



DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201



[We redact certain identifying information and certain potentially privileged, confidential, or proprietary information, unless otherwise approved by the requestor(s).]

Issued: June 17, 2022

Posted: June 23, 2022

[Address block redacted]

Re: OIG Advisory Opinion No. 22-13

Dear [redacted]:

The Office of Inspector General (“OIG”) is writing in response to your request for an advisory opinion on behalf of [redacted] (“Requestor”) regarding Requestor’s arrangements with two financial institutions to make zero-interest financing available to Requestor’s qualified customers (the “Arrangement”). Specifically, you have inquired whether the Arrangement constitutes grounds for the imposition of sanctions under the exclusion authority at section 1128(b)(7) of the Social Security Act (the “Act”) or the civil monetary penalty provision at section 1128A(a)(7) of the Act, as those sections relate to the commission of acts described in section 1128B(b) of the Act (the “Federal anti-kickback statute”).

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 Arrangement, and we have relied solely on the facts and information you provided. We have not undertaken an independent investigation of the certified facts and information presented to us by Requestor. This opinion is limited to the relevant facts presented to us by Requestor in connection with the Arrangement. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute.

This opinion may not be relied on by any person¹ 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

Requestor is a durable medical equipment (“DME”) manufacturer that sells its products to DME-supplier customers (“Customers”), some of whom dispense the products to Federal health care program beneficiaries. Under the Arrangement, Requestor has entered into agreements with two third-party financial institutions (each, a “Lender”)² to make zero-interest financing available to Customers, subject to certain terms and conditions described in the Lender’s loan documents with approved Customers. Requestor asserted that financing options like the Arrangement promote competition and patient choice because they may enable smaller DME suppliers to compete with large, corporate DME suppliers that can, as necessary, self-finance or obtain their own financing to purchase and dispense DME that may be subject to a lengthy reimbursement timeline.

Requestor certified that, at some point before or after a Customer’s payment is due to Requestor pursuant to the invoiced terms, the Customer may contact or be contacted by Requestor’s credit and collections personnel.³ If a Customer chooses not to or cannot pay Requestor the full amount of an invoice that is due, the Customer may request (or Requestor’s credit and collections personnel may offer) the opportunity to seek financing from a Lender. Under the Arrangement, Requestor’s credit and collections personnel may refer to a Lender any interested Customer that: (i) owes or will owe at least \$10,000 to Requestor; (ii) is in good standing with Requestor;⁴ and

¹ We use “person” herein to include persons, as referenced in the Federal anti-kickback statute, as well as individuals and entities, as referenced in the exclusion authority at section 1128(b)(7) of the Act.

² Neither Lender is a health care provider or supplier, bills or submits claims to any Federal health care program, or is in a position to refer Federal health care program business to Requestor. Lenders are independent from Requestor; Requestor does not have any direct or indirect ownership interest in Lenders or in the financing arrangements offered by Lenders.

³ Requestor’s sales personnel will not be permitted to offer zero-interest financing to any Customer. If a Customer inquires about zero-interest financing at the time of the Customer’s purchase from Requestor, Requestor’s sales representative will refer the Customer to Requestor’s credit and collections personnel. The credit and collections personnel will then provide to one of the Lenders the Customer’s name, account details, the equipment to be financed, the requested term, and the maximum total to be financed so that the Customer can learn in advance whether its purchase will be eligible for financing. Other than this advance credit approval, the remaining steps of the financing process do not change.

⁴ Requestor certified that, to be considered “in good standing,” the Customer must be in compliance with Requestor’s General Terms and Conditions of Sale as set forth on Requestor’s invoices, which include, but are not limited to, prohibitions on the unauthorized distribution of

(iii) is an acceptable credit risk, as reasonably determined by Requestor.⁵ Requestor does not advertise the potential for zero-interest financing in its marketing materials nor does Requestor guarantee to any Customer or potential Customer that zero-interest financing will be available from a Lender.

Once Requestor learns that a Customer desires zero-interest financing and meets the above-referenced criteria, Requestor's credit and collections personnel contact one of the Lenders. That Lender performs its own creditworthiness analysis to decide independently whether to offer financing to the particular Customer. If approved, the financing agreement is between the applicable Lender and the Customer. Requestor certified that the typical financing agreement between a Lender and a Customer results in a loan that is for 1 year at zero-percent interest and requires that the Customer make payments to the Lender in 12 equal installments. The Lender pays Requestor the invoiced amount that the Customer owes to Requestor, minus an amount that the Lender retains (the "Finance Charge") based on rates set forth in the agreement between Requestor and the Lender (e.g., 3 percent of the loan value). Requestor certified that these rates were the result of independent, arms-length negotiations with each Lender and are subject to change periodically based on fluctuations in certain published interest rates, such as the 12-month London Interbank Offered Rate (or "LIBOR rate") published in the Wall Street Journal. If a Customer uses financing from a Lender, Requestor's sales representative's commission on the Customer's purchase is reduced by the same percentage that Requestor is charged by the Lender.

