

APPENDIX

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APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 25-5133

Argued: February 23, 2026

Decided: September 4, 2026

VERTEX PHARMACEUTICALS INCORPORATED,
Appellant

v.

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

Douglas H. Hallward-Driemeier argued the cause for appellant. With him on the briefs was *Andrew J. O'Connor*.

Daniel Winik, Attorney, U.S. Department of Justice, argued the cause for appellee. With him on the brief were *Brett A. Shumate*, Assistant Attorney General, and *Michael S. Raab* and *Charles W. Scarborough*, Attorneys.

Michael S. Labson and *Deborah Malamud* were on the brief for amicus curiae Sick Cell Reproductive Health Education Directive in support of appellant.

John S. MacGregor was on the brief for amicus curiae Dravet Syndrome Foundation in support of appellant.

James C. Stansel, John T. Delacourt, and Kwaku A. Akowuah were on the brief for amici curiae Pharmaceutical Research and Manufacturers of America & Biotechnology Innovation Organization.

Before: RAO and WALKER, *Circuit Judges*, and Randolph, *Senior Circuit Judge*.

Opinion for the Court filed by *Circuit Judge Rao*.

RAO, *Circuit Judge*: Vertex Pharmaceuticals developed a gene therapy that treats two hereditary blood disorders but may have adverse effects on fertility. To address the risk that fertility concerns might deter individuals from taking the therapy, Vertex designed a program that would offer patients up to \$70,000 to support fertility services. Vertex requested an advisory opinion from the Department of Health and Human Services to ensure its program complied with federal law. After a long delay, HHS issued an unfavorable advisory opinion, concluding that Vertex's program would violate both the Anti-Kickback Statute and the Beneficiary Inducement Statute. Vertex sued, claiming the advisory opinion was unlawful and unreasonable. Vertex also challenged HHS's regulations regarding the timing for issuing advisory opinions. The district court granted summary judgment for HHS across the board.

HHS correctly determined that Vertex's program would run afoul of the Anti-Kickback Statute. We affirm summary judgment as to that part of the advisory opinion, but otherwise reverse. HHS failed to adequately explain why the program would violate the Beneficiary Inducement Statute, and the timing regulations unlawfully evade a statutory deadline for issuing advisory opinions.

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I.

A.

This case turns on two statutes that protect the integrity of federal healthcare programs: the Anti-Kickback Statute (“AKS”) and the Beneficiary Inducement Statute (“BIS”).

Medicare and Medicaid provide federal funds to cover healthcare costs for certain eligible groups. Concerned about the possibility that individuals would offer payments to influence medical decision making and inflate federal reimbursements, Congress enacted the AKS. *See* Social Security Amendments of 1972, Pub. L. No. 92-603, Title II, § 242(b), 86 Stat. 1329, 1419. Congress has amended the AKS multiple times, for instance to broaden the scope of illicit payments and to add a scienter requirement to ensure the statute penalizes only conduct that is both knowing and willful. As revised and relevant here, the AKS criminalizes “knowingly and willfully offer[ing] or pay[ing] any remuneration (including any kickback, bribe, or rebate) ... to any person to induce such person ... to purchase” a federally reimbursable medical product or service. 42 U.S.C. § 1320a-7b(b)(2)(B).

AKS violations are felonies punishable by up to a \$100,000 fine and 10 years of imprisonment. *Id.* § 1320a-7b(b)(2). The AKS contains safe harbors that except certain activities from criminal liability, and the HHS Secretary has authority to create additional safe harbors. *Id.* §§ 1320- 7b(b)(3), 1320a-7d(a)(1)(B).

The BIS imposes civil penalties for influencing a beneficiary’s choice of provider for services or goods paid for by Medicare or Medicaid. Specifically, the BIS

prohibits “offer[ing]” or “transfer[ring]” to a beneficiary “remuneration” that a person “knows or should know is likely to influence” a beneficiary’s choice of “provider, practitioner, or supplier.” *Id.* § 1320a-7a(a)(5). The BIS contains several unique exceptions, in addition to the AKS’s safe harbors, which generally extend to violations of the BIS. *Id.* § 1320a-7a(i)(6). Relevant here is an exception for remuneration that “promotes access to care and poses a low risk of harm to patients and Federal health care programs.” *Id.* § 1320a-7a(i)(6)(F) (“Promotes Access to Care Exception”).

Parties may seek an advisory opinion from the HHS Secretary regarding whether a proposed activity would violate either the AKS or the BIS. *Id.* § 1320a-7d(b)(1)-(2). The advisory opinion may determine whether a proposed action violates the AKS or the BIS, whether a statutory exception applies, and whether HHS will exercise discretion to not pursue violations because there is a low risk of fraud or abuse. An advisory opinion is “binding as to the Secretary and the party ... requesting the opinion.” *Id.* § 1320a-7d(b)(4)(A).

The statutory provisions governing advisory opinions instruct the Secretary to promulgate regulations establishing procedures for the issuance of advisory opinions. Importantly, one subsection outlines the “Specific contents” for those regulations, which include that “the Secretary shall be required to issue to a party requesting an advisory opinion by not later than 60 days after the request is received.” *Id.* § 1320a-7d(b)(5)(B)(i). HHS’s regulations provide that it will issue an advisory opinion “within 60 days after the request for an advisory opinion has been formally accepted.” 42 C.F.R. § 1008.43(c)(1). Furthermore, the regulations toll the 60-day period under certain circumstances, including from

when HHS requests additional information until the time the requested information is submitted. *Id.* § 1008.43(c)(3)(ii).

B.

Vertex Pharmaceuticals is a biotechnology company that developed Casgevy, a novel treatment for sickle cell disease and transfusion-dependent beta-thalassemia, two hereditary blood disorders that afflict thousands of Americans. As part of Casgevy's treatment course, patients must undergo intensive chemotherapy, which can have significant negative effects on fertility. Because older patients are often unable to tolerate the chemotherapy regimen, patients ideally take Casgevy when they are young, with their childbearing years ahead of them. And because of the side effects of chemotherapy, patients may require fertility treatments that can cost tens of thousands of dollars.

Recognizing that fertility concerns and the costs of associated treatment might deter some patients from choosing Casgevy, Vertex created the Fertility Support Program. The Program provides up to \$70,000 to Casgevy patients for fertility services. Vertex opened the Program to privately insured patients, but did not include patients with federally provided healthcare, fearing the Program might violate the AKS and the BIS by offering a valuable service to incentivize patients to take Casgevy and choose certain healthcare providers.

On June 13, 2023, Vertex requested an advisory opinion from HHS about the lawfulness of extending the Program to federally insured patients. Vertex argued the Program did not violate the AKS and the BIS. In the alternative, Vertex argued that under the AKS, the Program posed a low risk of fraud or abuse and so HHS

should exercise its discretion to withhold enforcement. And under the BIS, Vertex maintained the Program would satisfy the Promotes Access to Care Exception because fertility concerns are a barrier to treatment that the Program would address.

A prolonged back-and-forth between HHS and Vertex followed. On June 26, HHS formally accepted Vertex's request and then asked for additional information about the Program. HHS tolled the 60-day deadline until Vertex provided the requested information on October 10. At a teleconference in November, HHS informed Vertex that it was unable to issue a favorable advisory opinion. The next month, Vertex requested that HHS publish its written decision within the period required by its regulations, but HHS did not do so. Over the following months, Vertex repeatedly requested that HHS finalize and publish the advisory opinion.

On July 15, 2024, Vertex sued in district court to compel issuance of the advisory opinion.¹ Vertex also alleged that the timing procedures in the advisory opinion regulations were contrary to law.

Three days later, more than one year after Vertex first requested an advisory opinion, and nine months after Vertex provided additional information to the agency, HHS issued the advisory opinion. HHS concluded that the Program provides prohibited remuneration within the meaning of the AKS and the BIS. HHS explained that “[i]f a reason a patient would not receive

¹ Vertex sued HHS, the HHS Secretary, HHS's Office of Inspector General, and the HHS Inspector General. The Secretary has delegated his advisory opinion authority to the Office of Inspector General. *See* 42 C.F.R. § 1008.1.

treatment with [Casgevy] is the patient’s inability to pay the costs associated with fertility services,” the Program would “address that inability to pay for these costs and likely would influence” the decision to purchase Casgevy. J.A. 590. Providing such remuneration to patients thus would violate the AKS if undertaken with the requisite scienter. *Id.* at 590, 592. Similarly, HHS concluded the Program falls under the BIS because the Program is likely to “influence” patients to choose physicians and centers Vertex has approved to provide Casgevy. *Id.* at 586, 591. HHS also “decline[d] to offer prospective immunity” from prosecution under the AKS because the agency lacked sufficient information to evaluate the risk of fraud and abuse created by the Program. *Id.* at 590. Finally, HHS concluded the Program did not qualify for the Promotes Access to Care Exception because it “lack[ed] data” on whether the Program improved patient access to Casgevy. *Id.* at 591.

After receiving the advisory opinion, Vertex amended its complaint to seek vacatur of the opinion under the Administrative Procedure Act (“APA”). Vertex argued that HHS’s interpretation of the AKS and the BIS was contrary to law and that it was arbitrary and capricious to not explain why Vertex’s proffered evidence was insufficient to decide whether the Program fits within the Promotes Access to Care Exception.

The district court granted summary judgment for HHS across the board. *Vertex Pharms. Inc. v. U.S. Dep’t of Health & Hum. Servs.*, 774 F. Supp. 3d 211 (D.D.C. 2025). The court concluded that the terms “induce” and “remuneration” in the AKS reflect their ordinary meaning, and the Program would therefore violate the AKS by offering “recompense” in the form of payment for fertility services to “influence” patients to

choose Casgevy. *Id.* at 222-31, 234-35. On the Promotes Access to Care Exception, the district court acknowledged that HHS failed to articulate what additional data it needed but nonetheless deferred to the agency’s reasoning. Finally, the district court found Vertex’s challenge to the advisory opinion regulations nonjusticiable because Vertex had “no ongoing injuries” from those regulations after its advisory opinion had been issued. *Id.* at 235-37.

Vertex timely appealed. We review *de novo* the district court’s grant of summary judgment. *Sault Ste. Marie Tribe of Chippewa Indians v. Haaland*, 25 F.4th 12, 17 (D.C. Cir. 2022).

II.

We first address Vertex’s argument that HHS erred in determining the Program would violate the AKS.² The AKS 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 such person ... to purchase” a federally reimbursable medical product or service.³ 42 U.S.C. § 1320a-7b(b)(2)(B).

² Following its usual practice, HHS did not formally consider the AKS’s scienter requirement in issuing the advisory opinion. *See* 42 U.S.C. § 1320a-7b(b)(2) (prohibiting “knowing[] and willful[]” conduct). For simplicity, we speak of HHS as having concluded the Program would violate the AKS.

³ In full, the provision at issue makes it a felony to:

knowingly and willfully offer[] or pay[] any remuneration (including any kickback, bribe, or rebate) directly or indirectly,

At issue here is whether the Program provides “remuneration ... to induce” a person to purchase Casgevy. Vertex does not dispute that the AKS bars the Program if the statute uses “remuneration” and “induce” in line with their ordinary meanings. But Vertex argues that both terms should be read narrowly, such that the AKS prohibits only quid-pro-quo transactions that corrupt medical decisionmaking.

We conclude the AKS employs the ordinary meaning of these terms, and therefore HHS correctly found the Program would violate the AKS by providing “remuneration” in the form of financial support for fertility treatment to “induce” persons to purchase Casgevy.

A.

We start with “induce,” the more contested term. The meaning of “induce” depends on whether the AKS uses the term in its ordinary or specialized criminal law meaning. Statutes are typically interpreted according to their ordinary meaning at the time of enactment, but they sometimes contain “terms of art in which are accumulated the legal tradition and meaning of centuries of

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.

42 U.S.C. § 1320a-7b(b)(2).

practice.” *United States v. Hansen*, 143 S. Ct. 1932, 1942 (2023) (cleaned up).

In ordinary parlance, “induce” broadly means to influence or prevail on a person. *See Induce*, The Oxford English Dictionary (2d ed. 1989) (“To lead (a person), by persuasion or some influence or motive that acts upon the will *to* ... some action, condition, belief, etc.; to lead on, move, influence, prevail upon (any one) *to do* something.”); *Induce*, Black’s Law Dictionary (5th ed. 1979) (similar). By contrast, Congress sometimes employs “induce” in a “specialized, criminal-law sense” that “incorporat[es] common-law liability for solicitation and facilitation.” *Hansen*, 143 S. Ct. at 1942. Criminal solicitation requires that a person intentionally encourage another to commit a crime. 2 Wayne R. LaFave, *Substantive Criminal Law* § 11.1 (3d ed. 2018); Model Penal Code § 5.02(1) (A.L.I. 1985). Criminal facilitation, commonly known as aiding and abetting, is the “provision of assistance to a wrongdoer with the intent to further an offense’s commission.” *Hansen*, 143 S. Ct. at 1940. In this specialized sense, “induce” means to encourage a person to commit a crime or to assist that person in doing so.

We look to statutory context to determine whether the AKS uses “induce” to mean “influence” or instead to reflect criminal solicitation and facilitation. *See id.* at 1942-44. The scope of the AKS’s prohibition indicates the statute uses the ordinary meaning of “induce.” The AKS does not directly prohibit the inducement of clearly unlawful activity. It limits the ways in which one person can induce another to select medical services, but the selection of medical services by a recipient of Medicare and Medicaid is generally lawful, and the particular choice of services is not itself a crime. *See* 42 U.S.C. § 1320a-7b(b)(2).

By contrast, the statute at issue in *Hansen* criminalized “encourag[ing] or induc[ing]” illegal immigration. 143 S. Ct. at 1938 (quoting 8 U.S.C. § 1324(a)(1)(A)(iv)). Under that statute, the act being induced was itself a crime, and the Supreme Court thus interpreted “induce” in the criminal law sense. *See id.* at 1940-45. But any presumption that Congress carried over the old soil of common law solicitation or facilitation is weakened in the AKS, in which the prohibition on inducement is not directed at an unlawful act.

Furthermore, looking to the broader context of the statute, the AKS’s extensive list of safe harbors supports construing “induce” in line with its ordinary meaning. “It is a fundamental canon of statutory construction that the words of a statute must be read in their context and with a view to their place in the overall statutory scheme.” *West Virginia v. EPA*, 142 S. Ct. 2587, 2607 (2022) (cleaned up). When interpreting statutes, “every word and every provision is to be given effect” and constructions that result in provisions of “no consequence” are generally to be avoided. Antonin Scalia & Bryan A. Garner, *Reading Law: The Interpretation of Legal Texts* 174 (2012); *see also TRW Inc. v. Andrews*, 534 U.S. 19, 29 (2001) (rejecting an interpretation that would “render [a statutory] exception entirely superfluous in all but the most unusual circumstances”).

The ordinary meaning of “induce” gives effect to the safe harbors in the AKS. If the AKS prohibits remuneration offered to influence the purchase of federally reimbursable healthcare products and services, then the list of safe harbors identifies many ordinary transactions that are excluded from the AKS prohibition. *See* 42 U.S.C. § 1320a-7b(b)(3); *United States ex rel. Hart v. McKesson Corp.*, 96 F.4th 145, 155 (2d Cir. 2024) (“To

cabin the statute’s broad reach, Congress defined twelve exceptions to the AKS’s criminal penalties.”). For example, one safe harbor permits the payment of ordinary compensation from a hospital to its doctors. 42 U.S.C. § 1320a-7b(b)(3)(B). Another safe harbor allows the waiver of coinsurance by a healthcare center for a patient who qualifies for subsidized services. *Id.* § 1320a-7b(b)(3)(D). Yet another permits pharmacies to waive co-pays if certain conditions are met, including that the pharmacy “determin[es] in good faith that the individual is in financial need.” *Id.* §§ 1320a-7b(b)(3)(G), 1320a-7a(i)(6)(A). The safe harbors include many commonplace transactions that influence healthcare decisions and therefore accord with an understanding of “induce” that means simply to influence another person.

If we adopted Vertex’s specialized understanding of “induce” as akin to criminal solicitation, there would be no need to include the safe harbors for prosaic actions like hospitals paying their doctors or for waivers of co-pays. Because criminal inducement would never reach such conduct, the specialized meaning of “induce” would render many of the safe harbors wholly superfluous.

Drawing meaning from superfluity of course depends on context. Some repetition or overlap in a statute may reflect Congress’s effort to legislate in a “hyper-vigilant way” that can “remove any doubt as to things not particularly doubtful in the first instance.” *Cyan, Inc. v. Beaver Cnty. Emps. Ret. Fund*, 138 S. Ct. 1061, 1074 (2018) (cleaned up). In the AKS, however, the list of safe harbors is extensive and detailed, so accepting a criminal solicitation reading of “induce” would “create vast superfluity in the statute.” *Pharm. Coal. for Patient Access v. United States*, 126 F.4th 947, 958 (4th Cir. 2025). Such superfluity weighs heavily against Vertex’s

preferred construction. By giving the safe harbors work to do, the ordinary meaning of “induce” provides a coherent way of understanding the prohibition and safe harbors together. The statute’s structure confirms that “induce” reaches a wide range of conduct, including actions that may be beneficial or have a low risk of fraud and abuse.

