know is likely to influence a beneficiary's selection of a particular provider,

practitioner, or supplier for items or services reimbursable by Medicare or a State health care program.

For purposes of the Beneficiary Inducements CMP, pharmaceutical manufacturers are not "providers, practitioners, or suppliers" unless they also own or operate, directly or indirectly, pharmacies, pharmacy benefits management companies, or other entities that file claims for payment under the Medicare or Medicaid programs.[51] Here, Requestor is a pharmaceutical manufacturer, and it does not own or operate, directly or indirectly, any pharmacies that dispense the Medications. Therefore, Requestor is not a "provider, practitioner, or supplier" for purposes of the Beneficiary Inducements CMP. Because Requestor is not a "provider, practitioner, or supplier," the fact that the Subsidy Card would influence a beneficiary to purchase Requestor's product (the Medications) would not implicate the Beneficiary Inducements CMP with respect to Requestor, notwithstanding the fact that this same remuneration stream would implicate the Federal anti-kickback statute.

b. Analysis of Proposed Arrangement

Where a pharmaceutical manufacturer offers remuneration to a beneficiary that the manufacturer knows or should know is likely to influence the beneficiary to select a particular provider, practitioner, or supplier (e.g., a physician or a pharmacy), that remuneration would implicate the Beneficiary Inducements CMP. In other

[51] OIG, Special Advisory Bulletin, Offering Gifts and Other Inducements to Beneficiaries (Aug. 2002), available at https://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf.

words, a pharmaceutical manufacturer, such as Requestor, can be the offeror or transferor of remuneration that implicates (and violates) the Beneficiary Inducements CMP.[52] However, based on the unique combination of facts presented in the Proposed Arrangement, we conclude that the remuneration offered by the Requestor under the Proposed Arrangement is not likely to influence a beneficiary to order the Medications from a particular provider, practitioner, or supplier.

First, under the Proposed Arrangement, Requestor would not make eligibility for the Subsidy Card dependent on the beneficiary's use of certain prescribing providers or practitioners. Requestor certified that a beneficiary would be eligible to obtain a Subsidy Card regardless of which provider or practitioner prescribes the Medications, and Requestor has not provided any facts to indicate that a beneficiary's ability to obtain a Subsidy Card would otherwise be impacted in any way by his or her selection of a particular provider or practitioner. Thus, based on the facts available to us, the remuneration that would be provided to beneficiaries under the Proposed Arrangement would not influence their selection of a particular prescribing provider or practitioner.

Second, Requestor would not make eligibility for the Subsidy Card dependent on the beneficiary's use of a particular pharmacy. Specifically, the remuneration

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[52] See 2014 Bulletin, 79 Fed. Reg. at 31,121 (noting that a subsidy for cost-sharing obligations provided by a pharmaceutical manufacturer through an independent foundation's patient assistance program may implicate the Beneficiary Inducements CMP, if the subsidy is likely to influence a Medicare or State health care program beneficiary's selection of a particular provider, practitioner, or supplier, such as by making eligibility for the subsidy dependent on, for example, the patient's use of certain prescribing physicians).

would not be conditioned on the beneficiary using a particular Dispensing Pharmacy, and the Subsidy Program would not give preference to any particular Dispensing Pharmacy. An eligible beneficiary would be able to use the Subsidy Card at any Dispensing Pharmacy, and the amount of assistance that would be offered to a beneficiary under the Subsidy Program would not vary based on which Dispensing Pharmacy furnishes the Medications. That is, the Subsidy Program is structured such that the beneficiary would have the same limited cost-sharing obligation ($35 per monthly fill) regardless of the Dispensing Pharmacy he or she selects to fill the prescription for the Medications. Thus, the remuneration would not influence the beneficiary's selection of one Dispensing Pharmacy over another Dispensing Pharmacy.[53]

Requestor also certified that beneficiaries would have the opportunity to express a preference with respect to which Dispensing Pharmacy they use to obtain the Medications. Absent a preference, the Hub would select a Dispensing Pharmacy to fill a particular beneficiary's prescription based on the Dispensing Pharmacy with the lowest patient out-of-pocket costs or using a "round robin" process. While we recognize that some benefi-

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[53] We contrast this with an arrangement where the nature or structure of the arrangement is such that the offeror knows or should know that the beneficiary would select a particular provider, practitioner, or supplier following the offer or transfer of the remuneration, e.g., an arrangement that requires a beneficiary to use the provider, practitioner, or supplier that is geographically closest to the beneficiary's location. If the Requestor structured the Subsidy Program in such a manner, then the Beneficiary Inducements CMP would be implicated, and no exception would apply.

ciaries may face a more limited set of Dispensing Pharmacies to select from due to their Part D or MA-PD plans having a narrower list of Plan Pharmacies, that limitation is due to plan benefit design, not the remuneration offered by Requestor under the Proposed Arrangement. Any remuneration streams associated with such plan benefit designs are outside the scope of this advisory opinion.

