



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: December 13, 2021

Posted: December 16, 2021

[Name and address redacted]

Re: OIG Advisory Opinion No. 21-20

Dear [Name redacted]:

The Office of Inspector General (“OIG”) is writing in response to your request for an advisory opinion on behalf of [name redacted] (“Requestor”) regarding Requestor’s proposal to create an online platform for: (i) users to search for and contact home-based health care providers, where providers listed on the website would be charged on a per-click basis; and (ii) advertising by individuals and entities other than home-based health care providers (the “Proposed Arrangement”). Specifically, you have inquired whether the Proposed Arrangement would constitute grounds for the imposition of sanctions under: the civil monetary penalty provision 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, and we have relied solely on the facts and information Requestor 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 Proposed 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: (i) although the Proposed Arrangement, if undertaken, would

generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG would not impose administrative sanctions on Requestor in connection with the Proposed 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; and (ii) although the Proposed Arrangement, if undertaken, could generate prohibited remuneration under the Beneficiary Inducements CMP, the OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

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

A. The Platform

Under the Proposed Arrangement, Requestor would operate an online platform (the “Platform”) on which patients seeking home-based health care services (“Users”)² could search for providers of home-based health care services.³ The home-based health care services for which Users could search would include skilled and non-skilled home health services, home-based physician services, nursing services, non-emergency transportation, mental health counseling, therapy services, hospice care, and infusion services. Requestor would enroll providers of home-based health care services on the Platform who agree to Requestor’s terms of participation (“Enrolled Providers”). Requestor’s terms of participation would include paying the fees charged by Requestor and providing Requestor with a list of the: (i) services the provider offers; (ii) geographic areas in which the provider offers such services; and (iii) health insurance that the provider accepts for the services it offers. However, Requestor would not enroll a provider who accepts payment only from Federal health care programs or who has been excluded from participating in any Federal health care program.

¹ 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.

² For purposes of this opinion, family members or other representatives acting on behalf of patients seeking home-based health care services are considered “Users.”

³ Requestor is not a provider or supplier and is not affiliated with any provider who may be listed on the Platform, and although Requestor is owned, in part, by an individual who is licensed to provide certain health care services, none of the owners of Requestor is involved, directly or indirectly, in the provision of any home-based health care services that may be offered by providers

To use the Platform, Users would provide specified information, including age, gender, zip code, the services needed, insurance status or source of payment, and if they desire, certain optional preferences (e.g., preferred language).⁴ In response to User searches, the Platform would generate a list of the Enrolled Providers who meet a User’s specified criteria. If the Platform finds multiple Enrolled Providers who meet the User’s specified criteria, the Platform would prompt Users to choose a method for sorting the results. Users could sort the results by Enrolled Providers’: (i) percentage match to the User’s search criteria; (ii) geographic distance to the User’s location; (iii) star ratings (which are submitted by Users to the Platform); or (iv) names listed alphabetically. This list would include only Enrolled Providers, and the Platform would post conspicuous notices, both on the Platform’s informational page describing Requestor and at the bottom of each search page, stating that the search results include only providers who pay a fee to be listed and that there may be other providers in the User’s area who meet the User’s search criteria. Any contact with Requestor and use of the Platform must be initiated by the User. The Platform would not steer Users to any particular Enrolled Providers, and Requestor would show Enrolled Providers to Users only on the Platform (i.e., Requestor would not advertise specific Enrolled Providers by other means, such as through emails, mailings, or text messages).

If there are no Enrolled Providers who meet the User’s search criteria, the Platform would generate a list of providers who are not enrolled on the Platform but who appear to meet the User’s search criteria (“Non-Enrolled Providers”), which list would include a link to each Non-Enrolled Provider’s website if such website links are readily available to Requestor.⁵ The Platform would notify the User that it could not identify any Enrolled Providers who met the User’s search criteria and that the listed providers are not enrolled on the Platform.