Vertex also maintains that interpreting the AKS’s use of “induce” in line with criminal solicitation coheres with the BIS’s civil prohibition against offering remuneration “likely to influence” a beneficiary’s selection of providers, practitioners, or suppliers. 42 U.S.C. § 1320a-7a(a)(5). Vertex argues these different terms must carry different meanings, and therefore “induce” in the criminal AKS must mean something narrower than “influence” in the civil BIS. Although courts will often look across the U.S. Code when interpreting a particular statutory provision, there are limits to that approach. The BIS was enacted roughly two decades after the AKS. That a different Congress later used the term “influence” in the BIS does not necessarily mean that “induce” in the AKS refers only to conduct analogous to criminal solicitation.⁴ See *Pfizer, Inc. v. U.S. Dep’t of Health & Hum. Servs.*, 42 F.4th 67, 78 (2d Cir. 2022) (declining to draw any AKS inference from the BIS because of the long gap between enactments); *Pharm. Coal. for Patient Access*, 126 F.4th at 956-57 (same).

If anything, context likely weighs against drawing any distinction between “induce” and “influence” in the

⁴ On the facts of this case we have no occasion to determine whether “induce” in the AKS, while meaning generally to influence or prevail on, has an identical meaning to “influence” in the BIS.

two statutes. When Congress enacted the BIS, it prohibited remuneration “likely to influence” the selection of providers under the title, “Prohibition Against Offering *Inducements* to Individuals Enrolled Under Programs or Plans.” Health Insurance Portability and Accountability Act of 1996, Pub. L. No. 104-191, Title II, § 231(h), 110 Stat. 1936, 2014 (emphasis added). The statute expressly referred to acts that influence as inducements.

Vertex also maintains that we must read “induce” narrowly in the AKS because the statute does not contain the same safe harbors as the BIS, and it is absurd that Congress did not extend all of the BIS’s safe harbors to the AKS. Perhaps extending the BIS’s safe harbors to the AKS would be good policy; perhaps not. But courts cannot rewrite statutes based on perceived absurdity and policy preferences. *Englehardt v. Blanche*, --- F.4th ---, 2026 WL 2234240, at *8 (D.C. Cir. Aug. 4, 2026). In any event, because the BIS and the AKS prohibit different conduct, Congress’s policy choice to not extend a BIS safe harbor to the AKS provides little, if any, contextual evidence about the meaning of the AKS.

Applying the traditional tools of statutory construction, the term “induce” in the AKS is best read in line with its ordinary meaning—to influence or prevail on a person.

B.

We next consider the meaning of “remuneration.” The AKS prohibits “*any* remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind.” 42 U.S.C. § 1320a-7b(b)(2). As with “induce,” the parties disagree about

whether “remuneration” includes a wide range of payments or only corrupt payments and transactions.

The AKS employs “remuneration” in its ordinary sense, as including valuable compensation, such as payments, goods, or services. The ordinary meaning of “remuneration” is “[r]eward, recompense, repayment; payment, pay.” *Remuneration*, The Oxford English Dictionary (2d ed. 1989); see *Remuneration*, Black’s Law Dictionary (5th ed. 1979) (similar). Relatedly, the BIS’s definition of “remuneration” includes “transfers of items or services for free or for other than fair market value.” 42 U.S.C. § 1320a-7a(i)(6). We have suggested that “remuneration” in the AKS tracks this definition and encompasses “anything of value, including payments or services below fair market value.” *United States ex rel. Winnon v. Lozano*, 146 F.4th 1197, 1204 (D.C. Cir. 2025).

Importantly, Congress used broad language to capture the scope of covered remuneration, extending AKS liability to “any remuneration (including *any* kickback, bribe, or rebate).” 42 U.S.C. § 1320a-7b(b)(2) (emphasis added). The repeated use of “any,” which has an “expansive meaning,” makes clear the prohibition encompasses all forms of remuneration. *Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 219 (2008) (cleaned up). Similarly, Congress set off the parenthetical that follows “remuneration” with “including,” which indicates the types of remuneration are illustrative, rather than exhaustive. Remuneration in the AKS captures valuable compensation, including but not limited to “any kickback, bribe, or rebate.”

Vertex does not contest that remuneration generally captures payments or services below market value.

Rather, Vertex argues the adjacent parenthetical—“(including any kickback, bribe, or rebate)” —means that remuneration should be narrowly read to apply only to corrupt transactions that improperly skew medical decisionmaking. *See* 42 U.S.C. § 1320a-7b(b)(2). Under the interpretive principle of *noscitur a sociis*, a word is known by the company it keeps. When faced with a list sharing a common quality, courts may sensibly interpret the list in light of that common quality. But the actions listed in the parenthetical following “remuneration” are not all inherently corrupt. While “kickback” and “bribe” certainly have corrupt connotations, “rebate” does not. *See Rebate*, The Oxford English Dictionary (2d ed. 1989) (“A deduction from a sum of money to be paid, a discount; also, a repayment, drawback.”); *Rebate*, Black’s Law Dictionary (5th ed. 1979) (“Discount; deduction or refund of money in consideration of prompt payment.”). Looking to the text of the AKS, we decline to limit “remuneration” to only corrupt transactions when the neighboring and illustrative list extends beyond corrupt conduct.⁵

Next, Vertex relies on the rule of lenity and constitutional avoidance to support a construction of the AKS

⁵ Resisting this conclusion, Vertex argues that, when initially enacted, the AKS used “rebate” to refer only to corrupt rebates functioning as kickbacks and that Congress maintained this understanding of “rebate” with later amendments to the statute. 86 Stat. at 1419, § 242(b). This statutory history, however, weighs against Vertex’s preferred construction. When Congress amended the AKS in 1977, it extended the statute’s prohibition to cover “any remuneration (including any ... rebate).” Medicare-Medicaid Anti-Fraud and Abuse Amendments, Pub. L. No. 95-142, § 4, 91 Stat. 1175, 1179–80 (1977). In these amendments, Congress chose the broader term “remuneration” and specified that it extended beyond corrupt rebates.

that is limited to criminal solicitation or facilitation. Vertex contends that interpreting the AKS in line with the ordinary meaning of both “remuneration” and “induce” would sweep in a wide range of innocuous conduct and raise due process concerns. These arguments are unavailing because “neither lenity nor avoidance has any role to play where,” as here, “text, context, and structure decide the case.” *Bondi v. VanDerStok*, 145 S. Ct. 857, 876 (2025) (cleaned up).

More fundamentally, there is no constitutional problem to avoid. The “mere fact that close cases can be envisioned” does not “render[] a statute vague” in violation of due process. *United States v. Williams*, 553 U.S. 285, 305-06 (2008). And “[r]esolution of the pros and cons of whether a statute should sweep broadly or narrowly is for Congress.” *United States v. Rodgers*, 466 U.S. 475, 484 (1984). Although “remuneration” to “induce” the purchase of medical treatment is broad, it is not unbounded. Furthermore, the AKS’s scienter requirement “alleviates vagueness concerns.”⁶ *McFadden v. United States*, 576 U.S. 186, 197 (2015) (cleaned up).

“Remuneration” in the AKS carries its ordinary meaning: valuable compensation, such as payments, goods, or services. We join the Second and Fourth Circuits in concluding that “remuneration” extends beyond corrupt transactions. *See Pfizer*, 42 F.4th at 76-77; *Pharm. Coal. for Patient Access*, 126 F.4th at 958-61.

⁶ We note that the other circuits to consider the question have similarly rejected vagueness challenges to the AKS. *See, e.g., United States v. Starks*, 157 F.3d 833, 839-40 (11th Cir. 1998); *Hanlester Network v. Shalala*, 51 F.3d 1390, 1397-98 (9th Cir. 1995); *United States v. Bay State Ambulance & Hosp. Rental Serv., Inc.*, 874 F.2d 20, 32-33 (1st Cir. 1989).

Applying this interpretation, we hold that HHS correctly concluded that the Fertility Support Program would run afoul of the AKS because it provides remuneration to induce the purchase of Casgevy by patients who would otherwise decline it due to fertility concerns.⁷ To reach this conclusion, we need not determine the degree of influence required to constitute inducement under the AKS. Providing up to \$70,000 in financial support for fertility services constitutes “remuneration” to patients who are prescribed Casgevy. And that remuneration is intended to induce patients to choose Casgevy. Indeed, the entire point of the Program is to encourage patients to choose Casgevy, as opposed to other treatments, by promising to pay for fertility services that may be necessary to address the treatment’s side effects. Because the AKS sweeps in actions that go beyond corrupt transactions, HHS correctly concluded the Program would violate the AKS.⁸

⁷ Because this holding is sufficient to resolve Vertex’s AKS challenge, we do not reach HHS’s separate conclusion that the Program provides prohibited remuneration to doctors and medical centers by providing “the opportunity to earn fees related to treatment with [Casgevy],” which might induce them to recommend Casgevy over other treatments. J.A. 590.

⁸ Vertex properly does not seek judicial review of HHS’s decision that it lacked sufficient data about the risk of fraud and abuse to provide a favorable advisory opinion granting prospective immunity from enforcement of the AKS. HHS may of course take a different view on remand, particularly as it must reconsider whether the Promotes Access to Care Exception applies for civil liability under the BIS. *See infra* at 21.

III.

Vertex next challenges HHS's determination that the Program would subject Vertex to BIS sanctions. After reasoning that the Program would implicate the BIS's civil prohibition, HHS concluded that the Program would not qualify for the Promotes Access to Care Exception because HHS lacked data to make this determination. HHS's conclusion that the Program violated the BIS was arbitrary and capricious because it failed to reasonably explain why the Promotes Access to Care Exception does not apply.

The APA requires agencies to engage in reasoned decisionmaking. *See* 5 U.S.C. § 706. When issuing an advisory opinion, HHS must “articulate a satisfactory explanation for its action.” *Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983). “The agency’s statement must be one of ‘reasoning’; it must not be just a ‘conclusion.’” *Butte County v. Hogen*, 613 F.3d 190, 194 (D.C. Cir. 2010). “Conclusory explanations for matters involving a central factual dispute where there is considerable evidence in conflict do not suffice.” *Genuine Parts Co. v. EPA*, 890 F.3d 304, 312 (D.C. Cir. 2018) (cleaned up); *see also Erwin v. FAA*, 23 F.4th 999, 1007 (D.C. Cir. 2022) (requiring agency to give “explicit consideration” to a party’s arguments and evidence).

The statutory provisions governing advisory opinions state that HHS “shall” issue an advisory opinion as to whether a “proposed activity constitutes grounds for the imposition of a sanction under” the BIS. 42 U.S.C. § 1320a-7d(b)(2)(E). Sanctions under the BIS are available only when an activity falls under the statutory prohibition and fails to qualify for a statutory exception.

HHS must therefore consider the BIS's exceptions when an individual requests an advisory opinion as to whether a proposed program may lead to BIS sanctions. The Promotes Access to Care Exception, which covers activities that "promote[] access to care and pose[] a low risk of harm to patients and Federal health care programs," is one such exception. *Id.* § 1320a-7a(i)(6)(F). The Exception extends to items or services that (1) "improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid," and (2) "pose a low risk of harm to Medicare and Medicaid beneficiaries and ... programs." 42 C.F.R. § 1003.110.

Vertex requested an advisory opinion from HHS regarding whether the Program presents grounds for sanctions under the BIS. As part of its request and in response to requests for further information, Vertex provided significant evidence that the Program satisfies the Promotes Access to Care Exception. To begin with, Vertex demonstrated that the Program improves the ability of patients to access Casgevy and thus treat their blood disorders. For instance, Vertex submitted studies showing the risk of infertility from chemotherapy is a significant reason why sickle cell disease patients forgo potentially lifesaving treatment. The company also cited evidence indicating that many patients lack the financial means to secure fertility treatment and would not choose Casgevy due to fertility concerns. Finally, Vertex pointed to CMS guidance that recognizes the "[l]ack of access to fertility preservation services presents a significant access barrier" to individuals considering gene therapy treatments, such as Casgevy. J.A. 559.

Vertex further put forth evidence that the Program poses a low risk of harm to federal healthcare beneficiar-

ies and programs. For example, Vertex imposed controls such as making the Program available to patients only after they are prescribed Casgevy. Moreover, Vertex pointed to the high cost of care for sickle cell disease patients and suggested that increasing access to gene therapies could alleviate this burden on federal healthcare programs by treating additional patients.

In response to all of Vertex's arguments and evidence, HHS simply stated the Promotes Access to Care Exception was not applicable because HHS "lack[s] data that would allow [it] to determine that providing the [Program] to eligible patients improves the ability of patients to access [Casgevy]." *Id.* at 591. Despite months of delay, this was the full extent of its explanation. HHS did not explain what data it lacked, nor why it could not readily obtain that data, nor why Vertex's detailed evidence was insufficient to show that the Program would improve patient access to Casgevy. Advising that the Program violated the BIS without providing a meaningful explanation for why it did not satisfy the Promotes Access to Care Exception was inconsistent with HHS's statutory obligation and unreasonable.

We disagree with the district court's conclusion that HHS acted reasonably because its "path may reasonably be discerned." *Vertex Pharms.*, 774 F. Supp. 3d at 221 (cleaned up). The district court pointed to statements elsewhere in the advisory opinion emphasizing the novelty of gene therapies. That novelty, however, does not absolve HHS of its obligation to determine whether the Program fits within the statutory Exception. The district court also highlighted HHS's statement that it expects to acquire further information about gene therapies in the future. But none of these statements explain

why the detailed information provided by Vertex was insufficient to determine whether the Exception should apply to the Program.

The advisory opinion was conclusory and failed to engage with Vertex's evidence that the Program satisfied the Promotes Access to Care Exception. HHS's determination that the Program would run afoul of the BIS was arbitrary and capricious, and we set it aside.

IV.

Finally, Vertex maintains that HHS regulations unlawfully extend the time for responding to advisory opinion requests. The district court held Vertex lacked standing to challenge the timing provisions after HHS issued the advisory opinion. We disagree and reach the merits, concluding that the timing provisions are contrary to law and must be set aside.

A.

When Vertex initially sued, it challenged HHS's delay in responding to its advisory opinion request and the regulations governing the timing for advisory opinions. Issuance of the advisory opinion mooted Vertex's challenge that the opinion was being unlawfully withheld, but it did not moot the challenge to the advisory opinion regulations.

It is well established that "if a plaintiff challenges both a specific agency action and the *policy* that underlies that action, the challenge to the policy is not necessarily mooted merely because the challenge to the particular agency action is moot." *City of Houston v. Dep't of Hous. & Urb. Dev.*, 24 F.3d 1421, 1428 (D.C. Cir. 1994). In the context of the Freedom of Information Act

(“FOIA”), for instance, we have explained that a challenge to an agency’s policies “cannot be mooted by the release of the specific documents that prompted the suit.” *Payne Enters. v. United States*, 837 F.2d 486, 491 (D.C. Cir. 1988). HHS may not evade judicial review simply by releasing an advisory opinion. Vertex’s challenge to the timing provisions is not moot.

To maintain its challenge to HHS’s timing provisions, Vertex must still demonstrate it “has standing and the claim is ripe for review.” *Crowley Gov’t Servs. v. GSA*, 143 F.4th 518, 530 (D.C. Cir. 2025). We may properly consider Vertex’s claim if the timing provisions will harm its right to obtain timely advisory opinions in the future. *See Wash. Lawyers’ Comm. for Civil Rights & Urb. Affs. v. U.S. Dep’t of Justice*, 145 F.4th 63, 67 (D.C. Cir. 2025). In considering whether a party has standing to challenge an ongoing policy, we look to whether the party is “likely to be subject again to the agency practice she seeks to challenge.” *Khine v. U.S. Dep’t of Homeland Sec.*, 943 F.3d 959, 965 (D.C. Cir. 2019).

Vertex is an innovative biotechnology company that relies on HHS advisory opinions to verify that its programs to promote patient access are lawful, within a safe harbor, or create a sufficiently low risk of fraud and abuse for HHS to withhold enforcement. Vertex has requested two advisory opinions in the past. As a repeat player whose products and programs may implicate the AKS and the BIS, Vertex has credibly represented that it plans to seek future advisory opinions. *See Newport Aeronautical Sales v. Dep’t of Air Force*, 684 F.3d 160, 164 (D.C. Cir. 2012) (concluding a business that repeatedly requests agency records can challenge FOIA pol-

icy). Because HHS’s policy of extending the time for responding to requests is likely to harm Vertex, Vertex has standing to press its policy or practice claim.

Vertex’s claim is also ripe. Its challenge to the timing provisions raises “purely legal questions” that are “presumptively suitable for judicial review,” and HHS’s ability to extend the issuance of advisory opinions, essentially indefinitely, harms Vertex’s ability to ensure that its products and programs are lawful. *Better Gov’t Ass’n v. Dep’t of State*, 780 F.2d 86, 92-96 (D.C. Cir. 1986).

B.

On the merits, the challenged timing provisions are contrary to law.⁹ HHS has regulatory authority to specify procedures for the issuance of advisory opinions. But Congress also required “Specific contents” for the regulations, including that the agency “shall be required to issue to a party requesting an advisory opinion by not later than 60 days after [a] request is received.” 42 U.S.C. § 1320a-7d(b)(5)(B). This directive imposes a mandatory 60-day deadline for HHS to respond after receiving an advisory opinion request.¹⁰

⁹ Because the district court dismissed the claim on jurisdictional grounds, it did not reach the merits of Vertex’s challenge to the timing provisions. We review this question in the first instance because the issue is purely legal, fully briefed, and requires no further factual development. *See Aljabri v. bin Salman*, 106 F.4th 1157, 1163 n.5 (D.C. Cir. 2024).