Requester further certified that, to its knowledge, there has not been any instance where there were no Dispensing Pharmacies included among the preferred pharmacies in a beneficiary's Part D or MA-PD plan. Requester certified that, if such a circumstance were to arise, the Hub would send the prescription to the beneficiary's or the prescribing physician's preferred Dispensing Pharmacy. Absent a preference, the Hub would select a Dispensing Pharmacy to fill a particular beneficiary's prescription based on the Dispensing Pharmacy with the lowest patient out-of-pocket costs (that would otherwise be charged to the beneficiary but would instead, under the terms of the Subsidy Program, be paid for using the Subsidy Card) or using a "round robin" process.

In addition, Dispensing Pharmacies are the only pharmacies authorized by Requestor to dispense the Medications to any patient who wishes to purchase the Medications, regardless of whether the patient is eligible for the Subsidy Program. Thus, while we recognize that the Subsidy Card may only be used at a Dispensing Pharmacy, it is not the Subsidy Program that dictates that limitation?[54]

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[54] We distinguish the facts here, where the Medications arc available only through a limited number of Dispensing Pharmacies, from circumstances where remuneration influences beneficiaries to select a

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) the Proposed Arrangement, as structured, would not generate prohibited remuneration under the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act; and (ii) the Proposed Arrangement would generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals for, or purchases of, items and services reimbursable by a Federal health care program were present and that the OIG could potentially impose administrative sanctions on Pfizer Inc. under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with the Proposed Arrangement. Any definitive conclusion regarding the existence of an anti-kickback violation requires consideration of all of the facts and circumstances of the arrangement as implemented, including a party's intent. Where, as is the case here, the arrangement is proposed but has not yet been implemented, we cannot reach a definitive conclusion regarding the existence of an anti-kickback violation.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

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provider, practitioner, or supplier from a network over non-network providers, practitioners, or suppliers or where the value of remuneration to a beneficiary varies based on which provider, practitioner, or supplier the beneficiary selects. In such circumstances, the Beneficiary Inducements CMP would be implicated.

- This advisory opinion is issued only to Pfizer Inc., the requestor of this opinion. This advisory opinion has no application to, and cannot be relied upon by, any other individual or entity.
- This advisory opinion may not be introduced into evidence by a person or entity other than Pfizer Inc. to prove that the person or entity did not violate the provisions of sections 1128, 1128A, or 1128B of the Act or any other law.
- This advisory opinion is applicable only to the statutory provisions specifically noted above. No opinion is expressed or implied herein with respect to the application of any other Federal, state, or local statute, rule, regulation, ordinance, or other law that may be applicable to the Proposed Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).
- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party under the False Claims

Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion.

Sincerely,

Robert K. DeConti

Assistant Inspector General for Legal Affairs

APPENDIX D

1. 18 U.S.C. 220 provides in pertinent part:

Illegal remunerations for referrals to recovery homes, clinical treatment facilities, and laboratories

(a) OFFENSE.—Except as provided in subsection (b), whoever, with respect to services covered by a health care benefit program, in or affecting interstate or foreign commerce, knowingly and willfully—

(1) solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a recovery home, clinical treatment facility, or laboratory; or

(2) pays or offers any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) to induce a referral of an individual to a recovery home, clinical treatment facility, or laboratory; or

(B) in exchange for an individual using the services of that recovery home, clinical treatment facility, or laboratory,

shall be fined not more than $200,000, imprisoned not more than 10 years, or both, for each occurrence.

* * * * *

2. 42 U.S.C. 1320a-7 provides in pertinent part:

Exclusion of certain individuals and entities from participation in Medicare and State health care programs

(a) Mandatory exclusion

The Secretary shall exclude the following individuals and entities from participation in any Federal health care program (as defined in section 1320a–7b(f) of this title):

(1) Conviction of program-related crimes

Any individual or entity that has been convicted of a criminal offense related to the delivery of an item or service under subchapter XVIII of this chapter or under any State health care program.

* * * * *

(3) Felony conviction relating to health care fraud

Any individual or entity that has been convicted for an offense which occurred after August 21, 1996, under Federal or State law, in connection with the delivery of a health care item or service or with respect to any act or omission in a health care program (other than those specifically described in paragraph (1)) operated by or financed in whole or in part by any Federal, State, or local government agency, of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.

* * * * *

(b) Permissive exclusion

The Secretary may exclude the following individuals and entities from participation in any Federal health care program (as defined in section 1320a–7b(f) of this title):

* * * * *

(7) Fraud, kickbacks, and other prohibited activities

Any individual or entity that the Secretary determines has committed an act which is described in section 1320a–7a, 1320a–7b, or 1320a–8 of this title.