The Platform, which would be free to Users, would allow Users to contact Enrolled Providers by clicking either a hyperlink to the Enrolled Provider’s website or a contact button that allows the User to email the Enrolled Provider (each click by a User is considered a “Contact”).⁶ Users would

who enroll on the Platform. Further, Requestor certified that the Platform would not claim on its website or in marketing materials to be operated by a health care provider or supplier.

⁴ Requestor would use this information only for the purpose of generating search results that list Enrolled Providers who meet Users’ search criteria and not to influence Users’ decision making. Additionally, with the exception of User email addresses that Requestor would use solely to send the newsletter described below, the Platform would not store any User information or send any such information to Enrolled Providers or any other third party.

⁵ Requestor would obtain information about Non-Enrolled Providers from publicly available sources provided by the Federal and State agencies that regulate the Non-Enrolled Providers in the State in which the User is seeking services.

⁶ As a condition of enrolling on the Platform, each Enrolled Provider would have to agree that neither the hyperlink to its website nor its website will prohibit or impede Users from directly returning to the Platform. For example, Enrolled Providers could not disable the web browser’s

have the same ability to access the Platform and the same functionality available on the Platform regardless of their insurance status or source of payment. The Platform would track the number of Contacts an Enrolled Provider received each month and would provide that information to the Enrolled Provider but would not provide the names or any other identifiable information about the Users making the Contacts. Once Users interact with Enrolled Providers, Users could rate Enrolled Providers on the Platform on a scale from one to five stars. Users also could provide narrative reviews about their experiences with Enrolled Providers with whom they have directly interacted.⁷

B. Platform Fees

To be listed in search results on the Platform, Enrolled Providers would pay a fixed monthly participation fee (the “Participation Fee”) plus a monthly Contact fee determined by multiplying a fixed per-Contact amount by the number of Contacts the Enrolled Provider received during the month (the “Contact Fee”). While the Contact Fee owed by a particular Enrolled Provider would fluctuate based on the number of Contacts the Enrolled Provider receives, the fixed per-Contact amount would not vary by Enrolled Provider or based on the number of Contacts an Enrolled Provider receives. Additionally, neither the Participation Fee nor the Contact Fee would take into account whether Users receive items or services from Enrolled Providers, and Requestor certified that both the Participation Fee and the fixed per-Contact amount would be consistent with fair market value for the services Requestor would provide to Enrolled Providers. Requestor would not allow Enrolled Providers to set a cap on the Contact Fees they incur. Requestor further certified that the fees Enrolled Providers would pay Requestor would not affect the frequency with which Enrolled Providers appear, or their placement, in the Platform listings. Non-Enrolled Providers would not pay fees to Requestor.

C. The Newsletter

As part of the Proposed Arrangement, Requestor would distribute a newsletter that contains educational articles about home-based health care services and other health-related topics (the “Newsletter”). To receive the Newsletter, Users would affirmatively opt-in on the Platform. The Newsletter would include a disclaimer that the articles are for educational purposes only and that the Newsletter is not an advertisement for any good or service offered by the articles’ authors or the individuals or entities providing the articles. Other than free access to the Platform and the Newsletter, Requestor would not offer anything else to Users in connection with using the Platform.

“back” button or otherwise redirect Users to another site from which a User could not easily return to the Platform by using the web browser’s “back” button.

⁷ Users would be able to rate or review Enrolled Providers only after the User affirmatively represents that the User had direct contact with the Enrolled Provider about whom the User is leaving a rating or review. As part of that affirmation, the User would state whether the interaction with the Enrolled Provider involved the receipt of services, a consultation about the provision of services, or some other form of direct interaction. Except in certain circumstances where an Enrolled Provider or User reports inappropriate actions relating to the use of the star rating system or narrative reviews, Requestor would not curate or otherwise edit the information Users provide.

D. Advertising Spots

Requestor would sell advertising spots on the Platform and in the Newsletter to health care and non-health care advertisers (“Advertisers”); however, Requestor would not permit providers of home-based health care services to be Advertisers. Each Advertiser would enter into a contract with Requestor specifying the type of advertising, terms and conditions of the advertising, and advertising fee. Requestor would sell advertising spots on a first-come, first-served basis and would rotate the advertising spots among Advertisers. Advertisements in the Newsletters would be static, and thus, there would be only one advertisement in each spot in a single Newsletter.