¹⁰ HHS maintains it is ambiguous what object the verb “issue” references. But context makes clear that “issue” refers to the issuance of an advisory opinion. The sentence connects “issue” with “to a party requesting an advisory opinion,” and the statute’s header refers to the “Issuance of advisory opinions.” *Id.* § 1320a-7d(b)(1).

Nonetheless, the advisory opinion regulations allow HHS to extend the time it has to respond to requests in two ways. First, the regulations provide that the 60-day clock does not begin to run when a request for an advisory opinion has been received. Rather, the clock starts when a request has been “formally accepted,” and HHS can take up to 10 business days after receipt to formally accept or decline a request.¹¹ 42 C.F.R. §§ 1008.41(b), 1008.43(c)(1). These rules plainly conflict with the statute’s 60-day timeline, which is tied to when “the request is received.” 42 U.S.C. § 1320a-7d(b)(5)(B)(i). The statute says nothing about delaying the acceptance of advisory opinion requests. HHS’s regulatory expansion of the 60-day review period is contrary to law.

Second, the regulations permit HHS to toll the period for responding to a request when HHS requests additional information or awaits advice from an outside expert. 42 C.F.R. § 1008.43(c)(3)(ii), (iv). HHS presses its need for flexibility. Yet the statute does not provide any flexibility as to timing. It instead requires that HHS “shall ... issue” an advisory opinion within 60 days of receipt of the request. 42 U.S.C. § 1320a-7d(b)(5)(B)(i).

Neighboring provisions confirm that “issue” refers to the Secretary’s issuance of advisory opinions. *See* 42 U.S.C. § 1320a-7d(b)(1), (2), (4)(A).

¹¹ HHS’s guidance acknowledges the agency has created an additional 10-day regulatory buffer. *See* HHS Office of Inspector General, Advisory Opinions FAQs (last updated Apr. 23, 2026) (“The statute provides that advisory opinions should be issued within 60 days. In addition, the regulations establish a 10-day period for the initial review and processing of the incoming request.”).

HHS has no authority to circumvent this statutory deadline. The reasoning of our en banc decision in *Allegheny Defense Project v. FERC* is instructive. 964 F.3d 1 (D.C. Cir. 2020). We rejected FERC’s longstanding practice of using tolling to suspend clear statutory deadlines. Because FERC had 30 days to act on a petition before it was deemed to have been denied, we held that the agency’s tolling practice “delete[d] the thirty-day time limit ... from the statute.” *Id.* at 13, 15. HHS similarly has no “unwritten and unilateral power to indefinitely evade” the advisory opinion deadline established by Congress. *Id.* at 16. The challenged timing provisions are therefore contrary to law.¹²

HHS defends its timing provisions as a reasonable construction of the statute because they allow HHS to gather additional information and grapple with the complexity of advisory opinion requests. An agency’s practical need for additional time to act in a complicated area does not allow for the tolling of statutory time periods. *See id.* at 16-17. Nor can the reasonableness of a policy expand an agency’s statutory authority. *See Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2266-67 (2024).

¹² In particular, we set aside the regulatory provisions that allow HHS to toll the 60-day statutory deadline. *See* 5 U.S.C. § 706(2) (authorizing courts to “hold unlawful and set aside agency action” that is contrary to law); *id.* § 551(13) (defining “agency action” to include “the whole or a part of an agency rule”). These provisions include: 42 C.F.R. § 1008.39(a) (second sentence) (tolling the 60-day deadline after a request for information); 42 C.F.R. § 1008.43(c) (tolling the 60-day deadline); and 42 C.F.R. § 1008.41(e). HHS may otherwise administer advisory opinion requests in accordance with 42 C.F.R. § 1008.41 to the extent that such administration does not toll the 60-day time limit, which runs from the receipt of a request.

HHS also contends that its authority to set advisory opinion procedures provides flexibility to determine matters of timing. A “general grant of authority,” however, “cannot displace the clear, specific text of a statute.” *Allegheny Def. Project*, 964 F.3d at 16 (cleaned up). HHS has some discretion to set advisory opinion procedures, but Congress mandated a 60-day deadline as part of the “[s]pecific contents” of the advisory opinion regulations. 42 U.S.C. § 1320a-7d(b)(5)(B).

HHS finally argues that, unlike the statute at issue in *Allegheny Defense Project*, there is no consequence for failing to issue an advisory opinion in 60 days, and so tolling is permissible. But that absence does not mean Congress implicitly authorized HHS to regulate around the 60-day time limit.

In sum, Congress imposed a 60-day timeline for HHS to issue advisory opinions in response to a request. The agency has no authority to pause the clock and grant itself more time.

* * *

Regarding Vertex’s challenge to the advisory opinion, we hold that HHS properly concluded the Fertility Support Program would violate the AKS, but HHS’s determination that the Program would violate the BIS was arbitrary and capricious. With respect to the regulatory timing provisions, we hold that Vertex has standing and that these provisions are contrary to law. Accordingly, we affirm in part, reverse in part, and remand for further proceedings consistent with this opinion.

So ordered.

APPENDIX B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

24-2046 (JEB)

VERTEX PHARMACEUTICALS INCORPORATED, *Plaintiff*,
-against-

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

MEMORANDUM OPINION

Vertex Pharmaceuticals Incorporated has developed an innovative gene-editing therapy to treat — and potentially cure — two serious blood disorders: sickle-cell disease and transfusion-dependent beta-thalassemia. Patients who receive the therapy (called CASGEVY) must first undergo chemotherapy, which can have severe adverse effects on their fertility. Worried that those effects will deter many patients from opting for treatment with CASGEVY, Vertex proposed a program that would provide eligible CASGEVY patients with up to \$70,000 for fertility-support services. The company then sought an advisory opinion from the Department of Health and Human Services about the lawfulness of that program and, after a lengthy back-and-forth, was eventually informed that its proposal would run afoul of the Anti-Kickback Statute and the Beneficiary Inducement Statute. Vertex then initiated this suit against HHS, its Office of Inspector General, and their top officials, challenging the agency's interpretation of the relevant statutes as contrary to law. The parties have now filed Cross-Motions for Summary

Judgment. Although Vertex does admirable work in pressing its view of nuanced statutes, the Court ultimately concludes that HHS's interpretation was lawful and thus grants its Motion and denies Plaintiff's.

I. Background

A. Legal Background

Many elderly, disabled, and low-income Americans receive health insurance via Medicare or Medicaid. Through both programs, the Government reimburses healthcare providers for delivering medical care to qualifying individuals. See New LifeCare Hosps. of N.C., LLC v. Becerra, 7 F.4th 1215, 1219 (D.C. Cir. 2021). In 1972, in response to concerns that pecuniary motives were improperly driving healthcare decisions, Congress enacted the Medicare and Medicaid Fraud and Abuse Statute — popularly known as the Anti-Kickback Statute. See Pub. L. No. 92-603, § 242(b), 86 Stat. 1329, 1419 (1972). The law seeks to prevent providers from offering and patients from selecting, in exchange for financial rewards and on the Government's dime, healthcare services that are unnecessary, overly expensive, or otherwise medically inappropriate. To do so, it deems guilty of a felony anyone who

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.

42 U.S.C. § 1320a-7b(b)(2).

The initial 1972 version of the statute did not use word “remuneration” — instead applying solely to “kick-back[s],” “bribe[s],” and “rebate[s]” — and it imposed only misdemeanor penalties. See 86 Stat. at 1419. Congress expanded the scope of the statute in 1977, however, to encompass “any remuneration”; criminalize not only its offering and payment, but also its solicitation and receipt; and provide felony penalties for violations. See Pub. L. No. 95-142, § 4, 91 Stat. 1175, 1180 (1977). The Anti-Kickback Statute’s general prohibition is tempered by numerous exceptions. See 42 U.S.C. § 1320a-7b(b)(3). Congress has immunized from the statute’s reach, for example, “a bona fide mental health or behavioral health improvement or maintenance program.” Id. § 1320a-7b(b)(3)(L). In addition to those statutory exceptions, HHS can establish by regulation new safe harbors from the Anti-Kickback Statute’s general prohibition. Id. § 1320a-7d(a).

Decades later, Congress enacted the similar Beneficiary Inducement Statute, which targets patients’ choice of a particular provider as opposed to a particular product. See Pub. L. No. 104-191, § 231(h)(5), 110 Stat. 2012, 2014 (1996). That act imposes civil penalties on any person who

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 in part, under [a federal or state healthcare program].

42 U.S.C. § 1320a-7a(a)(5). Like the Anti-Kickback Statute, the Beneficiary Inducement Statute contains several carveouts, including what is referred to as the Promotes Access to Care Exception. That exception establishes that the statute does not proscribe “any . . . remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs.” Id. § 1320a-7a(i)(6)(F).

Because of the harsh penalties at stake, Congress has created a mechanism through which parties can request advisory opinions from HHS resolving whether certain activities would violate either statute. See id. § 1320a-7d(b). The agency has delegated that advisory-opinion function to its Office of Inspector General. See 42 C.F.R. pt. 1008. Such advisory opinions are binding on both HHS and the party requesting the opinion. See 42 U.S.C. § 1320a-7d(b)(4). HHS is obligated by statute to promulgate regulations that set out the procedures for requesting and issuing an advisory opinion, id., § 1320a-7d(b)(5)(A), and that require the agency to issue such “advisory opinion by not later than 60 days after the request is received.” Id. § 1320a-7d(b)(5)(B)(i).

B. Factual and Procedural Background

Sickle-cell disease is an inherited blood disorder affecting approximately 100,000 Americans. See ECF No. 25 (Joint Appendix) at ECF p. 3 (Vertex Request) at 5 [ECF p. 7]. Gene mutations cause red blood cells — normally disc shaped and flexible — to become “rigid, sickle-shaped, and sticky.” Id. at 6 [ECF p. 8]. Those sickle-shaped cells block the flow of blood and oxygen throughout the body, causing chronic (often intense)

pain, along with other physical and psychological difficulties. Id. at 6-7, 8-10 [ECF pp. 8-9, 10-12]. The disease is also associated with premature mortality: patients with the disease have a median age of death of 43 years. Id. at 8 [ECF p. 10]. Approximately 50% to 60% of people with sickle-cell disease are enrolled in Medicaid. See Joint Appendix at ECF p. 417 (Vertex Feb. 2024 Request for Opinion), Exh. A at ECF p. 420. Although several treatments can manage the disease's symptoms, see Vertex Request at 21-25 [ECF pp. 23-27], only one curative therapy exists: hematopoietic-stem-cell transplantation. Id. at 26 [ECF p. 28]. Fewer than 25% of people have an appropriate genetic donor for the standard stem-cell transplant procedure, however, and patients must be healthy enough to tolerate an intensive chemotherapy regimen. See Joint Appendix at ECF p. 475 (Stem Cell Transplant Study) at 1.

Transfusion-dependent beta-thalassemia (TDT), which affects approximately 2,000 Americans, is another hereditary blood disorder. See Vertex Request at 14 (ECF p. 16). It is caused by anomalies in the synthesis of hemoglobin that reduce red-blood-cell production and lead to anemia. Id. Approximately 45% of TDT patients who are insured are covered by Medicare, Medicaid, or the Department of Veterans Affairs. Id. at 15 [ECF p.17]. Like with sickle-cell disease, hematopoietic-stem-cell transplantation is the only established curative therapy for TDT. Id. at 30 [ECF p. 32]. Given the aforementioned challenges with that procedure, however, the current standard of care requires blood transfusions administered every two to five weeks for the duration of the patient's life. Id. at 28 [ECF p. 30]. Individuals with TDT need those regular blood transfusions to survive.

Id. at 14 [ECF p. 16]. Still, patients often develop complications as a result of such frequent transfusions, and the median age of death for a person with TDT is 37 years. Id. at 14-15 [ECF pp. 16-17].

Plaintiff Vertex is a biotechnology company “that develops and manufactures innovative medicines to treat patients with serious diseases.” ECF No. 12 (Am. Compl.), ¶ 3. One such treatment is a one-time therapy that is a functional cure for sickle-cell disease and TDT. That therapy, CASGEVY, uses genome-editing technology to modify patients’ stem cells in a way that induces them to produce fetal hemoglobin. See Vertex Request at 16-17 [ECF pp. 18-19]. That hemoglobin production “reduce[s] manifestation of their disease.” Id. at 16 [ECF p. 18]. Based on efficacy studies, CASGEVY promises to be a highly effective treatment for both sickle-cell disease and TDT. Id. at 19 [ECF p. 21]. CASGEVY patients, however, must undergo an arduous multistep process to prepare for the treatment. Id. at 17-18 [ECF pp. 19-20]. Part of that process is a chemotherapy regimen that suppresses the patient’s bone-marrow activity, which allows the edited stem cells to be grafted into the bone marrow. Id. at 18 [ECF p. 20]. That chemotherapy is “associated with numerous serious side effects,” including adverse consequences for patients’ fertility. Id. It is no surprise “that many [sickle-cell disease] patients may delay or reject gene therapy due to the risk and fear of infertility.” Joint Appendix at ECF p. 214 (Vertex Oct. 2023 Provision of Information) at 7 [ECF p. 220]. Fertility treatments, however, are “typically not covered by insurance, especially by federal health care programs.” Vertex Request at 46 [ECF p. 48].

In June 2023, see id. at 1 [ECF p. 3], Vertex requested an advisory opinion from HHS regarding a program it proposed “to facilitate appropriate access to [CASGEVY] and to foster the safety and well-being of patients to be treated with [CASGEVY] both before and after treatment.” Id. at 30 [ECF p. 32]. That program, which it called the Fertility Support Program, would “provide financial support, up to a maximum of \$70,000, for medically necessary fertility support for eligible male and female patients prescribed [CASGEVY] and whose insurance does not cover fertility.” Id. at 34 [ECF p. 36]. Vertex explained that the Program would “remove barriers to treatment and facilitate adherence to independent treatment decisions by making it possible for patients to . . . take steps to potentially preserve their fertility.” Id. at 40 [ECF p. 42].

Thirteen days later, HHS — via its Office of the Inspector General — formally accepted Vertex’s request for an advisory opinion and requested additional information it deemed necessary “to render an informed opinion.” Joint Appendix at ECF p. 212 (HHS Acceptance) at 1-2 [ECF pp. 212-13]. The agency told Vertex that, pursuant to internal regulations, “the time for preparing your advisory opinion will be tolled from the date of this letter until we receive the requested information.” Id. at 2 [ECF p. 213]. Vertex provided the requested information several months later, in October. See Vertex Oct. 2023 Provision of Information at 1 [ECF p. 214].

At the end of November, HHS verbally informed Plaintiff that it believed the Fertility Program would violate the Anti-Kickback and Beneficiary Inducement Statutes and that Vertex’s request would thus result in an unfavorable advisory opinion. See Joint Appendix at ECF p. 241 (Vertex Dec. 2023 Request for Opinion) at

1; ECF No. 19 (Vertex Mot.) at 6. After Vertex requested a written opinion, see Vertex Dec. 2023 Request for Opinion, the agency again asked for additional information about the Program and stated that “the time period for the issuance of the advisory opinion[] will be tolled until we receive the requested information.” Joint Appendix at ECF p. 248 (HHS Dec. 2023 Email) at 2 [ECF p. 249]. Around the same time, the Food and Drug Administration approved CASGEVY as a treatment for sickle-cell disease. See Joint Appendix at ECF p. 359 (Vertex Dec. 2023 Request for Reconsideration) at 1, 5-6 [ECF pp. 359, 363-64]; Vertex Mot. at 7. Citing that approval, Vertex requested that HHS reconsider its position on the Program’s lawfulness. See Vertex Dec. 2023 Request for Reconsideration at 2 [ECF p. 360].

In January 2024, HHS orally informed Vertex that it still would not issue a favorable opinion regarding the Fertility Program, and Vertex requested in response that the agency “move forward expeditiously with finalizing and publishing the advisory opinion.” Vertex Feb. 2024 Request for Opinion at 1 [ECF p. 417]. After Vertex followed up three more times in March, April, and June 2024 about the status of the written opinion, see Joint Appendix at ECF p. 441 (Vertex June 2024 Request for Opinion), HHS eventually informed Plaintiff at the end of June that it had completed the advisory opinion and was “awaiting final clearance from [the Department of Justice.” Joint Appendix at ECF p. 450 (June 2024 Email Thread) at 1. Vertex initiated this litigation in mid-July, requesting — among other things — that this Court compel HHS to issue a written advisory opinion. See ECF No. 1 (Compl.), ¶¶ 173-79. HHS delivered its final opinion three days later. See Joint Appendix at ECF p. 455 (Advisory Opinion).

As promised, HHS concluded in its advisory opinion that the Fertility Program would constitute “prohibited remuneration under” both the Anti-Kickback Statute and the Beneficiary Inducement Statute if the requisite intent were present. *Id.* at 2 [ECF p. 456]. Specifically, the agency determined that the Program would be “designed to remove a financial barrier so that eligible patients would purchase [CASGEVY]” and that it could induce healthcare providers to recommend CASGEVY over “competitor drugs or other clinically appropriate treatments.” *Id.* at 7 [ECF p. 461]. As a result, the Program would violate the Anti-Kickback Statute. HHS similarly decided that the Program was “valuable remuneration” that was likely to influence patients to select certain medical centers and physicians over other options and thus would violate the Beneficiary Inducement Statute. *Id.* at 8 [ECF p. 462]. Because of the novelty of gene therapies and the lack of information about them, the agency concluded that it could not determine that the Program would be sufficiently low risk to offer prospective immunity under the Anti-Kickback Statute or that it would fall under the Beneficiary Inducement Statute’s Promotes Access to Care Exception. *Id.* at 6, 8 [ECF pp. 460, 462]. The upshot of the advisory opinion is that Vertex cannot offer the Program to patients insured by government healthcare programs, including Medicare and Medicaid, for fear of inviting an enforcement action. It can, however, continue to offer the Program to commercially insured patients because their medical care is not eligible for federal reimbursement. See Vertex Mot. at 5-6.