* * * * *

3. 42 U.S.C. 1320a-7a provides:

Civil monetary penalties

(a) Improperly filed claims

Any person (including an organization, agency, or other entity, but excluding a beneficiary, as defined in subsection (i)(5)) that—

(1) knowingly presents or causes to be presented to an officer, employee, or agent of the United States, or of any department or agency thereof, or of any State agency (as defined in subsection (i)(1)), a claim (as defined in subsection (i)(2)) that the Secretary determines—

(A) is for a medical or other item or service that the person knows or should know was not provided as claimed, including any person who engages in a pattern or practice of presenting or

causing to be presented a claim for an item or service that is based on a code that the person knows or should know will result in a greater payment to the person than the code the person knows or should know is applicable to the item or service actually provided,

(B) is for a medical or other item or service and the person knows or should know the claim is false or fraudulent,

(C) is presented for a physician's service (or an item or service incident to a physician's service) by a person who knows or should know that the individual who furnished (or supervised the furnishing of) the service—

(i) was not licensed as a physician,

(ii) was licensed as a physician, but such license had been obtained through a misrepresentation of material fact (including cheating on an examination required for licensing), or

(iii) represented to the patient at the time the service was furnished that the physician was certified in a medical specialty by a medical specialty board when the individual was not so certified,

(D) is for a medical or other item or service furnished during a period in which the person was excluded from the Federal health care program (as defined in section 1320a–7b(f) of this title) under which the claim was made pursuant to Federal law.[1][1]

[1] So in original. Probably should be "law. or".

(E) is for a pattern of medical or other items or services that a person knows or should know are not medically necessary;

(2) knowingly presents or causes to be presented to any person a request for payment which is in violation of the terms of (A) an assignment under section 1395u(b)(3)(B)(ii) of this title, or (B) an agreement with a State agency (or other requirement of a State plan under subchapter XIX) not to charge a person for an item or service in excess of the amount permitted to be charged, or (C) an agreement to be a participating physician or supplier under section 1395u(h)(1) of this title, or (D) an agreement pursuant to section 1395cc(a)(1)(G) of this title;

(3) knowingly gives or causes to be given to any person, with respect to coverage under subchapter XVIII of inpatient hospital services subject to the provisions of section 1395ww of this title, information that he knows or should know is false or misleading, and that could reasonably be expected to influence the decision when to discharge such person or another individual from the hospital;

(4) in the case of a person who is not an organization, agency, or other entity, is excluded from participating in a program under subchapter XVIII or a State health care program in accordance with this subsection or under section 1320a–7 of this title and who, at the time of a violation of this subsection—

(A) retains a direct or indirect ownership or control interest in an entity that is participating in a program under subchapter XVIII or a State health care program, and who knows or should

know of the action constituting the basis for the exclusion; or

(B) is an officer or managing employee (as defined in section 1320a–5(b) of this title) of such an entity;

(5) offers to or transfers remuneration to any individual eligible for benefits under subchapter XVIII of this chapter, or under a State health care program (as defined in section 1320a–7(h) of this title) that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under subchapter XVIII, or a State health care program (as so defined);

(6) arranges or contracts (by employment or otherwise) with an individual or entity that the person knows or should know is excluded from participation in a Federal health care program (as defined in section 1320a–7b(f) of this title), for the provision of items or services for which payment may be made under such a program;

(7) commits an act described in paragraph (1) or (2) of section 1320a–7b(b) of this title;

(8)[2] knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program; or[3]

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[2] So in original. Two pars. (8) have been enacted.

[3] So in original. The word "or" probably should not appear.

(9)[4] fails to grant timely access, upon reasonable request (as defined by the Secretary in regulations), to the Inspector General of the Department of Health and Human Services, for the purpose of audits, investigations, evaluations, or other statutory functions of the Inspector General of the Department of Health and Human Services;

(8) 2 orders or prescribes a medical or other item or service during a period in which the person was excluded from a Federal health care program (as so defined), in the case where the person knows or should know that a claim for such medical or other item or service will be made under such a program;

(9) 4 knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program (as so defined), including Medicare Advantage organizations under part C of subchapter XVIII, prescription drug plan sponsors under part D of subchapter XVIII, medicaid managed care organizations under subchapter XIX, and entities that apply to participate as providers of services or suppliers in such managed care organizations and such plans;[5]

(10) knows of an overpayment (as defined in paragraph (4) of section 1320a-7k(d) of this title) and does not report and return the overpayment in accordance with such section;

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[4] So in original. Two pars. (9) have been enacted.

[5] So in original. Probably should be followed by "or".

shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $20,000 for each item or service (or, in cases under paragraph (3), $30,000 for each individual with respect to whom false or misleading information was given; in cases under paragraph (4), $20,000 for each day the prohibited relationship occurs; in cases under paragraph (7), $100,000 for each such act,[6] in cases under paragraph (8),[7] $100,000 for each false record or statement,[6] or[3] in cases under paragraph (9),[8] $15,000 for each day of the failure described in such paragraph);[9] or in cases under paragraph (9),[10] $100,000 for each false statement or misrepresentation of a material fact). In addition, such a person shall be subject to an assessment of not more than 3 times the amount claimed for each such item or service in lieu of damages sustained by the United States or a State agency because of such claim (or, in cases under paragraph (7), damages of not more than 3 times the total amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of such remuneration was offered, paid, solicited, or received for a lawful purpose; or in cases under paragraph (9), an assessment of not more than 3 times the total amount claimed for each item or service for which payment was made based upon the application containing the false statement or misrepresentation of a material fact). In addition the Secretary may make a determination in the same proceeding to exclude the person from

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[6] So in original. The comma probably should be a semicolon.
[7] So in original. Probably is a reference to the first paragraph (8).
[8] So in original. Probably is a reference to the first paragraph (9).
[9] So in original. Probably should be "paragraph:".
[10] So in original. Probably is a reference to the second paragraph (9).

participation in the Federal health care programs (as defined in section 1320a-7b(f)(1) of this title) and to direct the appropriate State agency to exclude the person from participation in any State health care program.