Requestor would clearly label all advertising spots as such and would include a disclaimer that the advertisements do not constitute a recommendation or endorsement of the products, services, or companies appearing in the advertisements. Additionally, as part of their contracts with Requestor, Advertisers would be prohibited from implying on their websites that Requestor endorses or has co-branded with any Advertiser. Requestor would contract with any individual or entity that wants to advertise on the Platform or in the Newsletter and who has the technological capabilities to do so (except providers of home-based health care services). Requestor would not have an exclusive advertising arrangement with any Advertiser.

Requestor would charge Advertisers a fixed monthly fee based on the type, size, and location of the advertisement. Requestor certified that the fee would be consistent with fair market value and would not vary by Advertiser (*i.e.*, Advertisers purchasing advertisements of the same type and size and in the same location on the Platform or in the Newsletter would be charged the same fixed monthly fee). Requestor would set the pricing for advertising spots on the Platform based on the number of times the Advertiser desires the advertisement to be displayed when a particular page on the Platform is opened, including the home page and pages with search results. For example, Requestor would charge more for a banner advertisement that appears at the top of the Platform’s home page each time a User opens the page than a banner advertisement that appears at the top of a search-results page only once every five searches. Requestor would not augment the advertising spots in any way by, for example, leveraging User data to target certain advertisements to specific Users in response to User searches or otherwise. In other words, each User would see the same advertisements on the same pages, subject only to the frequency with which advertisements are displayed, as contracted for by the Advertiser.

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.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 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.

Congress has developed several statutory exceptions to the Federal anti-kickback statute.¹¹ In addition, the U.S. Department of Health and Human Services has promulgated safe harbor regulations that specify certain practices that are not treated as an offense under the Federal anti-kickback statute and do not serve as the basis for an exclusion.¹² However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. Compliance with a safe harbor is voluntary. Arrangements that do not comply with a safe harbor are evaluated on a case-by-case basis.

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. The 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

⁸ Section 1128B(b) of the Act.

⁹ Id.

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).

¹¹ Section 1128B(b)(3) of the Act.

¹² 42 C.F.R. § 1001.952.

Inducements CMP as including “transfers of items or services for free or for other than fair market value.”

B. Analysis

The Proposed Arrangement would implicate the Federal anti-kickback statute in two ways. First, Enrolled Providers would pay Requestor on a per-click basis to recommend them, and by extension, their items and services, some of which may be reimbursable by a Federal health care program, by listing them on the Platform in response to User searches for which they meet the search criteria. Second, Requestor would provide remuneration to Users in the form of free use of the Platform, and Requestor’s provision of this remuneration to Users could be intended to induce Users to refer themselves to Enrolled Providers for the provision of items and services that are reimbursable by a Federal health care program.

The Proposed Arrangement also would include payments from Advertisers to Requestor for advertising spots on the Platform and in the Newsletter. In determining whether these payments would implicate the Federal anti-kickback statute, we must analyze whether Requestor’s provision of advertising spots on the Platform and in the Newsletter would constitute a recommendation by Requestor to purchase, lease, or order any good, facility, service, or item provided by Advertisers for which payment may be made in whole or in part under a Federal health care program. Several facts are relevant to this assessment. First, Requestor’s sole role with respect to Advertisers would be limited to the sale of space on the Platform and in the Newsletter, unlike, for example, a salesperson or an advertising agency that designs an advertisement. Requestor would not augment the advertising spots in any way by, for example, leveraging User data to target certain advertisements to specific Users in response to User searches on the Platform or otherwise. Second, Requestor would contract with any individual or entity that wants to advertise on the Platform or in the Newsletter and who has the technological capabilities to do so (except providers of home-based health care services), and Requestor would not have an exclusive advertising arrangement with any Advertiser. Third, Requestor would clearly label all advertising spots as such and would include a disclaimer that the advertisements do not constitute a recommendation or endorsement of the products, services, or companies appearing in the advertisements, and Advertisers would be prohibited from implying on their websites that Requestor endorses or has co-branded with any Advertiser. Fourth, Requestor would offer advertising spots on the Platform and in the Newsletter for a fixed monthly fee (i.e., a fee that does not change based on views, clicks, or otherwise) that would be consistent with fair market value and would not vary by Advertiser. Lastly, Requestor is a non-health care entity, and while Requestor is owned, in part, by an individual who provides certain health care services, the Platform would not claim on its website or in marketing materials to be operated by a health care provider or supplier. Based on the totality of these facts, we conclude that Requestor would not be recommending Advertisers under the Proposed Arrangement, and thus this aspect of the Proposed Arrangement would not implicate the Federal anti-kickback statute.