Following the release of HHS’s advisory opinion, Vertex filed an Amended Complaint claiming that the Fertility Program does not violate the Anti-Kickback

Statute or the Beneficiary Inducement Statute and that the agency’s advisory-opinion regulations are contrary to law for allowing untimely decisions. See Am. Compl., ¶¶ 139-70. Vertex seeks a declaratory judgment saying so. Id., ¶¶ 166-68. Both parties have now filed Motions for Summary Judgment. See Vertex Mot; ECF No. 21-1 (HHS Mot.).

II. Legal Standard

Although styled as Cross-Motions for Summary Judgment, the submissions in this case seek the Court’s review of an administrative decision. The summary-judgment standard set forth in Federal Rule of Civil Procedure 56 does not apply to Administrative Procedure Act claims because of the limited role of a court in reviewing the administrative record. See Sierra Club v. Mainella, 459 F. Supp. 2d 76, 89-90 (D.D.C. 2006). “[W]hen a party seeks review of agency action under the APA, . . . the district judge sits as an appellate tribunal.” Rempfer v. Sharfstein, 583 F.3d 860, 865 (D.C. Cir. 2009) (quotation marks and citation omitted). The APA “sets forth the full extent of judicial authority to review executive agency action for procedural correctness.” FCC v. Fox Television Stations, Inc., 556 U.S. 502, 513 (2009). It requires courts to “hold unlawful and set aside agency action, findings, and conclusions” that are “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2)(A). It also obligates courts to “exercise their independent judgment in deciding whether an agency has acted within its statutory authority.” Loper Bright Enters. v. Raimondo, 603 U.S. 369, 412 (2024).

III. Analysis

Vertex primarily takes issue with HHS's conclusions that its Program would violate both the Beneficiary Inducement Statute and the Anti-Kickback Statute. Because the Court's discussion of the former will inform how it reads the latter, it considers (and rejects) Plaintiff's arguments regarding those laws in that order. After doing so, the Court discusses Vertex's contention that HHS's regulations violate the statute's mandatory timeline for issuing advisory opinions and concludes that it lacks standing on that claim.

A. Beneficiary Inducement Statute

The Beneficiary Inducement Statute forbids “offer[ing] to or transferring] 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). HHS concluded that the Fertility Program would run afoul of that statute because the fertility-treatment funds constitute “valuable remuneration” that would likely influence patients to seek out particular treatment centers and physicians. See Advisory Opinion at 8 [ECF p. 462].

Vertex does not appear to disagree with that conclusion. See Vertex Mot. at 30-31. It instead hangs its hat on its belief that its Fertility Program should fall under the Beneficiary Inducement Statute's exception for “remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs.” Id. at 32-38 (quoting 42 U.S.C. § 1320a-

7a(i)(6)(F)). HHS has determined by regulation that the Promotes Access to Care Exception applies to:

Items or services that improve a beneficiary's ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by—

- (i) Being unlikely to interfere with, or skew, clinical decision making;
- (ii) Being unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and
- (iii) Not raising patient safety or quality-of-care concerns[.]

42 C.F.R. § 1003.110(6). The agency concluded that the Program does not satisfy that exception because it “lack[s] data that would allow [it] to determine that providing the [Fertility Program] to eligible patients improves the ability of patients to access [CASGEVY].” Advisory Opinion at 8 [ECF p. 462].

Vertex does not substantively challenge HHS's statement that there was a dearth of evidence for applying the exception, see Vertex Mot. at 32-38; ECF No. 22 (Vertex Reply) at 32, and it would face an uphill climb if it attempted to do so. Courts give “an extreme degree of deference to the agency when it is evaluating scientific data within its technical expertise,” City of Waukesha v. EPA, 320 F.3d 228, 248 (D.C. Cir. 2003) (quotation marks omitted), and are, moreover, “particularly deferential in matters implicating predictive judgments.” Alon Refin. Krotz Springs, Inc. v. EPA, 936 F.3d 628, 663 (D.C. Cir.

2019) (quotation marks omitted). The Department is therefore entitled to significant deference on its determination that it lacked sufficient information to find that the Program would improve access to care while posing a low risk of harm to patients.

To be sure, HHS's explanation of that point was brief. See Advisory Opinion at 8 [ECF p. 462]. The agency could have better articulated the open questions that remained and the nature of the data it needed. But its decision need not be "a model of analytic precision to survive a challenge." Dickson v. Sec'y of Def., 68 F.3d 1396, 1404 (D.C. Cir. 1995). Rather, "[a] reviewing court will 'uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned.'" Id. (quoting Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc., 419 U.S. 281, 286 (1974)). Here, the Department's conclusion about data came shortly after a full, evenhanded discussion of CASGEVY's promises and perils. HHS noted, for example, that "cell and gene therapies consist of an evolving field that holds significant promise for improving the health of patients, including Federal health care program enrollees." Advisory Opinion at 6 [ECF p. 460]. Acknowledging the "transform[ative]" potential of such therapies, the agency stated that the number "that are available in the marketplace is rapidly increasing" and that stakeholders were still "adapting to the proliferation of these innovative therapies (*e.g.*, paying for and providing these treatments)." Id. HHS went on to explain that the "novel[ty]" of the treatments meant that "much is yet unknown about them and optimal arrangements for ensuring appropriate access to them." Id. That "uncertainty," it explained, "makes it difficult to assess the risk of the" Fertility Program. Id. The Department finally stated that,

as gene therapies “become available to patients and the marketplace for them evolves, [it] expect[s] additional data to become available regarding the ability of Federal health care program enrollees to access these important treatments, as well as data regarding costs, benefits, risks, and outcomes of treatments.” Id. It is clear, then, that HHS’s conclusion regarding the Promotes Access to Care Exemption was informed by its earlier findings regarding the lack of available information about using and accessing novel gene therapies. Its determination thus was both reasonable and reasonably explained.

In drawing its conclusion, the agency did not depart from its precedents, as Vertex asserts. The company invokes several instances in which HHS approved what Plaintiff believes to be comparable programs, none of which the Court finds to be persuasive analogues. Vertex cites a program in which a pharmaceutical company provided patients with smartphones to collect and transmit biomedical information, see Vertex Mot. at 33, and another in which a company furnished travel, lodging, and meals to help patients visit certain medical facilities. See id. at 35. Those examples are inapposite. Neither involved novel treatments for which HHS’s primary concern was a lack of data. The type of compensation provided in those programs, moreover, directly enabled patients to access the treatment itself and therefore differs from the Fertility Program’s monetary reimbursement, which principally aims to make the treatment more attractive by offsetting a potential negative side effect.

Vertex next points to the Cell and Gene Therapy Access Model, a pilot program operated by the Centers for Medicare & Medicaid Services, a separate branch of HHS from the Office of Inspector General, the entity that issues advisory opinions. See Vertex Mot. at 37-39.

The Access Model “seeks to test” over eleven years whether “addressing a range of barriers to equitable access to cell and gene therapies,” including fertility-related obstacles, “will improve access and health outcomes for people with Medicaid.” Joint Appendix at ECF p. 443 (Cell and Gene Therapy Access Model Overview Factsheet) at 1-2 (ECF pp. 443-44). To do so, CMS requires participating drug manufacturers to, among other things, “cover certain fertility preservation services” because “the care journey for [sickle-cell-disease cell and gene therapy] typically results in infertility,” and “[l]ack of access to fertility preservation services presents a significant access barrier to individuals considering [cell and gene therapy].” *Id.* at 2 [ECF p. 444]. According to Plaintiff, the existence of the Access Model is tantamount not merely to a declaration by CMS that funding fertility treatment will increase access to care, but a proclamation that is binding on the rest of HHS. See Vertex Mot. at 37-38.

Vertex misunderstands both the nature of the Access Model and its relevance to the issue at hand. First, the Access Model is a limited, experimental program that explores — not endorses — the effect of eliminating certain obstacles to patients’ ability to access innovative gene therapies. Indeed, the Model’s very existence suggests that HHS remains unsure about the relationship between access to fertility-preservation services and access to care. See Advisory Opinion at 6 [ECF p. 460] (“[W]e expect additional data related to the provision of fertility services by a pharmaceutical manufacturer at no cost to Medicaid enrollees who receive gene therapy treatments from the Cell and Gene Therapy Access Model . . .”).

Second, the Court doubts that CMS's Access Model and any statements it made in the course of promoting that Model could bind CMS's own future actions, much less OIG's advisory opinions. There is "conflicting" caselaw about to what extent unofficial pronouncements like interpretive rules and policy statements are binding on the agency, but in general "the 'binding' quality of a particular rule or statement will depend on whether the agency intended to establish a 'substantive' rule, one which is not merely interpretative but which creates or modifies rights that can be enforced against the agency." Nat'l Latino Media Coal. v. FCC, 816 F.2d 785, 788 n.2 (D.C. Cir. 1987). For Vertex's purposes, the Access Model fails each of these preconditions. CMS never published a rule or statement announcing the supposedly positive consequences of fertility coverage on patients' access to care, and it certainly did not evince an intent for its descriptions of the Access Model to establish substantive rules or enforceable rights. The CMS Access Model thus holds little significance here.

In sum, the Court concludes that HHS reasonably determined that Vertex's Fertility Program would not fall under the Promotes Access to Care Exception and therefore that it would violate the Beneficiary Inducement Statute.

B. Anti-Kickback Statute

With the Beneficiary Inducement Statute out of the way, the parties dispute whether the Program violates the Anti-Kickback Statute, a statutory-interpretation morass that turns largely on the meaning of the words "induce" and "remuneration." Vertex insists that those terms carry specialized criminal connotations, while Defendants urge the Court to use their ordinary meanings.

In an exegesis that is admittedly involved, the Court takes each word in turn before addressing Vertex’s additional arguments regarding how to interpret the statute.

1. “*Induce*”

The Anti-Kickback Statute does not define the term “induce.” As a result, HHS urges the Court to give “induce” its common meaning: “entice or persuade another person to take a certain course of action.” HHS Mot. at 13 (cleaned up) (quoting Induce, Black’s Law Dictionary (11th ed. 2019)); accord Induce, Black’s Law Dictionary (4th ed. 1968) (“bring on or about, to affect, cause, to influence to an act or course of conduct, lead by persuasion or reasoning, incite by motives, prevail on”). For its part, Vertex does not dispute that the Government’s definition of “induce” is the ordinary one. It instead insists that, in the context of the Anti-Kickback Statute, the word “induce” should “carr[y] a specialized criminal-law meaning that restricts the reach of the statute to corrupt *quid-pro-quo* transactions.” Vertex Mot. at 13.

As the Supreme Court has noted, “A fundamental canon of statutory construction is that, unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning.” Perrin v. United States, 444 U.S. 37, 42 (1979); accord Mac’s Shell Serv., Inc. v. Shell Oil Prods. Co. LLC, 559 U.S. 175, 182-83 (2010). “[W]e do not assume that a . . . word is used as a term of art.” Johnson v. United States, 559 U.S. 133, 139 (2010). The Court therefore presumes that “induce” should be understood in this context to mean what it does in most other contexts.

Vertex pins its hopes chiefly on United States v. Hansen, 599 U.S. 762 (2023). See Mot. at 13-16. There,

the Supreme Court reviewed a provision making it unlawful to “encourag[e] or induc[e] an alien to come to, enter, or reside in the United States, knowing or in reckless disregard of the fact that such coming to, entry, or residence is or will be in violation of law.” Hansen, 599 U.S. at 770 (alterations in original) (quoting 8 U.S.C. § 1324(a)(1)(A)(iv)). Cautioning against “stack[ing] the deck in favor of ordinary meaning,” id. at 775, the Court held that the statute “uses ‘encourages or induces’ in its specialized, criminal-law sense.” Id. at 774. The Court noted that its decision was “not much of a contest” and concluded based on the statutory context and legislative history that “induce” should take “its criminal-law meaning” — “that is, as incorporating common-law liability for solicitation and facilitation.” Id. at 774-75. The Hansen Court defined solicitation as “the intentional encouragement of an unlawful act” and facilitation as “the provision of assistance to a wrongdoer with the intent to further an offense’s commission.” Id. at 771.

The parties’ dispute over “induce” largely boils down to a disagreement about whether Hansen’s conclusion regarding the term should apply to criminal statutes generally or only to those akin to the statute at issue there. At first glance, the Hansen holding appears to be, as Plaintiff insists, an appropriate match for today’s conundrum. The Supreme Court at times couched its interpretation of the statute in wide-ranging language. For example, it noted that “when a criminal-law term is used in a criminal-law statute, that — in and of itself — is a good clue that it takes its criminal-law meaning.” Id. at 775. In that way, the Court explained, “induce” was similar to “attempt,” which “we would not understand . . . in its ordinary sense of ‘try’” when consid-

ering “a criminal prohibition”; “[w]e would instead understand it to mean taking ‘a substantial step’ toward the completion of a crime with the requisite *mens rea*.” Id. at 774-75. The Court also chided the lower court for neglecting to “give[] specialized meaning a fair shake.” Id. at 775.

Upon closer inspection, however, the Hansen statute reveals itself to be an unsuitable analog to the Anti-Kickback Statute. The Court there made clear that its holding was grounded in the specific language and circumstances of that statute, which differ meaningfully and in several ways from those of the Anti-Kickback Statute.

To begin with, the Hansen statute is a bare prohibition on “encourag[ing] or induc[ing] an alien to come to, enter, or reside in the United States”; aside from a *mens rea* requirement, it contains no caveats or other limitations on its scope. See 8 U.S.C. § 1324(a)(1)(A)(iv). The Anti-Kickback Statute, on the other hand, is peppered with congressionally enacted safe harbors for broad swaths of conduct, with room for HHS to establish even more. See 42 U.S.C. § 1320a-7b(b)(3)(A)–(L); id. § 1320a-7d(a).

“It is a cardinal principle of statutory construction that a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant.” TRW Inc. v. Andrews, 534 U.S. 19, 31 (2001) (quotation marks omitted). That principle, also known as the canon against surplusage, guides the Court’s understanding of the Anti-Kickback Statute’s use of the word “induce.” If Plaintiff were correct that the statute prohibits only “corrupt *quid-pro-quo* transactions,” Vertex Mot. at 13,

its twelve exceptions would be mere surplusage. See 42 U.S.C. § 1320a-7b(b)(3)(A)-(L). Those exceptions, painstakingly spelled out by Congress, would do nothing to curb the statute’s reach that is not already accomplished by a specialized meaning of “induce.”

Take, for example, § 1320a-7b(b)(3)(B), which exempts from the statute’s ambit “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.” That provision makes clear that if an employer (*e.g.*, a hospital) makes a payment (*e.g.*, a salary) to its bona-fide employee (*e.g.*, a doctor) to “induce” the doctor to provide federally reimbursable medical services, neither the employer nor the doctor runs afoul of the Anti-Kickback Statute. Such run-of-the-mill income payments are plainly not “corrupt *quid-pro-quo* transactions,” *Vertex Mot.* at 13, and therefore would already be perfectly legal under Vertex’s understanding of the statute. Were that the case, it would be odd — indeed, wholly unnecessary — for Congress to have expressly exempted those innocent transactions from liability under the statute. The same is true for the other exceptions, each of which concerns an ordinary economic interaction that would not need to be explicitly protected if the word “induce” were limited on its own terms to unlawful conduct.

That is not even to mention § 1320a-7d(a), which gives HHS virtually unlimited discretion to create “safe harbors specifying payment practices that shall not be treated as a criminal offense under section 1320a-7b(b)” as well as to modify existing safe harbors. See 42 U.S.C. § 1320a-7d(a)(1)(A)(i)-(ii). The statute provides only that the agency “may consider” the extent to which a partic-

ular safe harbor “may result” in, for example, “[a]n increase or decrease in access to health care services,” “[a]n increase or decrease in the quality of health care services,” and “[a]ny other factors [HHS] deems appropriate.” Id. § 1320a-7d(a)(2). If Vertex is correct that the statute applies only to already unlawful transactions, § 1320a-7d(a) grants HHS unbounded license to exempt forms of “criminal solicitation,” Vertex Mot. at 16, from criminal liability. The Court finds it difficult to imagine that HHS actually possesses the ability to inoculate certain types of corrupt solicitation and facilitation against criminal penalties, much less that Congress intended to bestow that staggering power in the same breath that it outlawed corrupt transactions in federal healthcare programs in the first place. In the interest of giving effect to all of the Anti-Kickback Statute’s provisions, the Court believes that the Government’s reading is the better one.