The Lenders have the sole right to seek payment from the Customers after entering into the financing agreements.⁶ Requestor's agreement with each Lender makes clear that the Lenders, using their own personnel, are responsible for administering, enforcing, collecting, litigating, settling, waiving, or compromising on any defaulted transaction, as the Lender would do for any other debt in the exercise of its reasonable business judgement.

Requestor's products and the impermissible use of Requestor's intellectual property and various regulatory compliance requirements.

⁵ Requestor certified that a Customer that already is delinquent on payment obligations for past purchases would not be a good credit risk for financing future purchases. In contrast, a Customer that was in good financial standing at the time it purchased equipment but encountered a financial setback preventing it from making full payment at a given time might be eligible (i.e., the Customer might be delinquent on the purchase for which it seeks financing, but is up-to-date on any payments for previous purchases); the opportunity to pay the invoice over time might enable the Customer to pay the full amount owed, rather than potentially defaulting on its debt to Requestor.

⁶ Requestor may elect to repurchase a defaulted contract between a Customer and Lender; this option—which is limited to defaulted contracts falling in Requestor's loss pool—is intended to provide for situations where: (i) Requestor may have better success collecting on a defaulted contract than the Lender would; (ii) Requestor has an interest in reacquiring unsold or returned devices that could be sold and dispensed to patients in need; or (iii) repurchasing a defaulted contract allows for administrative convenience.

Although each Lender has the sole right and responsibility to collect payment from Customers with whom the Lender enters into financing agreements, and Customers remain liable only to the Lender, the agreement between each Lender and Requestor under the Arrangement establishes a “loss pool” to allocate responsibility between the applicable Lender and Requestor in the event of a Customer default.⁷ The loss pool allocations are different with each Lender, but in each case the loss pool is based on the total amount of Customer contracts funded by the Lender in a particular year. Each loss pool has three layers of liability. The Lender assumes the first layer of liability, which is calculated as a percentage amount of the loss pool. If the defaulted amount exceeds this first layer, then Requestor bears the loss amount in the second layer of liability, which is the greater of a defined dollar amount or percentage of the loss pool. The Lender is responsible for any losses beyond this second layer (i.e., if the Lender’s losses exceed the defined dollar amount or percentage of the loss pool borne by Requestor under its agreement with the Lender, the Lender assumes responsibility for the remainder).

II. LEGAL ANALYSIS

A. Law

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.⁸ 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.⁹ 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

⁷ Requestor certified that, historically, the default rate for amounts financed by Lenders on behalf of Customers has been approximately 2.5 percent of the total amount financed but that in Requestor’s Fiscal Year 2021 (July 1, 2020–June 30, 2021), the default rate was approximately 0.2 percent of the total amount financed by Lenders. In addition, because the financing agreement is solely between a Customer and a Lender, and the Lender pursues all collection efforts, the Customer would have no reason to expect Requestor to cover any loss amounts because Requestor provides no information to Customers about the terms of its agreements with Lenders with respect to the loss pools. Further, in the very limited situations where Requestor might choose to exercise its option to repurchase a defaulted contract falling in Requestor’s loss pool, the Customer’s obligation remains unchanged, and the Customer likewise would have no reason to expect Requestor to cover any loss amounts.

⁸ Section 1128B(b) of the Act.

⁹ Id.

program.¹⁰ Violation of the statute constitutes a felony punishable by a maximum fine of \$100,000, imprisonment up to 10 years, or both. Conviction also 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, the OIG may initiate administrative proceedings to impose civil monetary penalties on such person under section 1128A(a)(7) of the Act. The OIG also may initiate administrative proceedings to exclude such person from Federal health care programs under section 1128(b)(7) of the Act.

B. Analysis

Under the Arrangement, Requestor has entered into agreements with Lenders that make zero-interest financing available to eligible Customers. This benefit to Customers, many of which submit claims to Federal health care programs for the DME financed by the Arrangement, constitutes remuneration and implicates the Federal anti-kickback statute. However, for the following reasons, we conclude that the Arrangement poses a sufficiently low risk of fraud and abuse under the Federal anti-kickback statute.