(b) Payments to induce reduction or limitation of services

(1) If a hospital or a critical access hospital knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit medically necessary services provided with respect to individuals who—

(A) are entitled to benefits under part A or part B of subchapter XVIII or to medical assistance under a State plan approved under subchapter XIX, and

(B) are under the direct care of the physician,

the hospital or a critical access hospital shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $5,000 for each such individual with respect to whom the payment is made.

(2) Any physician who knowingly accepts receipt of a payment described in paragraph (1) shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $5,000 for each individual described in such paragraph with respect to whom the payment is made.

(3)

(A) Any physician who executes a document described in subparagraph (B) with respect to an in-

dividual knowing that all of the requirements referred to in such subparagraph are not met with respect to the individual shall be subject to a civil monetary penalty of not more than the greater of—

(i) $10,000, or

(ii) three times the amount of the payments under subchapter XVIII for home health services which are made pursuant to such certification.

(B) A document described in this subparagraph is any document that certifies, for purposes of subchapter XVIII, that an individual meets the requirements of section 1395f(a)(2)(C) or 1395n(a)(2)(A) of this title in the case of home health services furnished to the individual.

(c) Initiation of proceeding; authorization by Attorney General, notice, etc., estoppel, failure to comply with order or procedure

(1) The Secretary may initiate a proceeding to determine whether to impose a civil money penalty, assessment, or exclusion under subsection (a) or (b) only as authorized by the Attorney General pursuant to procedures agreed upon by them. The Secretary may not initiate an action under this section with respect to any claim, request for payment, or other occurrence described in this section later than six years after the date the claim was presented, the request for payment was made, or the occurrence took place. The Secretary may initiate an action under this section by serving notice of the action in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure.

(2) The Secretary shall not make a determination adverse to any person under subsection (a) or (b) until the person has been given written notice and an opportunity for the determination to be made on the record after a hearing at which the person is entitled to be represented by counsel, to present witnesses, and to cross-examine witnesses against the person.

(3) In a proceeding under subsection (a) or (b) which—

(A) is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements, and

(B) involves the same transaction as in the criminal action, the person is estopped from denying the essential elements of the criminal offense.

(4) The official conducting a hearing under this section may sanction a person, including any party or attorney, for failing to comply with an order or procedure, failing to defend an action, or other misconduct as would interfere with the speedy, orderly, or fair conduct of the hearing. Such sanction shall reasonably relate to the severity and nature of the failure or misconduct. Such sanction may include—

(A) in the case of refusal to provide or permit discovery, drawing negative factual inferences or treating such refusal as an admission by deeming the matter, or certain facts, to be established,

(B) prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense,

(C) striking pleadings, in whole or in part,

(D) staying the proceedings,

(E) dismissal of the action,

(F) entering a default judgment,

(G) ordering the party or attorney to pay attorneys' fees and other costs caused by the failure or misconduct, and

(H) refusing to consider any motion or other action which is not filed in a timely manner.

(d) Amount or scope of penalty, assessment, or exclusion

In determining the amount or scope of any penalty, assessment, or exclusion imposed pursuant to subsection (a) or (b), the Secretary shall take into account—

(1) the nature of claims and the circumstances under which they were presented,

(2) the degree of culpability, history of prior offenses, and financial condition of the person presenting the claims, and

(3) such other matters as justice may require.

(e) Review by courts of appeals

Any person adversely affected by a determination of the Secretary under this section may obtain a review of such determination in the United States Court of Appeals for the circuit in which the person resides, or in which the claim or specified claim was presented, by filing in such court (within sixty days following the date the person is notified of the Secretary's determination) a written petition requesting that the determination be modified or set aside. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary, and

thereupon the Secretary shall file in the Court[11] the record in the proceeding as provided in section 2112 of title 28. Upon such filing, the court shall have jurisdiction of the proceeding and of the question determined therein, and shall have the power to make and enter upon the pleadings, testimony, and proceedings set forth in such record a decree affirming, modifying, remanding for further consideration, or setting aside, in whole or in part, the determination of the Secretary and enforcing the same to the extent that such order is affirmed or modified. No objection that has not been urged before the Secretary shall be considered by the court, unless the failure or neglect to urge such objection shall be excused because of extraordinary circumstances. The findings of the Secretary with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive. If any party shall apply to the court for leave to adduce additional evidence and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the hearing before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be made a part of the record. The Secretary may modify his findings as to the facts, or make new findings, by reason of additional evidence so taken and filed, and he shall file with the court such modified or new findings, which findings with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive, and his recommendations, if any, for the modification or setting aside of his original order. Upon the filing of the record with it, the jurisdiction of the court shall be exclusive and its judgment and

[11] So in original. Probably should not be capitalized.

decree shall be final, except that the same shall be subject to review by the Supreme Court of the United States, as provided in section 1254 of title 28.