True, “[t]he canon against surplusage is not an absolute rule.” Marx v. Gen. Revenue Corp., 568 U.S. 371, 385 (2013); see Cook Inlet Tribal Council, Inc. v. Doto-main, 10 F.4th 892, 896 (D.C. Cir. 2021) (interpreting another statute in “a belt-and-suspenders manner”). But there are strong indications that the canon should apply here. First, the Court is not presented with competing interpretations that would both produce surplusage. See Marx, 568 U.S. at 385 (“[T]he canon against surplusage ‘assists only where a competing interpretation gives effect to every clause and word of a statute.’”) (quoting Microsoft Corp. v. i4i Ltd. P’ship, 564 U.S. 91, 106 (2011)). Rather, Vertex’s proposed understanding of the statute creates superfluity, rendering needless the enumerated exemptions, while the Government’s does not. The Anti-Kickback Statute, moreover, does not address

the kind of substantive issue — such as attorney fees and costs, see Marx, 568 U.S. at 385-86, or burdens of persuasion and standards of proof, see Microsoft, 564 U.S. at 106-07 — where redundancies are known to be commonplace. While Plaintiff insists that Congress must have included superfluous exceptions in an attempt to “make crystal clear” that certain activities would not be criminalized, the only reason it provides to explain why the legislature would have included so many redundancies is that the Anti-Kickback Statute “is a criminal law that carries serious penalties.” Vertex Reply at 10-11. Vertex, however, ignores that courts regularly apply the canon of surplusage to serious criminal laws without fear of loosening statutory belts and suspenders. See, e.g., Fischer v. United States, 603 U.S. 480, 493-96 (2024); Pulsifer v. United States, 601 U.S. 124, 143 (2024); Yates v. United States, 574 U.S. 528, 543 (2015). Last, “the canon against surplusage is strongest when an interpretation would render superfluous another part of the same statutory scheme,” Marx, 568 U.S. at 386 (considering two different statutes), as is the case here.

Vertex responds by invoking Mission Product Holdings, Inc. v. Tempnology, LLC, 587 U.S. 370 (2019), which it contends “rejected . . . that, under the rule against superfluities, a general rule had to be read in a manner that would normally encompass an enumerated list of exceptions.” Vertex Reply at 10. The Supreme Court chose not to apply the canon against surplusage in that case because the enumerated exceptions “emerged at a different time, over a span of half a century,” and “each responded to a discrete problem,” often “correcting a judicial ruling.” Mission Prod. Holdings, 587 U.S. at 383. The exceptions in the Anti-Kickback Statute similarly arose over decades — although Plaintiff does

not claim that they were likewise enacted to respond to and correct individual events. See Vertex Reply at 10 n.3. But the Mission Product Holdings Court declined to rely on the canon against surplusage largely because it would have led to an incoherent understanding of the statute “to say essentially its opposite.” 587 U.S. at 383. Given those unique circumstances, this Court understands Mission Product Holdings to counsel only gently against applying the canon against surplusage and in circumstances not present here. Because significant force militates in favor of the canon’s application in this case, the Court is comfortable relying on it.

This Court’s reading of the Anti-Kickback Statute is bolstered by other aspects of Hansen that made the broad meaning of “induce” particularly dubious there. The Supreme Court was asked to decide whether the statute “punishes so much protected speech” that it is facially unconstitutional under the First Amendment. See 599 U.S. at 769. The Court determined the meaning of “induce,” then, only as a first step toward its ultimate constitutional holding: it had to “determine what [the statute] covers” in order to “judge whether [it] is overbroad.” Id. at 770. Given that First Amendment framing, it is unsurprising that the Justices were loath to give “induce” its more expansive ordinary meaning. As the Court explained, the everyday meaning of “induce” would have “turned an ordinary solicitation and facilitation offense into a novel and boundless restriction on speech.” Id. at 777. The Court doubted that Congress meant to impose that “sweeping — and constitutionally dubious” — restriction. Id. at 778. Indeed, the Court made a point to “emphasi[ze]” that the canon of constitutional avoidance “counsel[ed]” it to adopt the narrow, specialized reading of “induce.” Id. at 781. Noting that

its task was “to seek harmony” between the statute and the Constitution, “not to manufacture conflict,” Hansen acknowledged that its statutory holding was motivated in part by a desire to avoid the constitutional issues that would attend reading the statute to criminalize a virtually unlimited range of conduct. See id. All the more reason, then, to understand the Supreme Court’s holding there as tailored — and thus limited — to the unique circumstances of that statute and challenge at issue.

The Anti-Kickback Statute, moreover, differs from the Hansen statute in several other important ways. For one, the two statutes criminalize different types of actions. The Hansen statute proscribes the inducement itself, while the Anti-Kickback Statute criminalizes the offering or payment of remuneration with the goal of inducement. Compare 8 U.S.C. § 1324(a)(1)(A)(iv) (“encourages or induces an alien to come to, enter, or reside in the United States, knowing or in reckless disregard of the fact that such coming to, entry, or residence is or will be in violation of law”), with 42 U.S.C. § 1320a-7b(b)(2) (“knowingly and willfully offers or pays any remuneration . . . to induce such person [to take certain actions]”). In the Anti-Kickback Statute, inducement is relevant only because it provides the improper motive that a person who runs afoul of the statute possesses. In other words, a person does not violate the Anti-Kickback Statute by inducing another individual to perform certain actions; he violates it only if he offers or pays remuneration to that individual with the goal of such inducement. By contrast, a person violates the Hansen statute purely through inducing a violation of law.

Resisting that distinction, Vertex contends that both statutes prohibit inducement and that “[t]he only difference is the form and object of the inducement.”

Vertex Reply at 7. According to Plaintiff, the prohibited inducement in Hansen “took the form of persuasive speech,” while inducement here takes the form of remuneration. See id. Vertex is mistaken. The Hansen statute prohibits all forms of inducement; a person would presumably violate the law by inducing a nonresident to enter the United States via a wide range of speech and conduct, such as issuing threats, withholding resources in the home country, leading by example, and — of course — offering or providing remuneration. Indeed, as the Supreme Court explained there, “To the extent that [the statute] reaches any speech, it stretches no further than speech integral to unlawful conduct.” 599 U.S. at 783. The Hansen statute, then, criminalized inducement broadly, not just persuasive speech. Vertex cannot rewrite the DNA of that statute to serve its own purposes. By contrast, the Anti-Kickback Statute prohibits inducement only in the form of remuneration. A person could induce the purchase of healthcare services through persuasive speech alone and remain in compliance with the statute. The word “induce,” then, plays an entirely different role in the Anti-Kickback Statute than it does in the Hansen statute. And when inducement itself is the criminal activity, it stands to reason that “induce” would take its criminal-law meaning. It would be bizarre, however, to apply the specialized, criminal-law meaning of induce to statutes that use inducement only to describe the motive with which it is unlawful to perform some other action. See HHS Mot. at 16 (providing examples).

Take, for example, 18 U.S.C. § 706, which makes it a crime for a person to “wear[] or display[] the sign of the Red Cross . . . for the fraudulent purpose of inducing the

belief that he is a member of or an agent for the American National Red Cross.” It is perplexing to imagine how the specialized meaning of “induce” Plaintiff urges — *i.e.*, the word “inducing” in a criminal statute always means the “intentional encouragement of an unlawful act,” Hansen, 599 U.S. at 771 — could operate in the context of 18 U.S.C. § 706. Plaintiff insists that, when a statute criminalizes certain conduct performed with the purpose of inducing a particular action, a prerequisite for liability is that the induced action is unlawful. For the Red Cross statute, the “unlawful act” would be “believe[ving]” that the person wearing the Red Cross insignia “is a member of or an agent for the American National Red Cross.” 18 U.S.C. § 706. It is of course not unlawful to think that another person is a member of the Red Cross. If Vertex is to be believed, then, no unlawful act would ever be induced, so no criminal liability would ever attach to the act of fraudulently wearing the sign of the Red Cross. Title 18 U.S.C. § 706 would be rendered completely inoperative — an outcome that would defy reason. Because the Anti-Kickback Statute is structured identically to 18 U.S.C. § 706 — each forbids conduct (offering or paying remuneration; wearing or displaying the sign of the Red Cross) with the motivation of inducing an action (purchasing healthcare services; believing another person is a member of the Red Cross) — the same logic applies.

Next, the Hansen statute prohibits the inducement of an independent criminal act: a violation of the immigration laws. See 8 U.S.C. § 1324(a)(1)(A)(iv) (“encourages or induces an alien to come to, enter, or reside in the United States knowing . . . that such coming to, entry, or residence is or will be in violation of law”) (emphasis added). The Supreme Court itself noted that it

was more confident in its conclusion that “induce” took its criminal-law meaning because of the statute’s “focus” on inducing “a violation of law.” Hansen, 599 U.S. at 775. The Anti-Kickback Statute, on the other hand, is concerned with the inducement of conduct that is not inherently criminal: purchasing federally reimbursable healthcare services. Because the Anti-Kickback Statute does not “necessarily link[]” inducement “to other criminal conduct,” this Court doubts that Congress meant to limit its scope to criminal solicitation and facilitation. See Pharm. Coal. for Patient Access v. United States (PCPA), 126 F.4th 947, 956 (4th Cir. 2025) (making same distinction). As the Fourth Circuit explained when considering the same issue, “By limiting the inducing offense to encompass only encouraging other criminal conduct, the Hansen statute, by its very language, left no room for inducement of any non-criminal acts.” Id. at 955. That court noted that many of the criminal statutes cited by Hansen — and many statutes forbidding inducement — outlaw the inducement of independent violations of law. Id. (collecting statutes). In those contexts, it is perfectly sensible to give “induce” a narrow meaning rooted in the criminal nature of the induced conduct. But when no independent violation of law is induced, that justification does not apply.

In short, aside from containing the word “induce,” the Hansen statute and the Anti-Kickback Statute are far from mirror images of each other. Rather, they employ different structures to criminalize wholly different categories of conduct. Given those incompatibilities, the Court is unwilling to simply transplant the Supreme Court’s holding in Hansen into the Anti-Kickback Statute.

The D.C. Circuit decisions cited by Vertex likewise shed little light on the dispute at hand. One opinion concerned a statute that “makes it a felony to ‘own[], manage[], or operate[]’ an interactive computer service — for example, a website, chat room, or search engine — ‘with the intent to promote or facilitate the prostitution of another person.’” Woodhull Freedom Found. v. United States, 72 F.4th 1286, 1292 (D.C. Cir. 2023) (alterations in original) (quoting 18 U.S.C. § 2421A(a)). There, the Circuit held in the context of a First Amendment challenge that the statute used the term “promoting prostitution” in its specialized, criminal-law sense: “aid[ing] and abet[ting] prostitution.” Id. at 1300 (citing Hansen, 599 U.S. at 771). Like in Hansen, the Woodhull statute involved an independent violation of law (*i.e.*, prostitution) and was subject to First Amendment overbreadth and vagueness challenges. And like in Hansen, those characteristics indicate that its lessons are of limited relevance here. As for the other case Plaintiff cites, the Circuit indeed noted that “inducement generally requires a showing that the government agent actually solicited or suggested the criminal conduct.” United States v. Williamson, 903 F.3d 124, 132 (D.C. Cir. 2018) (emphasis added) (quotation marks omitted). It made that statement, however, when discussing the entrapment defense, not a criminal statute, and it caveated its assertion with an acknowledgment that “[a] range of government conduct could qualify as inducement . . . , including persuasion, fraudulent representations, threats, coercive tactics, harassment, promises of reward, or pleas based on need, sympathy or friendship.” Id. (quotation marks omitted). The Court thus finds little utility in those cases.

Vertex also invokes a DOJ guidance document concerning a statute that makes it unlawful to “knowingly or willfully . . . pay[] or offer[] to pay or accept[] payment either for registration to vote or for voting.” Vertex Reply at 13 (alterations in original) (quoting 52 U.S.C. § 10307(c)). Plaintiff cites a portion of the guidance explaining that giving voters “a ride to the polls or time off from work” does not constitute a “payment” that violates the statute. *Id.* at 14 (quoting Richard C. Pilger, Federal Prosecution of Election Offenses, Dep’t of Just. 44 (8th ed. Dec. 2017), <https://perma.cc/LD5T-EM7K>). Even assuming DOJ’s guidance regarding one statute could bind HHS’s interpretation of a wholly different law, Justice limited its instruction to items that “are given to make [voting] easier” to “individuals who have already made up their minds to vote.” *Id.* It is unsurprising that DOJ does not consider such interactions to be payments that induce individuals to vote. That conclusion matters little when considering whether a transaction would persuade an individual to purchase certain healthcare services. DOJ’s internal policy regarding a separate statute that does not even use the word “induce” does not shift the calculus here.

In sum, the Court concludes that the ordinary meaning of “induce” — “influence to an act or course of conduct, lead by persuasion or reasoning, incite by motives, prevail on,” Induce, Black’s Law Dictionary (4th ed. 1968) — controls.

2. “Remuneration”

Vertex does not stop at “induce”; it also relies on the word “remuneration.” Recall, the statute criminalizes “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 such person” to take certain actions. See 42 U.S.C. § 1320a-7b(b)(2). “Remuneration” ordinarily means “[r]eward; recompense; salary.” Remuneration, Black’s Law Dictionary (4th ed. 1968); accord Pfizer, Inc. v. HHS, 42 F.4th 67, 75 (2d Cir. 2022) (“payment; compensation, especially for a service that someone has performed”) (cleaned up) (quoting Remuneration, Black’s Law Dictionary (11th ed. 2019)). Plaintiff, however, believes that “remuneration” within the Anti-Kickback Statute refers only to “transactions that corrupt physicians’ and patients’ decision making and thus solicit or facilitate an unlawful act on the part of the recipient.” Vertex Mot. at 18.

In support of this interpretation, Vertex points to the heading of 42 U.S.C. § 1320a-7b(b), which reads “Illegal remunerations,” to argue that the Anti-Kickback Statute prohibits only “illegal,” not “innocuous or even beneficial remuneration.” Vertex Mot. at 21. Plaintiff’s effort to rely on that heading is understandably half-hearted. While section headings can sometimes be instructive, see Dubin v. United States, 599 U.S. 110, 120-21 (2023), they “are not binding, may not be used to create an ambiguity, and do not control an act’s meaning by injecting a legislative intent or purpose not otherwise expressed in the law’s body.” iTech U.S., Inc. v. Renaud, 5 F.4th 59, 65 (D.C. Cir. 2021) (quotation marks omitted). Besides, even if the section heading were edifying, it expresses little beyond the uncontroversial fact that the provision denotes which remunerations are illegal.

In addition to the section heading, Vertex relies chiefly on the *ejusdem generis* and *noscitur a sociis* canons, which together counsel that general words should

be understood in light of the more specific terms surrounding them. See Fischer, 603 U.S. at 487. Specifically, Plaintiff argues that the meaning of the word “remuneration” should be limited by the listed examples of “kickback, bribe, or rebate,” which it believes all share an element of corruption. See Vertex Mot. at 18-22.

The Court first takes issue with Vertex’s premise. “Kickback” and “bribe” do generally carry corrupt connotations — although that implication is not a given. See Kickback, Black’s Law Dictionary (5th ed. 1979) (“Payment back of the purchase price to buyer . . . by seller to induce purchase or to influence improperly future purchases or leases”); Bribe, Black’s Law Dictionary (4th ed. 1968) (“Anything of value; any gift, advantage, or emolument; any price, reward or favor. Any money, goods, right in action, property, thing of value, or any preferment, advantage, privilege or emolument, or any promise or undertaking to give any, asked, given, or accepted, with a corrupt intent to induce or influence action, vote, or opinion of person”) (citation omitted). The word “rebate,” however, does not contain the same undercurrent of dishonesty. See Rebate, Black’s Law Dictionary (4th ed. 1968) (“Discount . . . A deduction or drawback from a stipulated payment, charge, or rate”). That is true notwithstanding Vertex’s attempt to argue that an Anti-Kickback Statute rebate must involve corruption, for which it cites only a footnote in an out-of-circuit case that was decided before the relevant amendment to the law. See Vertex Mot. at 18-19 (citing United States v. Zacher, 586 F.2d 912, 916 n.9 (2d Cir. 1978)); Pfizer, 42 F.4th at 75 (“[I]n Zacher we interpreted the original 1972 version of the [Anti-Kickback Statute], which prohibited only kickbacks, bribes, or rebates.

Congress did not expand the statute to cover ‘any remuneration’ until the statute was amended in 1977. Zacher’s reading of the 1972 statute thus gives us little guidance on resolving the current appeal.”) (citation omitted).

Even accepting *arguendo* that kickbacks, bribes, and rebates are all necessarily corrupt transactions, however, Vertex’s argument fails to clear several additional obstacles. It is, for one thing, unclear that the *ejusdem generis* canon applies when the general word precedes rather than follows the list of specific terms. See HHS Mot. at 22 (noting this point); Antonin Scalia & Bryan A. Garner, Reading Law: The Interpretation of Legal Texts 202-05 (2012) (explaining that “the *ejusdem generis* canon is properly limited to its traditional application: a series of specifics followed by a general,” providing reasons, and citing historical examples). Although Vertex attempts to bolster its point with this Court’s decision in Chestnut Hill Benevolent Ass’n v. Burwell, 142 F. Supp. 3d 91 (D.D.C. 2015), its reliance on that case is misplaced. See Vertex Reply at 18. There, the Court did apply the *ejusdem* canon to a regulation in which the specific words followed the general one, but it nevertheless described the enumeration of the terms as an “illustrative,” “nonexclusive list . . . [of] exemplars.” Chestnut Hill Benevolent Ass’n, 142 F. Supp. 3d at 104.