First, while arranging for zero-interest financing is remuneration and a clear benefit for Customers, the Customers do not receive a discount or other price concession from Requestor under the Arrangement. Other than Customers that default, which Requestor certified occurs with only 2.5 percent (or significantly less, in the most recent fiscal year) of the total amount financed on behalf of Customers across all Lender loans, Customers pay the total amount Requestor charged, just over a longer timeframe.

Second, the involvement of risk-bearing Lenders in the Arrangement reduces the risk associated with providers, suppliers, or manufacturers that might offer, subsidize, or forgive loans to secure future referrals. The Lenders, which are third-party financial institutions, make and collect on the loans to Customers. The Lenders perform their own creditworthiness analysis on each Customer-applicant and make their own decisions, independent of Requestor, regarding whether to enter into a financing agreement. Further, the Lenders are responsible for collecting payments and, if applicable, bear the first and third layers of responsibility for defaulted loans.

Third, Requestor's agreement with Lenders to receive less than the total amount owed by the Customer (in the form of the Finance Charge) does not increase the risk of fraud and abuse under the Federal anti-kickback statute. Under the Arrangement, Requestor receives payment up front from the Lender and is relieved of the administrative burden of determining creditworthiness; administering the loan; and administering, enforcing, collecting, litigating, settling, waiving, or compromising on any defaulted transaction, which has value to Requestor. While we have not been asked, and are not opining on, whether the amount of the Finance Charge Requestor agrees to pay each Lender is fair market value, Requestor certified that the Finance Charge results from independent, arms-length negotiations with each Lender, and we reiterate that neither Lender is a

¹⁰ 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).

health care provider or supplier and neither is in a position to refer Federal health care program business to Requestor.

Fourth, the Arrangement presents a sufficiently low risk with respect to many of the other fraud and abuse concerns that we consider when examining arrangements under the Federal anti-kickback statute. For example, the Arrangement should not result in increased costs to Federal health care programs because the items are reimbursed based on fee schedule amounts, regardless of the amount DME suppliers pay to acquire them. Because DME suppliers do not prescribe equipment, the Arrangement should not result in overutilization. Requestor asserted that the Arrangement may favorably impact competition between smaller DME suppliers and larger companies because it creates an opportunity for the smaller suppliers to finance the equipment, while larger companies might be able to acquire the equipment outright (or have other financing opportunities). While facilitating the zero-interest financing might give Requestor a competitive advantage over other manufacturers who do not have similar arrangements, we believe this factor presents limited risk of fraud and abuse under the Federal anti-kickback statute, particularly because Requestor does not market the possibility of, or guarantee access to, zero-interest loans, and the sales representative's commission is reduced if a Customer receives zero-interest financing.

Finally, we recognize that Requestor assumes partial liability in the event that Customers default on the loans. However, as discussed above, the Lender decides whether to extend the zero-interest financing to a Customer and bears the first layer of liability on defaulted loans in a given year before Requestor's shared liability is triggered. Under the Arrangement, Requestor's liability is limited, and if defaulted loan amounts exceed both the first and second layers of liability, then the Lender is responsible for the remaining amounts. Because of this shared liability, Requestor's incentive to initiate the zero-interest financing by contacting a Lender on the Customer's behalf, and the Lenders' incentive to approve such requests, from Customers who may be unlikely to pay their obligations, is limited. Moreover, each Lender uses its own personnel to engage in the same collection and enforcement activities to collect the amount due from each Customer as the Lender would use for any other debt. In the event of a default following such collection efforts, the Customer would have no reason to know if Requestor subsidized part of a default through the loss pool.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Arrangement would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG will not impose administrative sanctions on Requestor in connection with the Arrangement under sections 1128A(a)(7) or 1128(b)(7) of the Act, as those sections relate to the commission of acts described in the Federal anti-kickback statute.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is limited in scope to the 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 other than Requestor to prove that the person 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 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, claims submission, cost reporting, or related conduct.

This opinion is also subject to any additional limitations set forth at 42 C.F.R. Part 1008.

The OIG will not proceed against Requestor with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, as long as all of the material facts have been fully, completely, and accurately presented, and the Arrangement in practice comports with the information provided. The OIG reserves the right to reconsider the questions and issues raised in this advisory opinion and, where the public interest requires, to rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against Requestor with respect to any action that is part of the Arrangement taken in good faith reliance upon this advisory opinion, where all of the relevant facts were fully, completely, and accurately presented and where such action was promptly discontinued upon notification of the modification or termination of this advisory opinion. An advisory opinion may be rescinded only if the relevant and material facts have not been fully, completely, and accurately disclosed to the OIG.

Sincerely,

/Susan A. Edwards/

Susan A. Edwards
Acting Assistant Inspector General for Legal Affairs