(f) Compromise of penalties and assessments; recovery; use of funds recovered

Civil money penalties and assessments imposed under this section may be compromised by the Secretary and may be recovered in a civil action in the name of the United States brought in United States district court for the district where the claim or specified claim (as defined in subsection (r)) was presented, or where the claimant (or, with respect to a person described in subsection (o), the person) resides, as determined by the Secretary. Amounts recovered under this section shall be paid to the Secretary and disposed of as follows:

(1)

(A) In the case of amounts recovered arising out of a claim under subchapter XIX, there shall be paid to the State agency an amount bearing the same proportion to the total amount recovered as the State's share of the amount paid by the State agency for such claim bears to the total amount paid for such claim.

(B) In the case of amounts recovered arising out of a claim under an allotment to a State under subchapter V, there shall be paid to the State agency an amount equal to three-sevenths of the amount recovered.

(2) Such portion of the amounts recovered as is determined to have been paid out of the trust funds under sections 1395i and 1395t of this title shall be repaid to such trust funds.

(3) With respect to amounts recovered arising out of a claim under a Federal health care program (as defined in section 1320a-7b(f) of this title), the portion of such amounts as is determined to have been paid by the program shall be repaid to the program, and the portion of such amounts attributable to the amounts recovered under this section by reason of the amendments made by the Health Insurance Portability and Accountability Act of 1996 (as estimated by the Secretary) shall be deposited into the Federal Hospital Insurance Trust Fund pursuant to section 1395i(k)(2)(C) of this title.

(4) The remainder of the amounts recovered shall be deposited as miscellaneous receipts of the Treasury of the United States.

The amount of such penalty or assessment, when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States or a State agency (or, in the case of a penalty or assessment under subsection (o), by a specified State agency (as defined in subsection (q)(6)), to the person against whom the penalty or assessment has been assessed.

(g) Finality of determination respecting penalty, assessment, or exclusion

A determination by the Secretary to impose a penalty, assessment, or exclusion under subsection (a) or (b) shall be final upon the expiration of the sixty-day period referred to in subsection (e). Matters that were raised or that could have been raised in a hearing before the Secretary or in an appeal pursuant to subsection (e) may not be raised as a defense to a civil action by the United

States to collect a penalty, assessment, or exclusion assessed under this section.

(h) Notification of appropriate entities of finality of determination

Whenever the Secretary's determination to impose a penalty, assessment, or exclusion under subsection (a) or (b) becomes final, he shall notify the appropriate State or local medical or professional organization, the appropriate State agency or agencies administering or supervising the administration of State health care programs (as defined in section 1320a-7(h) of this title), and the appropriate utilization and quality control peer review organization, and the appropriate State or local licensing agency or organization (including the agency specified in section 1395aa(a) and 1396a(a)(33) of this title) that such a penalty, assessment, or exclusion has become final and the reasons therefor.

(i) Definitions

For the purposes of this section:

(1) The term "State agency" means the agency established or designated to administer or supervise the administration of the State plan under subchapter XIX of this chapter or designated to administer the State's program under subchapter V or division A[12] of subchapter XX of this chapter.

(2) The term "claim" means an application for payments for items and services under a Federal health care program (as defined in section 1320a-7b(f) of this title).

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[12] See References in text note below.

(3) The term "item or service" includes (A) any particular item, device, medical supply, or service claimed to have been provided to a patient and listed in an itemized claim for payment, and (B) in the case of a claim based on costs, any entry in the cost report, books of account or other documents supporting such claim.

(4) The term "agency of the United States" includes any contractor acting as a fiscal intermediary, carrier, or fiscal agent or any other claims processing agent for a Federal health care program (as so defined).

(5) The term "beneficiary" means an individual who is eligible to receive items or services for which payment may be made under a Federal health care program (as so defined) but does not include a provider, supplier, or practitioner.

(6) The term "remuneration" includes the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value. The term "remuneration" does not include—

(A) the waiver of coinsurance and deductible amounts by a person, if—

(i) the waiver is not offered as part of any advertisement or solicitation;

(ii) the person does not routinely waive coinsurance or deductible amounts; and

(iii) the person—

(I) waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need; or

(II) fails to collect coinsurance or deductible amounts after making reasonable collection efforts;

(B) subject to subsection (n), any permissible practice described in any subparagraph of section 1320a-7b(b)(3) of this title or in regulations issued by the Secretary;

(C) differentials in coinsurance and deductible amounts as part of a benefit plan design as long as the differentials have been disclosed in writing to all beneficiaries, third party payers, and providers, to whom claims are presented and as long as the differentials meet the standards as defined in regulations promulgated by the Secretary not later than 180 days after August 21, 1996;

(D) incentives given to individuals to promote the delivery of preventive care as determined by the Secretary in regulations so promulgated;

(E) a reduction in the copayment amount for covered OPD services under section 1395l(t)(5)(B)[12] of this title; or[13]

(F) any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1320a-7b(f) of this title and designated by the Secretary under regulations);

(G) the offer or transfer of items or services for free or less than fair market value by a person, if—

[13] So in original. the word "or" probably should not appear.