To the extent that the canon does have force here, the Anti-Kickback Statute makes clear that kickbacks, bribes, and rebates are merely examples of remuneration. The first clue is the statute’s use of the word “including.” See 42 U.S.C. § 1320a-7b(b)(2) (“including any kickback, bribe, or rebate”) (emphasis added). “[T]he word ‘includes’ is usually a term of enlargement, and not of limitation.” Burgess v. United States, 553 U.S. 124,

131 n.3 (2008) (alteration in original); accord Fabi Constr. Co., Inc. v. Sec’y of Lab., 508 F.3d 1077, 1086 (D.C. Cir. 2007) (“It is hornbook law that the use of the word ‘including’ indicates that the specified list . . . that follows is illustrative, not exclusive.”) (omission in original) (quotation marks omitted). The Court is therefore reluctant to read a list introduced with the word “including” to limit rather than expand the meaning of “remuneration.”

Next, the provision uses the word “any” — which “has an expansive meaning that usually indicates” an “indiscriminate[]” category “of whatever kind,” Del. Dep’t of Nat. Res. & Env’t Control v. EPA, 895 F.3d 90, 97 (D.C. Cir. 2018) (quotation marks omitted) — not once, but twice. See 42 U.S.C. § 1320a-7b(b)(2)(A) (“any remuneration (including any kickback, bribe, or rebate)”) (emphases added). On top of that, the statute’s “use of parentheses emphasizes the fact that that which is within is meant simply to be illustrative, hence redundant — a circumstance underscored by the lack of any suggestion that Congress intended the illustrative list to be complete.” Chickasaw Nation v. United States, 534 U.S. 84, 89 (2001). And if that were not enough, Congress took pains to make clear that it intended to prohibit a broad scope of transactions by emphasizing that remuneration is barred whether it is “direct[] or indirect[], overt[] or covert[], in cash or in kind.” 42 U.S.C. § 1320a-7b(b)(2). The word “remuneration” is therefore best read to refer to a wide range of payments, not only corrupt ones, and the parenthetical is best understood as a nonexhaustive list of examples.

Vertex rejoins that, if the “kickback, bribe, or rebate” parenthetical does not limit the meaning of remu-

neration, it constitutes an unacceptably redundant locution. But the remuneration parenthetical, unlike the exemptions from liability that would be rendered superfluous under Vertex's interpretation of the Anti-Kickback Statute, has good reason to exist even if "remuneration" is read to cover many types of transactions.

The statutory history demonstrates that the enacting Congress viewed kickbacks, bribes, and rebates as the prototypical types of payments forbidden by the Anti-Kickback Statute. The original 1972 version of the statute criminalized the solicitation, offering, or receipt of "any . . . kickback or bribe" or "rebate." 86 Stat. at 1419. In 1977, Congress changed that provision to the version that remains in force today: "any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind." 91 Stat. at 1180. Those additions reflect a clear congressional effort to expand the Anti-Kickback Statute's reach beyond only kickbacks, bribes, and rebates. See Hanlester Network v. Shalala, 51 F.3d 1390, 1398 (9th Cir. 1995) ("The phrase 'any remuneration' was intended to broaden the reach of the law which previously referred only to kickbacks, bribes, and rebates."). As the Government notes, it would have been reasonable for Congress to retain the statute's mentions of kickbacks, bribes, and rebates "to foreclose any unwarranted inference that it meant to remove such payments from the statute's ambit by deleting reference to them." HHS Mot. at 21. Indeed, unlike when a list of specific terms is followed by a general word, "[f]ollowing the general term with specifics can serve the function of making doubly sure that the broad (and intended-to-be- broad) general term is taken to include the specifics," particularly when the specifics are

introduced “with a term such as including.” Scalia & Garner, *supra*, at 204.

The Court is thus satisfied that the Government’s interpretation of the statute does not render wholly superfluous the “kickback, bribe, or rebate” parenthetical. Even if it did, the Court would still find that to be the better reading. To read remuneration to be only criminal in nature, as Vertex urges, would nullify the statute’s reticulated scheme of exceptions, while the Government’s position would at most make a short list of illustrative transactions redundant. “The sacrifice is easy — a few words saves the whole.” United States v. Akinyoyenu, 199 F. Supp. 3d 106, 117 (D.D.C. 2016); accord Pulsifer, 601 U.S. at 143 (“When a statutory construction . . . renders an entire subparagraph meaningless, this Court has noted, the canon against surplusage applies with special force.”) (cleaned up); Mowrer v. U.S. Dep’t of Transp., 14 F.4th 723, 732 (D.C. Cir. 2021) (“[O]ne short, unavoidably redundant catchall phrase is a far cry from . . . the pointless incorporation . . . of one . . . requirement after another.”).

The Court, in sum, concludes that the best understanding of the term “remuneration” is again the ordinary one: any “[r]eward; recompense; [or] salary.” Remuneration, Black’s Law Dictionary (4th ed. 1968).

3. *Beneficiary Inducement Statute*

In addition to its contentions based on the statutory language, Vertex argues that the Anti-Kickback Statute should be read with reference to the Beneficiary Inducement Statute. The Court finds those arguments unpersuasive.

Despite the similarities between the two statutes, they were enacted at different times by different Congresses. The Anti-Kickback Statute was enacted in 1972 and reworked in 1977, and the Beneficiary Inducement Statute was not enacted until 1996. The Supreme Court has declined to use one provision to interpret another when they “were not considered or enacted together.” Gomez-Perez v. Potter, 553 U.S. 474, 486 (2008) (discussing statutes enacted seven years apart). The Beneficiary Inducement Statute, then, provides little guidance for interpreting the Anti-Kickback Statute. See Pfizer, 42 F.4th at 78 (drawing same conclusion). The Court, unlike Vertex, accordingly finds little significance in the fact that the Anti-Kickback Statute uses the word “induce,” while the Beneficiary Inducement Statute uses “influence.” It is far from clear that the two Congresses, decades apart, made a conscious decision to use “distinct language” or denote a “narrower scope” in the Anti-Kickback Statute, see Vertex Mot. at 16 — not least because the heading for that section of the enacted version of the Beneficiary Inducement Statute is titled “Prohibition Against Offering Inducements to Individuals Enrolled Under Programs or Plans.” 110 Stat. at 2014 (emphasis added).

In fact, many of Vertex’s arguments are premised on the notion that the Beneficiary Inducement Statute is simply the “civil penalty counterpart” of the Anti-Kickback Statute. See Vertex Reply at 3-4. As a result, Plaintiff contends, the criminal activity outlawed by the Anti-Kickback Statute must comprise a subset of the civil conduct forbidden by the Beneficiary Inducement Statute. Because Plaintiff maintains that the Fertility Program does not violate the latter, it insists that the Program thereby cannot violate the former.

As previously explained, the Court disagrees that the Fertility Program falls under the Promotes Access to Care Exception and therefore concludes that it does violate the Beneficiary Inducement Statute. Even absent such a violation, the Program's status under that statute does not necessarily affect its footing with regard to the Anti-Kickback Statute. The two laws are motivated by different concerns and consequently prohibit different activities. The Anti-Kickback Statute guards against improperly induced purchases, while the Beneficiary Inducement Statute focuses on a beneficiary's choice of provider. See Pfizer, 42 F.4th at 78 (making same distinction). One can imagine why Congress might have drawn this distinction: there may be good reasons to criminalize inducing a patient's choice of a particular treatment but only civilly punish inducing a patient's choice of a hospital. Certain conduct could, as a result, violate the former but not the latter — if, for example, a manufacturer intended to induce a patient's purchase of a drug but did not attempt to influence the patient's choice of provider from whom to obtain the drug — which HHS has concluded in the past and which a court upheld. See id. Indeed, the Beneficiary Inducement Statute is not the sole path for entities to incur civil penalties for offering behavior-changing remuneration; individuals are independently subject to civil damages for violating the Anti-Kickback Statute. See 42 U.S.C. § 1320a-7a(a)(7). Vertex is wrong to suggest, then, that its liability *vel non* under one statute inevitably has implications for the other.

The Court likewise sees no reason to — *pace* Vertex, see Vertex Mot. at 30-32 — transport the Beneficiary Inducement Statute's Promotes Access to Care Exception to the Anti-Kickback Statute. Congress knows how to

write exceptions into the Anti-Kickback Statute, see 42 U.S.C. § 1320a-7b(b)(3)(A)-(L), and evidently has opted not to include the Promotes Access to Care Exception in that law. The Court will not do so itself.

4. *Other Canons of Interpretation*

Needing to stanch the bleeding, Vertex resorts to several extratextual rationales to contend that the Anti-Kickback Statute should be read to cover only corrupt transactions. In arguing for its preferred interpretation, Plaintiff often relies on policy considerations — going so far as to state that blocking the Fertility Program is an “absurd” result that cannot be tolerated. See Vertex Mot. at 22-23. Because CASGEVY has the potential to help ill patients who until now have had nowhere to turn, Vertex’s argument goes, HHS cannot block its attempt to make the treatment more widely available. The Court, recognizing the importance of mitigating the harmful side effects brought on by potentially life-saving treatments, does not doubt that CASGEVY is an innovative and important treatment that could increase many patients’ access to medical care. Indeed, the Government itself “recognize[d] that cell and gene therapies consist of an evolving field that holds significant promise for improving the health of patients, including Federal health care program enrollees.” Advisory Opinion at 6 [ECF p. 460]. It acknowledged that “cell and gene therapies, like [CASGEVY], can transform the lives of individuals living with” sickle-cell disease and TDT. Id.

At the same time, the Anti-Kickback Statute addresses complicated and high-stakes issues of healthcare, fraud, and medical decisionmaking. Congress determined how those questions are best answered and left HHS to fill in any gaps. The Court does

not have the authority — and would not be equipped — to construe the statute’s words based on its own assessment of which medical treatments are sufficiently valuable to justify influencing patients’ and providers’ healthcare decisions. As Defendants have explained, gene-editing therapies are “novel” treatments, and “much is yet unknown about them and optimal arrangements for ensuring appropriate access to them.” Advisory Opinion at 6 [ECF p. 460]. It is not implausible that Vertex’s Fertility Program could change doctors’ and patients’ decisionmaking in undesirable ways that should, for now, be avoided. Today’s outcome, then, certainly does not “def[y] rationality by rendering a statute nonsensical or superfluous,” nor is it “so contrary to perceived social values that Congress could not have intended it.” United States v. Cook, 594 F.3d 883, 891 (D.C. Cir. 2010) (cleaned up); accord Scalia & Garner, *supra*, at 237 (explaining absurdity canon is limited to dispositions “that no reasonable person could intend. . . . where the absurdity and injustice of applying the provision to the case would be so monstrous, that all mankind would, without hesitation, unite in rejecting the application” of canon) (quotation marks omitted). The Court thus sees no reason to doubt its holding on policy grounds.

Vertex also points to the lenity canon and due-process principles, which it argues require the Court to construe the Anti-Kickback Statute “narrowly to avoid improperly criminalizing innocent behavior.” Vertex Mot. at 23-26. For starters, there is reason to doubt that lenity and due-process concerns should play much of a role here: the purpose of the lenity canon is to provide individuals with “fair warning concerning conduct rendered illegal,” Liparota v. United States, 471 U.S. 419, 427

(1985), and “adequate notice lies at the heart of due process.” Gray Panthers v. Schweiker, 652 F.2d 146, 168 (D.C. Cir. 1980). Vertex has not been subject to any enforcement actions; this case instead arises out of the advisory-opinion mechanism that Congress created for potential violators to learn whether their activities would run afoul of the law. There is therefore no reason to fear that Vertex will be subject to enforcement without receiving adequate notice.

In any case, the lenity canon is a last resort that should be employed only when all other interpretive methods have been exhausted. See Moskal v. United States, 498 U.S. 103, 107-08 (1990). Given the accumulation of evidence in favor of Defendants’ diagnosis, the Court will not turn to alternative medicines.

* * *

In sum, the Court agrees with Defendants that the Anti-Kickback Statute forbids all forms of remuneration done with the purpose of inducing the purchase of federally reimbursable healthcare services, regardless of whether the remuneration or induced conduct is independently unlawful.

5. *Violation of Statute*

With the meaning of the statute established, the Court can now turn to the final task at hand: whether HHS reasonably determined that Vertex’s Program would violate the law. Plaintiff does not meaningfully dispute that, under the Government’s interpretation, the Program would run afoul of the Anti-Kickback Statute if implemented with the necessary *mens rea*. Rightly so.

The Program would provide patients with \$70,000 for fertility services; recompense for the potentially negative effects of CASGEVY on fertility or, in other words, remuneration. Medical providers could also prescribe CASGEVY in order to earn remuneration in the form of fees related to the treatment. See Advisory Opinion at 7 [ECF p. 461]. Plaintiff protests that, if the Program falls under Defendants’ interpretation of “remuneration,” so too would an alternative treatment regimen that does not have adverse effects on patients’ fertility. See Vertex Mot. at 27-28; Vertex Reply at 24-25. That is not correct. Unlike a payment of up to \$70,000 for fertility services, such an enhancement in the product could not conceivably be considered a “reward” or “recompense” to patients or providers; rather, it would simply be a different and improved treatment.

With the Fertility Program, Vertex’s motive for providing remuneration (in the form of payment for fertility services or treatment-related fees) would be “to facilitate appropriate access to [CASGEVY],” Vertex Request at 30 [ECF p. 32], and “remove barriers to treatment.” Id. at 40 [ECF p. 42]. Because Vertex seeks to “influence . . . an act or course of conduct,” Induce, Black’s Law Dictionary (4th ed. 1968) — specifically, to motivate patients to pursue treatment with CASGEVY or lead medical providers to prescribe CASGEVY over other treatment options — its motive is to induce others to purchase a service for which payment may be made under a federal healthcare program. Resisting the notion that the Program would change patients’ and physicians’ behavior, Plaintiff repeatedly insists that there are many reasons to select CASGEVY aside from the Fertility Program. See Vertex Mot. at 26-30; Vertex Reply at 21-23. The Court does not doubt that. Given

the inclusive definition of “induce” the Court adopts today, it is enough that the Program “removes the financial barrier to fertility preservation services necessary to counteract the side effect of infertility, which would otherwise prevent patients from undergoing this potentially life-altering treatment.” Vertex Reply at 24.

HHS’s conclusion that Vertex’s Program would violate the Anti-Kickback Statute if undertaken knowingly and willfully was therefore not contrary to law.

C. Timeliness

Loosing its final arrow, Vertex aims a procedural challenge at HHS’s actions. The statute requires the agency to issue its advisory opinion to the requested party “by not later than 60 days after the request is received.” 42 U.S.C. § 1320a-7d(b)(5)(B)(i). The statute also instructs the Department to “issue regulations to carry out” the advisory-opinion process, which must provide for:

- (i) the procedure to be followed by a party applying for an advisory opinion;
- (ii) the procedure to be followed by the Secretary in responding to a request for an advisory opinion; [and]
- (iii) the interval in which the Secretary shall respond

Id. § 1320a-7d(b)(5)(A). Pursuant to that requirement, HHS has established by regulation a procedure for issuing advisory opinions. As relevant here, the agency must decide whether to “[f]ormally accept the request,” “[n]otify the requestor of what additional information is needed,” or “[f]ormally decline to accept the request” “[w]ithin 10 working days of receipt of the request.” 42

C.F.R. § 1008.41(b). Once it “has formally accepted the request for an advisory opinion,” the “60-day period for issuance of an advisory opinion” begins. Id. § 1008.41(e); id. § 1008.43(c)(1). That 60-day period, however, can be extended. HHS “toll[s]” the 60-day response period when it:

- (i) Notifies the requestor that the costs have reached, or are likely to exceed, the triggering amount until the time when the OIG receives written notice from the requestor to continue processing the request;
- (ii) Requests additional information from the requestor until the time the OIG receives the requested information;
- (iii) Notifies the requestor of the full amount due until the time the OIG receives payment of the full amount owed; and
- (iv) Notifies the requestor of the need for expert advice until the time the OIG receives the expert advice.

Id. § 1008.43(c)(3).

Here, Vertex requested an advisory opinion on the legality of the Fertility Program on June 13, 2023. See Vertex Request at 1 [ECF p. 3]. HHS formally accepted that request 13 days (or nine working days) later. See HHS Acceptance at 1 [ECF p. 212]. At the same time, it requested additional information and, pursuant to its regulations, tolled the response period. Id. at 1-2 [ECF pp. 212-13]. After several months of back and forth, including an additional request for information from the agency, see HHS Dec. 2023 Email at 1-2 [ECF pp. 248-49], HHS finally issued a written advisory opinion on

July 18, 2024 — more than a year after Vertex’s original request. See Advisory Opinion at 1 [ECF p. 455].

Plaintiff now challenges both the 10-business-day buffer period and the tolling power as contrary to the statutory command for the agency to issue an advisory opinion within 60 days. Although Defendants dispute Vertex’s argument solely on the merits, the Court “has an independent obligation to assure that standing exists, regardless of whether it is challenged by any of the parties.” Summers v. Earth Island Inst., 555 U.S. 488, 499 (2009). A plaintiff, moreover, “must demonstrate standing for each claim he seeks to press.” DaimlerChrysler Corp. v. Cuno, 547 U.S. 332, 352 (2006); see Am. Compl., ¶¶ 157-65 (setting out challenge to advisory-opinion regulations as separate count). Because Vertex lacks standing to pursue this claim, the Court declines to rule on the legality of HHS’s arguably shaky regulations.