(i) the items or services consist of coupons, rebates, or other rewards from a retailer;

(ii) the items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and

(iii) the offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under subchapter XVIII or a State health care program (as defined in section 1320a-7(h) of this title);

(H) the offer or transfer of items or services for free or less than fair market value by a person, if—

(i) the items or services are not offered as part of any advertisement or solicitation;

(ii) the items or services are not tied to the provision of other services reimbursed in whole or in part by the program under subchapter XVIII or a State health care program (as so defined);

(iii) there is a reasonable connection between the items or services and the medical care of the individual; and

(iv) the person provides the items or services after determining in good faith that the individual is in financial need;

(I) effective on a date specified by the Secretary (but not earlier than January 1, 2011), the waiver by a PDP sponsor of a prescription drug plan un-

der part D of subchapter XVIII or an MA organization offering an MA–PD plan under part C of such subchapter of any copayment for the first fill of a covered part D drug (as defined in section 1395w-02(e) of this title) that is a generic drug for individuals enrolled in the prescription drug plan or MA–PD plan, respectively; or

(J) the provision of telehealth technologies (as defined by the Secretary) on or after January 1, 2019, by a provider of services or a renal dialysis facility (as such terms are defined for purposes of subchapter XVIII) to an individual with end stage renal disease who is receiving home dialysis for which payment is being made under part B of such subchapter, if—

(i) the telehealth technologies are not offered as part of any advertisement or solicitation;

(ii) the telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual's end stage renal disease; and

(iii) the provision of the telehealth technologies meets any other requirements set forth in regulations promulgated by the Secretary.

(7) The term "should know" means that a person, with respect to information—

(A) acts in deliberate ignorance of the truth or falsity of the information; or

(B) acts in reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required.

(j) Subpoenas

(1) The provisions of subsections (d) and (e) of section 405 of this title shall apply with respect to this section to the same extent as they are applicable with respect to subchapter II. The Secretary may delegate the authority granted by section 405(d) of this title (as made applicable to this section) to the Inspector General of the Department of Health and Human Services for purposes of any investigation under this section.

(2) The Secretary may delegate authority granted under this section and under section 1320a-7 of this title to the Inspector General of the Department of Health and Human Services.

(k) Injunctions

Whenever the Secretary has reason to believe that any person has engaged, is engaging, or is about to engage in any activity which makes the person subject to a civil monetary penalty under this section, the Secretary may bring an action in an appropriate district court of the United States (or, if applicable, a United States court of any territory) to enjoin such activity, or to enjoin the person from concealing, removing, encumbering, or disposing of assets which may be required in order to pay a civil monetary penalty if any such penalty were to be imposed or to seek other appropriate relief.

(*l*) Liability of principal for acts of agent

A principal is liable for penalties, assessments, and an exclusion under this section for the actions of the principal's agent acting within the scope of the agency.

(m) Claims within jurisdiction of other departments or agencies

(1) For purposes of this section, with respect to a Federal health care program not contained in this chapter, references to the Secretary in this section shall be deemed to be references to the Secretary or Administrator of the department or agency with jurisdiction over such program and references to the Inspector General of the Department of Health and Human Services in this section shall be deemed to be references to the Inspector General of the applicable department or agency.

(2)

(A) The Secretary and Administrator of the departments and agencies referred to in paragraph (1) may include in any action pursuant to this section, claims within the jurisdiction of other Federal departments or agencies as long as the following conditions are satisfied:

(i) The case involves primarily claims submitted to the Federal health care programs of the department or agency initiating the action.

(ii) The Secretary or Administrator of the department or agency initiating the action gives notice and an opportunity to participate in the investigation to the Inspector General of the department or agency with primary jurisdiction over the Federal health care programs to which the claims were submitted.

(B) If the conditions specified in subparagraph (A) are fulfilled, the Inspector General of the department or agency initiating the action is authorized

to exercise all powers granted under the Inspector General Act of 1978 (5 U.S.C. App.) with respect to the claims submitted to the other departments or agencies to the same manner and extent as provided in that Act with respect to claims submitted to such departments or agencies.

(n) Safe harbor for payment of medigap premiums

(1) Subparagraph (B) of subsection (i)(6) shall not apply to a practice described in paragraph (2) unless—

(A) the Secretary, through the Inspector General of the Department of Health and Human Services, promulgates a rule authorizing such a practice as an exception to remuneration; and

(B) the remuneration is offered or transferred by a person under such rule during the 2-year period beginning on the date the rule is first promulgated.

(2) A practice described in this paragraph is a practice under which a health care provider or facility pays, in whole or in part, premiums for medicare supplemental policies for individuals entitled to benefits under part A of subchapter XVIII pursuant to section 426–1 of this title.

(*o*) Penalties for violations of grants, contracts, and other agreements

Any person (including an organization, agency, or other entity, but excluding a program beneficiary, as defined in subsection (q)(4)) that, with respect to a grant, contract, or other agreement for which the Secretary provides funding—

(1) knowingly presents or causes to be presented a specified claim (as defined in subsection (r)) under

such grant, contract, or other agreement that the person knows or should know is false or fraudulent;

(2) knowingly makes, uses, or causes to be made or used any false statement, omission, or misrepresentation of a material fact in any application, proposal, bid, progress report, or other document that is required to be submitted in order to directly or indirectly receive or retain funds provided in whole or in part by such Secretary pursuant to such grant, contract, or other agreement;

(3) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent specified claim under such grant, contract, or other agreement;

(4) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation (as defined in subsection (s)) to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement; or

(5) fails to grant timely access, upon reasonable request (as defined by such Secretary in regulations), to the Inspector General of the Department, for the purpose of audits, investigations, evaluations, or other statutory functions of such Inspector General in matters involving such grants, contracts, or other agreements;

shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty in

cases under paragraph (1), of not more than $10,000 for each specified claim; in cases under paragraph (2), not more than $50,000 for each false statement, omission, or misrepresentation of a material fact; in cases under paragraph (3), not more than $50,000 for each false record or statement; in cases under paragraph (4), not more than $50,000 for each false record or statement or $10,000 for each day that the person knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay; or in cases under paragraph (5), not more than $15,000 for each day of the failure described in such paragraph. In addition, in cases under paragraphs (1) and (3), such a person shall be subject to an assessment of not more than 3 times the amount claimed in the specified claim described in such paragraph in lieu of damages sustained by the United States or a specified State agency because of such specified claim, and in cases under paragraphs (2) and (4), such a person shall be subject to an assessment of not more than 3 times the total amount of the funds described in paragraph (2) or (4), respectively (or, in the case of an obligation to transmit property to the Secretary described in paragraph (4), of the value of the property described in such paragraph) in lieu of damages sustained by the United States or a specified State agency because of such case. In addition, the Secretary may make a determination in the same proceeding to exclude the person from participation in the Federal health care programs (as defined in section 1320a–7b(f)(1) of this title) and to direct the appropriate State agency to exclude the person from participation in any State health care program.

(p) Applicability of rules to penalties or assessments for violations of grants, contracts, and other agreements

The provisions of subsections (c), (d), (g), and (h) shall apply to a civil money penalty or assessment under subsection (*o*) in the same manner as such provisions apply to a penalty, assessment, or proceeding under subsection (a). In applying subsection (d), each reference to a claim under such subsection shall be treated as including a reference to a specified claim (as defined in subsection (r)).

(q) Definitions of terms used in subsections (*o*) and (p)

For purposes of this subsection and subsections (*o*) and (p):

(1) The term "Department" means the Department of Health and Human Services.

(2) The term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

(3) The term "other agreement" includes a cooperative agreement, scholarship, fellowship, loan, subsidy, payment for a specified use, donation agreement, award, or subaward (regardless of whether one or more of the persons entering into the agreement is a contractor or subcontractor).

(4) The term "program beneficiary" means, in the case of a grant, contract, or other agreement designed to accomplish the objective of awarding or otherwise furnishing benefits or assistance to individuals and for which the Secretary provides funding, an individual who applies for, or who receives, such benefits or assistance from such grant, contract, or other agreement. Such term does not include, with respect to such

grant, contract, or other agreement, an officer, employee, or agent of a person or entity that receives such grant or that enters into such contract or other agreement.

(5) The term "recipient" includes a subrecipient or subcontractor.

(6) The term "specified State agency" means an agency of a State government established or designated to administer or supervise the administration of a grant, contract, or other agreement funded in whole or in part by the Secretary.

(r) Definition of "specified claim"

For purposes of this section, the term "specified claim" means any application, request, or demand under a grant, contract, or other agreement for money or property, whether or not the United States or a specified State agency has title to the money or property, that is not a claim (as defined in subsection (i)(2)) and that—

(1) is presented or caused to be presented to an officer, employee, or agent of the Department or agency thereof, or of any specified State agency; or

(2) is made to a contractor, grantee, or any other recipient if the money or property is to be spent or used on the Department's behalf or to advance a Department program or interest, and if the Department—

(A) provides or has provided any portion of the money or property requested or demanded; or

(B)will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

(s) Definition of "obligation"

For purposes of subsection (*o*), the term "obligation" means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, for a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.

4. 42 U.S. Code 1320a-7b provides:

Criminal penalties for acts involving Federal health care programs

(a) Making or causing to be made false statements or representations

Whoever—

(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program (as defined in subsection (f)),

(2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment,

(3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or

quantity than is due or when no such benefit or payment is authorized,

(4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person,

(5) presents or causes to be presented a claim for a physician's service for which payment may be made under a Federal health care program and knows that the individual who furnished the service was not licensed as a physician, or

(6) for a fee knowingly and willfully counsels or assists an individual to dispose of assets (including by any transfer in trust) in order for the individual to become eligible for medical assistance under a State plan under subchapter XIX, if disposing of the assets results in the imposition of a period of ineligibility for such assistance under section 1396p(c) of this title,

shall (i) in the case of such a statement, representation, concealment, failure, or conversion by any person in connection with the furnishing (by that person) of items or services for which payment is or may be made under the program, be guilty of a felony and upon conviction thereof fined not more than $100,000 or imprisoned for not more than 10 years or both, or (ii) in the case of such a statement, representation, concealment, failure, conversion, or provision of counsel or assistance by any other person, be guilty of a misdemeanor and upon conviction thereof fined not more than $20,000 or imprisoned for not more than one year, or both. In addition, in any case where an individual who is otherwise eligible

for assistance under a Federal health care program is convicted of an offense under the preceding provisions of this subsection, the administrator of such program may at its option (notwithstanding any other provision of such program) limit, restrict, or suspend the eligibility of that individual for such period (not exceeding one year) as it deems appropriate; but the imposition of a limitation, restriction, or suspension with respect to the eligibility of any individual under this sentence shall not affect the eligibility of any other person for assistance under the plan, regardless of the relationship between that individual and such other person.