Vertex claims that HHS has failed to adhere to a required procedure and thus seeks to enforce a procedural right: its entitlement to receive an advisory opinion within 60 days of requesting one. Assuming *arguendo* that the agency did act inconsistently with the statute, however, “[t]he mere violation of a procedural requirement . . . does not permit any and all persons to sue to enforce the requirement.” Fla. Audubon Soc’y v. Bentsen, 94 F.3d 658, 664 (D.C. Cir. 1996) (*en banc*). That is because a plaintiff must show that the procedural violation “will cause a distinct risk to a particularized interest of the plaintiff,” *id.*, a risk that must be “ongoing” when — as here — the plaintiff seeks declaratory relief. Dearth v. Holder, 641 F.3d 499, 501 (D.C. Cir. 2011); see Am. Compl., ¶¶ 165, 168. Whether this precept is couched as standing or as mootness is beside the point. After all, mootness is “the doctrine of standing set in a

time frame: The requisite personal interest that must exist at the commencement of the litigation (standing) must continue throughout its existence (mootness).” Arizonaans for Official English v. Arizona, 520 U.S. 43, 68 n.22 (1997) (quotation marks omitted).

To the extent that Vertex suffered a concrete harm purely as a result of HHS’s tardiness, rather than the substance of HHS’s determinations, that injury dissipated when the agency issued its advisory opinion. “[U]nder Article III, it is not enough for [Vertex] to allege that it was injured because [HHS] unlawfully delayed the [advisory opinion]; plaintiffs must show a ‘discrete injury flowing from’ such alleged delay.” All. for Democracy v. FEC, 335 F. Supp. 2d 39, 48 (D.D.C. 2004) (quoting Common Cause v. FEC, 108 F.3d 413, 418 (D.C. Cir. 1997)). If the Court allowed Plaintiff to establish standing to challenge the Department’s actions on the sole ground that it did not timely issue an advisory opinion, it “would be tantamount to recognizing a justiciable enforcement in the enforcement of the law. This we cannot do.” Common Cause, 108 F.3d at 418. Otherwise, the Court would risk allowing Congress to “create standing by conferring upon all persons an abstract, self-contained, noninstrumental right to have the Executive observe the procedures required by law.” Id. (cleaned up).

That is especially true when, as here, Plaintiff has “received everything [it is] entitled to” substantively “under the” statute. All. for Democracy, 335 F. Supp. 2d at 48. Courts have often declined to grant — or even entertain requests for — relief when the agency has fulfilled its substantive obligations, even if it did so sluggishly. In the context of Freedom of Information Act requests, for example, the D.C. Circuit has explained

that, “however fitful or delayed the release of information under the FOIA may be[,] . . . if we are convinced [the agencies] have, however belatedly, released all non-exempt material, we have no further judicial function to perform under the FOIA.” Tijerina v. Walter, 821 F.2d 789, 799 (D.C. Cir. 1987) (omission in original) (quoting Perry v. Block, 684 F.2d 121, 125 (D.C. Cir. 1982)). In other words, “[o]nce the records are produced[,] the substance of the controversy disappears and becomes moot.” Perry, 684 F.2d at 125 (quoting Crooker v. U.S. State Dep’t, 628 F.2d 9, 10 (D.C. Cir. 1980)). District courts in our Circuit have long followed that approach in FOIA cases. See, e.g., Ocasio v. DOJ, 70 F. Supp. 3d 469, 476-77 (D.D.C. 2014); Bangoura v. U.S. Dep’t of Army, 607 F. Supp. 2d 134, 142 n.6 (D.D.C. 2009); Sellers v. DOJ, 684 F. Supp. 2d 149, 157 (D.D.C. 2010). Similarly, in a case involving the Federal Energy Regulatory Commission, the Circuit has explained that “once the Commission has rendered a decision . . . , the issue of the timeliness of the Commission’s decision will be moot.” Potomac Elec. Power Co. v. ICC, 702 F.2d 1026, 1032 (D.C. Cir. 1983). As a result, if judicial review does not occur until after the Commission issues its decision, “there will be no effective remedy for the parties harmed by the Commission’s delay, even if that delay directly contravenes the intent of Congress.” Id.

The same principle holds true here: dilatory as HHS may have been, Vertex cannot now challenge the timeliness of its advisory opinion. Because the agency fulfilled its substantive obligations under the statute before the Court had a chance to weigh in on Plaintiff’s procedural claim, it has no ongoing injuries that can be remedied or

rights that must be vindicated. The Court therefore declines to address whether HHS's advisory-opinion regulations are inconsistent with the authorizing statute.

IV. Conclusion

For the foregoing reasons, the Court will grant Defendants' Motion for Summary Judgment and deny Plaintiff's Motion. A separate Order so stating will issue this day.

/s/ James E. Boasberg
JAMES E. BOASBERG
Chief Judge

Date: March 31, 2025

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APPENDIX C

DEPARTMENT OF HEALTH AND HUMAN SERVICES
OFFICE OF INSPECTOR GENERAL

Washington, DC 20201

OFFICE OF COUNSEL TO THE INSPECTOR GENERAL
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July 18, 2024

Duncan McKechnie
Senior Vice President,
Head of North America Commercial
Vertex Pharmaceuticals Incorporated
50 North Ave.
Boston, MA 02210

Re: OIG Advisory Opinion No. 24-06 (Unfavorable)

Dear Duncan McKechnie:

The Office of Inspector General (“OIG”) is writing in response to your request for an advisory opinion on behalf of Vertex Pharmaceuticals Incorporated (“Requestor”) regarding proposed financial support in the form of fertility services for eligible patients receiving exagamglogene autotemcel (the “Product”), a gene therapy product manufactured by Requestor (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement, if undertaken, would constitute grounds for the imposition of sanctions under: the civil monetary penalty provision at section 1128A(a)(7) of the Social Security Act (the “Act”), as that section relates to the commission of acts described in section 1128B(b) of

the Act (the “Federal anti-kickback statute”); the civil monetary penalty provision prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Act (the “Beneficiary Inducements CMP”); or the exclusion authority at section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Federal anti-kickback statute and the Beneficiary Inducements CMP.

Requestor has certified that all of the information provided in the request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties in connection with the Proposed Arrangement. In issuing this opinion, we have relied on the facts and information Requestor presented to us and, in accordance with 42 C.F.R. § 1008.39(d), other publicly available information. This opinion is limited to the relevant facts Requestor presented to us, which we have not independently investigated, and the other publicly available information we reviewed in connection with our assessment of the Proposed Arrangement.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions and the limited data available regarding, for example, the impact of fertility support on access to health care services; costs to Federal health care programs; patient outcomes; competition; and the risk of improper steering, we conclude that the Proposed Arrangement, if undertaken: (i) would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and section 1128(b)(7) of the Act; and (ii) would generate prohibited remuneration under the Beneficiary Inducements CMP, which would constitute

grounds for the imposition of sanctions under the Beneficiary Inducements CMP and section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

As OIG has previously emphasized, an unfavorable advisory opinion does not prohibit the party or parties to whom the advisory opinion is issued from carrying out the arrangement or proposed arrangement that is the subject of the advisory opinion.¹ Importantly, where an unfavorable opinion relates to the application of the Federal anti-kickback statute, it is not a determination by OIG that the arrangement violates the Federal anti-kickback statute. Any such determination would require an assessment of intent, and OIG does not opine on intent as part of the advisory opinion process.

This opinion may not be relied on by any person² other than Requestor and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. The Product

Requestor is a pharmaceutical manufacturer that offers gene editing therapies for severe genetic diseases. Relevant to the Proposed Arrangement:

- The U.S. Food and Drug Administration (“FDA”) has approved the use of the Product as a gene

¹ OIG, Advisory Opinion FAQs, <https://oig.hhs.gov/faqs/advisory-opinion-faqs/>.

² We use “person” herein to include persons, as referenced in the Federal anti-kickback statute and Beneficiary Inducements CMP, as well as individuals and entities, as referenced in the exclusion authority at section 1128(b)(7) of the Act.

therapy for the treatment of transfusion-dependent beta-thalassemia (“Condition A”) in patients ages 12 and older. Condition A is the most severe form of beta-thalassemia; patients are dependent on regular blood transfusions to avoid severe anemia and, when the patient is a child, debilitating developmental complications. Requestor certified that the Product is a one-time, potentially curative treatment for Condition A.³

- The FDA has approved the use of the Product as a gene therapy for the treatment of sickle cell disease (“Condition B”) in patients ages 12 years and older with recurrent vaso-occlusive crises (“VOCs”). Condition B is a debilitating genetic blood disorder that affects the shape of the patient’s blood cells and can make blood cells stickier than usual. When blood cells stick to one another, they can form clusters in the bloodstream. These clusters then block the flow of blood and oxygen, which can damage the blood vessels and organs. These blockages can lead to VOCs. Requestor certified that the Product is a one-time, potentially curative treatment for Condition B.⁴

³ According to Requestor, in clinical trials for Condition A, the Product eliminated transfusion dependence for 91.4% of patients.

⁴ The safety and effectiveness of the Product were evaluated in an ongoing single-arm, multi-center trial in adult and adolescent patients with Condition B. The primary efficacy outcome was freedom from severe VOC episodes for at least 12 consecutive months during the 24-month follow-up period. A total of 44 patients were treated with the Product. Of the 31 patients with sufficient follow-up time to be evaluable, 29 (93.5%) achieved this outcome. All treated patients achieved successful engraftment with no patients experienc-

The list price of the Product is over \$2 million. There are multiple treatment stages for Condition A and Condition B patients who are treated with the Product. Patients first must undergo one or more consultations with a physician at a hospital treatment center approved by Requestor (“Treatment Center”) to determine eligibility for treatment with the Product. When a physician determines treatment with the Product is clinically appropriate, and the patient (or the patient’s caregiver(s)) elects to move forward with such treatment, then the physician prescribes the Product for the patient and subsequently oversees the patient’s entire treatment program. In addition to determining eligibility and overseeing treatment, the treating physician manages the patient’s medical care throughout treatment and recovery, in consultation with a Treatment Center’s care team. As part of the treatment regimen but prior to treatment with the Product, Condition A and Condition B patients must undergo chemotherapy-based fully-myeloablative conditioning (“Conditioning”), which clears existing stem cells from the bone marrow so they can be replaced with the edited cells. Conditioning can result in significant side effects, including infertility.

Requestor certified that there is one alternative gene therapy treatment to the Product available for Condition A and Condition B patients. Other than gene therapies, the only other established, curative treatment for Condition A and Condition B is hematopoietic stem cell

ing graft failure or graft rejection. Press Release, FDA, FDA Approves First Gene Therapies to Treat Patients with Sickle Cell Disease (Dec. 8, 2023), <https://www.fda.gov/news-events/press-announcements/fda-approves-first-gene-therapies-treat-patients-sickle-cell-disease>.

transplant; however, the availability of stem cell donors is limited. Conditioning is also required for hematopoietic stem cell transplant. There is ongoing research that may: (i) expand the availability of hematopoietic stem cell transplant; and (ii) lessen the side effects from Conditioning, which would potentially benefit Condition A and Condition B patients.⁵

B. The Proposed Arrangement

Under the Proposed Arrangement, Requestor would provide financial support, up to a maximum of \$70,000, for fertility services, including patient counseling, fertility drugs, collection and storage of oocytes or sperm, genetic testing, intrauterine insemination, and in-vitro fertilization procedures, as applicable to the individual patient, to eligible male and female patients, including Federal health care program enrollees, who are prescribed the Product and whose insurance does not cover fertility services. According to Requestor, the Proposed Arrangement would assist patients who may otherwise forgo treatment because of the risk of infertility associated with the Product and their inability to afford fertility services. Requestor would utilize a vendor to coordinate the fertility services (the “Fertility Vendor”). The Fertility Vendor would assist eligible patients and their

⁵ Jonathan Wosen, Bone Marrow Transplant Advance Could Widen Use Of This Less Buzzy Cure For Sickle Cell Disease, STAT (Dec. 12, 2023), <https://www.statnews.com/2023/12/12/sickle-cell-disease-bone-marrow-transplant-advance/>; Press Release, American Society of Hematology, Modified Stem Cell Transplant Procedure Shows Favorable Results In Adults Living With Severe Sickle Cell Disease (Dec. 12, 2023), <https://www.hematology.org/newsroom/press-releases/2023/lba4>.

caregiver(s) (for patients under the age of 18) by identifying fertility services providers. Patients and their caregivers would select their fertility providers and treatments; neither Requestor nor the Fertility Vendor would select the fertility providers or treatments, and Requestor would not receive any information about the selected fertility providers or treatments. The Fertility Vendor would pay fertility providers for the fertility services provided to patients, and neither Requestor nor the Fertility Vendor would make any payments to patients or their caregivers for fertility services.

Requestor certified that its employees would provide non-promotional information to Treatment Centers about the Proposed Arrangement (e.g., patient eligibility criteria) using materials and messages approved by the company's internal review procedures. Requestor certified that it would not use the Proposed Arrangement as a marketing tool to drive product selection, utilization, or referrals.

The Proposed Arrangement would be available to patients who: (i) reside in the United States or a U.S. territory; (ii) have an annual household income at or below 670 percent of the Federal Poverty Level; (iii) are prescribed the Product for an on-label indication; and (iv) have insurance coverage that does not include fertility services. Moreover, Requestor would require patients (or their caregiver(s)) to acknowledge and agree that they would not seek reimbursement from any insurance provider or other third-party source for fertility services paid for by Requestor.

II. LEGAL ANALYSIS

A. Law

1. Federal Anti-Kickback Statute

The Federal anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce, or in return for, the referral of an individual to a person for the furnishing of, or arranging for the furnishing of, any item or service reimbursable under a Federal health care program.⁶ The statute's prohibition also extends to remuneration to induce, or in return for, the purchasing, leasing, or ordering of, or arranging for or recommending the purchasing, leasing, or ordering of, any good, facility, service, or item reimbursable by a Federal health care program.⁷ For purposes of the Federal anti-kickback statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration is to induce referrals for items or services reimbursable by a Federal health care program.⁸ Violation of the statute constitutes a felony punishable by a maximum fine of \$100,000, imprisonment up to 10 years, or both. Conviction also

⁶ Section 1128B(b) of the Act.

⁷ Id.

⁸ 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).

will lead to exclusion from Federal health care programs, including Medicare and Medicaid. When a person commits an act described in section 1128B(b) of the Act, OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

2. Beneficiary Inducements CMP

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 beneficiary that the person 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. OIG also may initiate administrative proceedings to exclude such person from Federal health care programs. Section 1128A(i)(6) of the Act defines "remuneration" for purposes of the Beneficiary Inducements CMP as including "transfers of items or services for free or for other than fair market value." Section 1128A(i)(6) of the Act contains an exception to the definition of "remuneration" that may apply in the context of the Proposed Arrangement.

Section 1128A(i)(6)(F) of the Act provides that, for purposes of the Beneficiary Inducements CMP, the term "remuneration" does not include "remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128B(f) and designated by the Secretary under

regulations)” (the “Promotes Access to Care Exception”). We have interpreted this provision to apply to:

[i]tems or services that improve a beneficiary’s ability to obtain items and services payable by Medicare or Medicaid, and pose a low risk of harm to Medicare and Medicaid beneficiaries and the Medicare and Medicaid programs by—(i) [b]eing unlikely to interfere with, or skew, clinical decision making; (ii) [b]eing unlikely to increase costs to Federal health care programs or beneficiaries through overutilization or inappropriate utilization; and (iii) [n]ot raising patient safety or quality-of-care concerns . . .⁹

B. Analysis

As we explain in greater detail below, OIG has concluded that it lacks sufficient data to determine that the Proposed Arrangement is sufficiently low risk to issue a favorable advisory opinion at this time.

We recognize that cell and gene therapies consist of an evolving field that holds significant promise for improving the health of patients, including Federal health care program enrollees. Indeed, we understand that cell and gene therapies, like the Product, can transform the lives of individuals living with Condition A and Condition B. The number of cell and gene therapies that are available in the marketplace is rapidly increasing; payors, clinicians, and other stakeholders are adapting to the proliferation of these innovative therapies (e.g., paying for and providing these treatments).¹⁰ These treatments

⁹ 42 C.F.R. § 1003.110 (defining “remuneration”).

¹⁰ See, e.g., Medicaid and CHIP Payment and Access Commission, Payment and Coverage of High-Cost Specialty Drugs Report from

are novel, and much is yet unknown about them and optimal arrangements for ensuring appropriate access to them. This uncertainty makes it difficult to assess the risk of the Proposed Arrangement and offer prospective immunity under our fraud and abuse authorities.

As these transformative therapies become available to patients and the marketplace for them evolves, we expect additional data to become available regarding the ability of Federal health care program enrollees to access these important treatments, as well as data regarding costs, benefits, risks, and outcomes of treatments. Illustratively, we expect additional data related to the provision of fertility services by a pharmaceutical manufacturer at no cost to Medicaid enrollees who receive gene therapy treatments from the Cell and Gene Therapy Access Model developed by the Center for Medicare and Medicaid Innovation (“Innovation Center”) at the Centers for Medicare & Medicaid Services (“CMS”). As more data become available, we may consider them in future risk assessments regarding arrangements similar to the Proposed Arrangement.

Nothing in this opinion forecloses CMS from testing a model that includes fertility services through the Innovation Center, including through the Cell and Gene Therapy Access Model.¹¹ Safe harbor protection is available for CMS-sponsored model arrangements and CMS-

Technical Advisory Panel (Jan. 2021), <https://www.macpac.gov/publication/payment-and-coverage-of-high-cost-specialty-drugs-report-from-technical-advisory-panel/>.