(b) Illegal remunerations

(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or

rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(3) Paragraphs (1) and (2) shall not apply to—

(A) a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program;

(B) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services;

(C) any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program if—

(i) the person has a written contract, with each such individual or entity, which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract, and

(ii) in the case of an entity that is a provider of services (as defined in section 1395x(u) of this title), the person discloses (in such form and manner as the Secretary requires) to the entity and, upon request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity;

(D) a waiver of any coinsurance under part B of subchapter XVIII by a Federally qualified health care center with respect to an individual who qualifies for subsidized services under a provision of the Public Health Service Act [42 U.S.C. 201 et seq.];

(E) any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 or in regulations under section 1395w-104(e)(6)[14] of this title;

(F) any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1395mm of this title or if the written agreement, through a risk-sharing

[14] See References in Text note below.

arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide;

(G) the waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under part D of subchapter XVIII, if the conditions described in clauses (i) through (iii) of section 1320a-7a(i)(6)(A) of this title are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1395w-114(a)(3) of this title), section 1320a-7a(i)(6)(A) of this title shall be applied without regard to clauses (ii) and (iii) of that section);

(H) any remuneration between a federally qualified health center (or an entity controlled by such a health center) and an MA organization pursuant to a written agreement described in section 1395w-23(a)(4) of this title;

(I) any remuneration between a health center entity described under clause (i) or (ii) of section 1396d(l)(2)(B) of this title and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the

quality, of services provided to a medically underserved population served by the health center entity;

(J) a discount in the price of an applicable drug (as defined in paragraph (2) of section 1395w-114a(g) of this title) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1395w-114a of this title; and

(K) an incentive payment made to a Medicare fee-for-service beneficiary by an ACO under an ACO Beneficiary Incentive Program established under subsection (m) of section 1395jjj of this title, if the payment is made in accordance with the requirements of such subsection and meets such other conditions as the Secretary may establish.

(4) Whoever without lawful authority knowingly and willfully purchases, sells or distributes, or arranges for the purchase, sale, or distribution of a beneficiary identification number or unique health identifier for a health care provider under subchapter XVIII, subchapter XIX, or subchapter XXI shall be imprisoned for not more than 10 years or fined not more than $500,000 ($1,000,000 in the case of a corporation), or both.

(c) False statements or representations with respect to condition or operation of institutions

Whoever knowingly and willfully makes or causes to be made, or induces or seeks to induce the making of, any false statement or representation of a material fact with respect to the conditions or operation of any institution,

facility, or entity in order that such institution, facility, or entity may qualify (either upon initial certification or upon recertification) as a hospital, critical access hospital, skilled nursing facility, nursing facility, intermediate care facility for the mentally retarded, home health agency, or other entity (including an eligible organization under section 1395mm(b) of this title) for which certification is required under subchapter XVIII or a State health care program (as defined in section 1320a–7(h) of this title), or with respect to information required to be provided under section 1320a–3a of this title, shall be guilty of a felony and upon conviction thereof shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(d) Illegal patient admittance and retention practices

Whoever knowingly and willfully—

(1) charges, for any service provided to a patient under a State plan approved under subchapter XIX, money or other consideration at a rate in excess of the rates established by the State (or, in the case of services provided to an individual enrolled with a medicaid managed care organization under subchapter XIX under a contract under section 1396b(m) of this title or under a contractual, referral, or other arrangement under such contract, at a rate in excess of the rate permitted under such contract), or

(2) charges, solicits, accepts, or receives, in addition to any amount otherwise required to be paid under a State plan approved under subchapter XIX, any gift, money, donation, or other consideration (other than a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to the patient)—

(A) as a precondition of admitting a patient to a hospital, nursing facility, or intermediate care facility for the mentally retarded, or

(B) as a requirement for the patient's continued stay in such a facility,

when the cost of the services provided therein to the patient is paid for (in whole or in part) under the State plan,

shall be guilty of a felony and upon conviction thereof shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(e) Violation of assignment terms

Whoever accepts assignments described in section 1395u(b)(3)(B)(ii) of this title or agrees to be a participating physician or supplier under section 1395u(h)(1) of this title and knowingly, willfully, and repeatedly violates the term of such assignments or agreement, shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than $4,000 or imprisoned for not more than six months, or both.

(f) "Federal health care program" defined

For purposes of this section, the term "Federal health care program" means—

(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of title 5); or

(2) any State health care program, as defined in section 1320a-7(h) of this title.

(g) Liability under subchapter III of chapter 37 of title 31

In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31.

(h) Actual knowledge or specific intent not required

With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.