¹¹ See, e.g., CMS, Cell and Gene Therapy (CGT) Access Model, <https://www.cms.gov/priorities/innovation/innovation-models/cgt>. While sickle cell disease is the initial focus of the model, CMS has indicated that additional cell and gene therapies for other diseases

sponsored model patient incentives, as set forth at 42 C.F.R. § 1001.952(ii). Moreover, nothing in this opinion addresses fertility services that are covered by a Federal health care program and nothing in this opinion impacts arrangements for patients who are uninsured or have private insurance.

1. Federal Anti-Kickback Statute

The Proposed Arrangement would implicate the Federal anti-kickback statute in two ways. First, the Proposed Arrangement would constitute remuneration to patients—including Federal health care program enrollees—that may induce them to purchase the Product. In particular, the Proposed Arrangement would cover up to \$70,000 in fertility services, including patient counseling, fertility drugs, collection and storage of oocytes or sperm, genetic testing, intrauterine insemination, and in-vitro fertilization procedures. Further, Requestor explained that the Proposed Arrangement would assist patients who would otherwise forgo treatment because of the risk of infertility associated with Product treatment and their inability to afford fertility services. If a reason a patient would not receive treatment with the Product is the patient’s inability to pay the costs associated with fertility services, then the Proposed Arrangement would address that inability to pay for these costs and likely would influence the patient’s purchasing decision in connection with the Product. Consequently, the Proposed Arrangement would be designed to remove a financial barrier so that eligible patients would purchase the Product. Second, the Proposed Arrangement would constitute remuneration to the Treatment Centers and

may be included in the model in the future.

the treating physicians in the form of the opportunity to earn fees related to treatment with the Product (for patients—including Federal health care program enrollees—who otherwise would forgo treatment but for the Proposed Arrangement), which could induce Treatment Centers to recommend the Product and physicians to order the Product, as opposed to competitor drugs or other clinically appropriate treatments. No safe harbor would apply to the streams of remuneration resulting from the Proposed Arrangement.

As explained in greater detail above, in connection with the Proposed Arrangement, OIG currently lacks data to evaluate the factors OIG considers when assessing the risk of fraud and abuse under the Federal anti-kickback statute (e.g., increased or decreased access to health care services; increased or decreased costs to Federal health care programs; improved or worsened patient outcomes; competitive effects; and the risk of improper steering) and without such data, OIG cannot conclude at this time that the Proposed Arrangement would pose a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute to grant prospective immunity. OIG's conclusion regarding the Proposed Arrangement does not impose any obligations on Requestor. This conclusion also is not a determination by OIG that the Proposed Arrangement would violate the Federal anti-kickback statute; it simply means that, in an exercise of its enforcement discretion, OIG declines to offer prospective immunity—through a favorable advisory opinion—to the Proposed Arrangement.

2. Beneficiary Inducements CMP

Under the Beneficiary Inducements CMP, we analyze whether Requestor knows or should know that the Proposed Arrangement would be likely to influence a 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. The facts here implicate the Beneficiary Inducements CMP because Treatment Centers and physicians practicing at Treatment Centers are providers and suppliers that recipients of the Proposed Arrangement could be induced to select.

Requestor's offer of the Proposed Arrangement valued at up to \$70,000 constitutes remuneration to eligible patients, including State health care program beneficiaries. This valuable remuneration is likely to influence patients and Requestor should know that patients likely would be influenced to select a Treatment Center and a physician practicing at a Treatment Center over other providers and suppliers that are outside the Proposed Arrangement because, as Requestor certified, the Proposed Arrangement would assist patients who would otherwise forgo treatment because of the risk of infertility associated with the Product and their inability to afford fertility services. For the foregoing reasons, unless an exception applies, the Proposed Arrangement would generate prohibited remuneration under the Beneficiary Inducements CMP.

At this time, we conclude that neither the Promotes Access to Care Exception nor any other exception would be available to protect the Proposed Arrangement. We

reach this conclusion because we lack data that would allow us to determine that providing the Proposed Arrangement to eligible patients improves the ability of patients to access the Product. It is possible that with time such data may become available and OIG could potentially make the determination that the Proposed Arrangement would constitute “[i]tems or services that improve a beneficiary’s ability to obtain items and services payable by Medicare or Medicaid” for the purposes of the Promotes Access to Care Exception. However, due to the lack of available data, we cannot conclude that the Proposed Arrangement would improve the patient’s ability to obtain Federally reimbursable items or services for the purposes of this exception.¹²

No other exception to the Beneficiary Inducements CMP applies and the Proposed Arrangement would generate prohibited remuneration under the Beneficiary Inducements CMP. There is no exception that unconditionally protects the offer or provision of remuneration to individuals with financial need. We have long emphasized that “there is no meaningful statutory basis for a broad exemption based on the financial need of a category of patients . . . [and] that categorical financial need is not a sufficient basis for permitting valuable gifts.”¹³ The financial need requirement here similarly does not resolve the lack of data available to OIG to appropriately

¹² As with any exception to the Beneficiary Inducements CMP, one element of an exception is not more important than any other element; all must squarely be satisfied to meet the applicable exception.

¹³ OIG, Special Advisory Bulletin: Offering Gifts and Other Inducements to Beneficiaries (2002), <http://oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf>.

assess the fraud and abuse risks of the Proposed Arrangement.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions and the limited data available regarding, for example, the impact of fertility support on access to health care services; costs to Federal health care programs; patient outcomes; competition; and the risk of improper steering, we conclude that the Proposed Arrangement, if undertaken: (i) would generate—if the requisite intent were present—prohibited remuneration under the Federal anti-kickback statute, which would constitute grounds for the imposition of sanctions under sections 1128A(a)(7) and section 1128(b)(7) of the Act; and (ii) would generate prohibited remuneration under the Beneficiary Inducements CMP, which would constitute grounds for the imposition of sanctions under the Beneficiary Inducements CMP and section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

As OIG has previously emphasized, an unfavorable advisory opinion does not prohibit the party or parties to whom the advisory opinion is issued from carrying out the arrangement or proposed arrangement that is the subject of the advisory opinion. Importantly, where an unfavorable opinion relates to the application of the Federal anti-kickback statute, it is not a determination by OIG that the arrangement violates the Federal anti-kickback statute. Any such determination would require an assessment of intent, and OIG does not opine on intent as part of the advisory opinion process.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the Proposed Arrangement and has no applicability to any other arrangements that may have been disclosed or referenced in your request for an advisory opinion or supplemental submissions.
- This advisory opinion is issued only to Requestor. This advisory opinion has no application to, and cannot be relied upon by, any other person.
- This advisory opinion may not be introduced into evidence by a person or entity other than Requestor 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 applies only to the statutory provisions specifically addressed in the analysis above. We express no opinion 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.
- We express no opinion herein regarding the liability of any person under the False Claims Act or other legal authorities for any improper billing,

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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. 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,

SUSAN EDWARDS

Susan A. Edwards
Assistant Inspector General
for Legal Affairs

APPENDIX D

1. 8 U.S.C. 1324 provides in pertinent part:

Bringing in and harboring certain aliens

(a) Criminal penalties

(1)(A) Any person who—

* * * * *

(iv) encourages or induces an alien to come to, enter, or reside in the United States, knowing or in reckless disregard of the fact that such coming to, entry, or residence is or will be in violation of law; or

(v)(I) engages in any conspiracy to commit any of the preceding acts, or

(II) aids or abets the commission of any of the preceding acts, shall be punished as provided in subparagraph (B).

(B) A person who violates subparagraph (A) shall, for each alien in respect to whom such a violation occurs--

(i) in the case of a violation of subparagraph (A)(i) or (v)(I) or in the case of a violation of subparagraph (A)(ii), (iii), or (iv) in which the offense was done for the purpose of commercial advantage or private financial gain, be fined under title 18, imprisoned not more than 10 years, or both;

(ii) in the case of a violation of subparagraph (A)(ii), (iii), (iv), or (v)(II), be fined under title 18, imprisoned not more than 5 years, or both;

(iii) in the case of a violation of subparagraph (A)(i), (ii), (iii), (iv), or (v) during and in relation to which the person causes serious bodily injury (as defined in section 1365 of title 18) to, or places in jeopardy the life of, any person, be fined under title 18, imprisoned not more than 20 years, or both; and

(iv) in the case of a violation of subparagraph (A)(i), (ii), (iii), (iv), or (v) resulting in the death of any person, be punished by death or imprisoned for any term of years or for life, fined under title 18, or both.

(C) It is not a violation of clauses [1] (ii) or (iii) of subparagraph (A), or of clause (iv) of subparagraph (A) except where a person encourages or induces an alien to come to or enter the United States, for a religious denomination having a bona fide nonprofit, religious organization in the United States, or the agents or officers of such denomination or organization, to encourage, invite, call, allow, or enable an alien who is present in the United States to perform the vocation of a minister or missionary for the denomination or organization in the United States as a volunteer who is not compensated as an employee, notwithstanding the provision of room, board, travel, medical assistance, and other basic living expenses, provided the minister or missionary has been a member of the denomination for at least one year.

* * * * *

2. 18 U.S.C. 220 provides:

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.

(b) Applicability.--Subsection (a) shall not apply to--

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

(2) a payment made by an employer to an employee or independent contractor (who has a bona fide employment or contractual relationship with such employer) for employment, if the employee's payment is not determined by or does not vary by—

(A) the number of individuals referred to a particular recovery home, clinical treatment facility, or laboratory;

(B) the number of tests or procedures performed; or

(C) the amount billed to or received from, in part or in whole, the health care benefit program from the individuals referred to a particular recovery home, clinical treatment facility, or laboratory;

(3) a discount in the price of an applicable drug of a manufacturer that is furnished to an applicable beneficiary under the Medicare coverage gap discount program under section 1860D–14A(g) of the Social Security Act (42 U.S.C. 1395w–114a(g));

(4) a payment made by a principal to an agent as compensation for the services of the agent under a personal services and management contract that meets the requirements of section 1001.952(d) of title 42, Code of Federal Regulations, as in effect on the date of enactment of this section;

(5) a waiver or discount (as defined in section 1001.952(h)(5) of title 42, Code of Federal Regulations, or any successor regulation) of any coinsurance or copayment by a health care benefit program if—

(A) the waiver or discount is not routinely provided; and

(B) the waiver or discount is provided in good faith;

(6) a remuneration described in section 1128B(b)(3)(I) of the Social Security Act (42 U.S.C. 1320a–7b(b)(3)(I));

(7) a remuneration made pursuant to an alternative payment model (as defined in section 1833(z)(3)(C) of the Social Security Act) or pursuant to a payment arrangement used by a State, health insurance issuer, or group health plan if the Secretary of Health and Human Services has determined that such arrangement is necessary for care coordination or value-based care; or

(8) any other payment, remuneration, discount, or reduction as determined by the Attorney General, in consultation with the Secretary of Health and Human Services, by regulation.

(c) Regulations.--The Attorney General, in consultation with the Secretary of Health and Human Services, may promulgate regulations to clarify the exceptions described in subsection (b).

(d) Preemption.--

(1) Federal law.-- This section shall not apply to conduct that is prohibited under section 1128B of the Social Security Act (42 U.S.C. 1320a–7b).

(2) State law.--Nothing in this section shall be construed to occupy the field in which any provisions of this section operate to the exclusion of State laws on the same subject matter.

(e) Definitions.-- In this section--

(1) the terms “applicable beneficiary” and “applicable drug” have the meanings given those terms in

section 1860D–14A(g) of the Social Security Act (42 U.S.C. 1395w–114a(g));

(2) the term “clinical treatment facility” means a medical setting, other than a hospital, that provides detoxification, risk reduction, outpatient treatment and care, residential treatment, or rehabilitation for substance use, pursuant to licensure or certification under State law;

(3) the term “health care benefit program” has the meaning given the term in section 24(b);

(4) the term “laboratory” has the meaning given the term in section 353 of the Public Health Service Act (42 U.S.C. 263a); and

(5) the term “recovery home” means a shared living environment that is, or purports to be, free from alcohol and illicit drug use and centered on peer support and connection to services that promote sustained recovery from substance use disorders.

3. 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 or under any State health care program.

(2) Conviction relating to patient abuse

Any individual or entity that has been convicted, under Federal or State law, of a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service.

(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.

(4) Felony conviction relating to controlled substance

Any individual or entity that has been convicted for an offense which occurred after August 21, 1996, under Federal or State law, of a criminal offense consisting of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

(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):

(1) Conviction relating to fraud

Any individual or entity that has been convicted for an offense which occurred after August 21, 1996, under Federal or State law--

(A) of a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct--

(i) in connection with the delivery of a health care item or service, or

(ii) with respect to any act or omission in a health care program (other than those specifically described in subsection (a)(1)) operated by or financed in whole or in part by any Federal, State, or local government agency; or

(B) of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct with respect to any act or omission in a program (other than a health

care program) operated by or financed in whole or in part by any Federal, State, or local government agency.

(2) Conviction relating to obstruction of an investigation or audit

Any individual or entity that has been convicted, under Federal or State law, in connection with the interference with or obstruction of any investigation or audit related to--

(i) any offense described in paragraph (1) or in subsection (a); or

(ii) the use of funds received, directly or indirectly, from any Federal health care program (as defined in section 1320a-7b(f) of this title).

(3) Misdemeanor conviction relating to controlled substance

Any individual or entity that has been convicted, under Federal or State law, of a criminal offense consisting of a misdemeanor relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

* * * * *

(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.

* * * * *

(h) "State health care program" defined

For purposes of this section and sections 1320a-7a and 1320a-7b of this title, the term “State health care program” means--

- (1) a State plan approved under subchapter XIX,
- (2) any program receiving funds under subchapter V or from an allotment to a State under such subchapter,
- (3) any program receiving funds under division A of subchapter XX or from an allotment to a State under such division, or
- (4) a State child health plan approved under subchapter XXI.

(i) “Convicted” defined

For purposes of subsections (a) and (b), an individual or entity is considered to have been “convicted” of a criminal offense--

- (1) when a judgment of conviction has been entered against the individual or entity by a Federal, State, or local court, regardless of whether there is an appeal pending or whether the judgment of conviction or other record relating to criminal conduct has been expunged;
- (2) when there has been a finding of guilt against the individual or entity by a Federal, State, or local court;
- (3) when a plea of guilty or nolo contendere by the individual or entity has been accepted by a Federal, State, or local court; or

(4) when the individual or entity has entered into participation in a first offender, deferred adjudication, or other arrangement or program where judgment of conviction has been withheld.

(j) Definition of immediate family member and member of household

For purposes of subsection (b)(8)(A)(iii):

(1) The term “immediate family member” means, with respect to a person --

(A) the husband or wife of the person;

(B) the natural or adoptive parent, child, or sibling of the person;

(C) the stepparent, stepchild, stepbrother, or step-sister of the person;

(D) the father-, mother-, daughter-, son-, brother-, or sister-in-law of the person;

(E) the grandparent or grandchild of the person; and

(F) the spouse of a grandparent or grandchild of the person.

(2) The term “member of the household” means, with respect to any person, any individual sharing a common abode as part of a single family unit with the person, including domestic employees and others who live together as a family unit, but not including a roomer or boarder.

4. 42 U.S.C. 1320a-7a provides in pertinent part:

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.

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

* * * * *

(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;

* * * * *

(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;

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, in cases under paragraph (8), \$100,000 for each false record or statement, or in cases under paragraph (9), \$15,000 for each day of the failure described in such paragraph); or in cases under paragraph (9), \$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 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 individual 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.

* * * * *

(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.

* * * * *

(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 or designated to administer the State’s program under subchapter V or division A of subchapter XX.

(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).

(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 pay-

ment 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) of this title; or

(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--

(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 under 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-102(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.

* * * * *

(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.

* * * * *

5. 42 U.S.C. 1320a-7b provides in pertinent part:

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

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(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;

(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) 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 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;

(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; and

(L) a bona fide mental health or behavioral health improvement or maintenance program, if--

(i) such program--

(I) consists of counseling, mental health services, a suicide prevention program, or a substance use disorder prevention and treatment program;

(II) is made available to a physician or other clinician for the primary purpose of preventing suicide, improving mental health and resiliency, or providing training in appropriate strategies to promote the mental health and resiliency of such physician or other clinician;

(III) is set out in a written policy, approved in advance of the operation of the program by the governing body of the entity providing such program (and which shall be updated accordingly in advance to substantial changes to the operation of such program), that includes--

(aa) a description of the content and duration of the program;

(bb) a description of the evidence-based support for the design of the program;

(cc) the estimated cost of the program;

(dd) the personnel (including the qualifications of such personnel) implementing the program; and

(ee) the method by which such entity will evaluate the use and success of the program;

(IV) is offered by an entity described in clause (ii) with a formal medical staff to all physicians and other clinicians who practice in the geographic area served by such entity, including physicians who hold bona fide appointments to the medical staff of such entity or otherwise have clinical privileges at such entity;

(V) is offered to all such physicians and clinicians on the same terms and conditions and without regard to the volume or value of referrals or other business generated by a physician or clinician for such entity;

(VI) is evidence-based and conducted by a qualified health professional; and

(VII) meets such other requirements the Secretary may impose by regulation as needed to protect against program or patient abuse;

(ii) such entity is--

(I) a hospital;

(II) an ambulatory surgical center;

(III) a community health center;

(IV) a rural emergency hospital;

(V) a skilled nursing facility; or

(VI) any similar entity, as determined by the Secretary; and

(iii) neither the provision of such program, nor the value of such program, are contingent upon the number or value of referrals made by a physician or other clinician to such entity or the amount or value of other business generated by such physician for the entity.

(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.

* * * * *

(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

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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.