Because two streams of remuneration under the Proposed Arrangement would implicate the Federal anti-kickback statute, and the Proposed Arrangement would not have safe harbor protection, we assess the Proposed Arrangement in its totality, and for the combination of the following reasons,

we conclude that the Proposed Arrangement would present a minimal risk of fraud and abuse under the Federal anti-kickback statute.

First, Requestor certified that the fixed fees it would charge under the Proposed Arrangement would be consistent with fair market value and would not vary by Enrolled Provider.¹³ While Enrolled Providers would pay a Contact Fee that would take into account the number of Contacts an Enrolled Provider received during the month, the traditional fraud and abuse risks associated with per-click arrangements would be mitigated because: (i) Requestor would charge the Contact Fee regardless of whether the Users making the Contacts ultimately sought services from the Enrolled Provider, meaning the Contact Fee would not take into account the volume or value of any Federal health care program business (or other business) ultimately generated by the Platform; and (ii) neither the Participation Fee nor the fixed per-Contact amount charged to Enrolled Providers would fluctuate based on the number of Contacts an Enrolled Provider receives. Importantly, the fees Enrolled Providers would pay Requestor would not affect the frequency with which Enrolled Providers appear, or their placement, in the Platform listings. The Platform would generate a list of Enrolled Providers using only Users' specified criteria, and Users could order the search results using any of four user-centric methodologies.

Second, Requestor is not a provider or supplier and is not affiliated with any Enrolled Provider who may be listed on the Platform. Although Requestor is owned, in part, by an individual who is licensed to provide certain health care services, none of the owners of Requestor is involved, directly or indirectly, in the provision of any home-based health care services that may be offered by Enrolled Providers. Further, the Platform would not claim on its website or in marketing materials to be operated by a health care provider or supplier. Therefore, Requestor's relationship with Users under the Proposed Arrangement is distinguishable from potentially problematic arrangements involving marketing by health care providers and suppliers. In particular, "white coat" marketing by health care professionals, such as physicians, is subject to closer scrutiny, since health care providers and suppliers are in a position of trust and may exert undue influence when recommending health care items or services, especially to their own patients. Because Requestor is not a provider or supplier, is not affiliated with any potential Enrolled Providers, and would not steer Users to any particular Enrolled Providers, this same concern is not present in the Proposed Arrangement.

Third, Requestor's potential base of Users is the general public, meaning any individual, regardless of insurance status or source of payment, can access the Platform and view Enrolled Providers and Advertisers. Although Requestor would collect certain identifiable information about Users, including their insurance status or source of payment, Requestor would use this information only for the purpose of generating search results that list Enrolled Providers who meet Users' search criteria and not to influence Users' decision making. Any contact with Requestor and use of the Platform must be initiated by the User, and Requestor would show Enrolled Providers to Users only on the Platform (i.e., Requestor would not advertise specific Enrolled Providers by other means, such as through emails, mailings, or text messages). Additionally, Users would have the same

¹³ We are precluded by statute from opining on whether fair market value shall be or was paid for goods, services, or property. 42 U.S.C. § 1320a-7d(b)(3)(A).

ability to access the Platform and the same functionality available on the Platform regardless of their insurance status or source of payment. Further, Requestor would not provide remuneration to Users, including Federal health care program beneficiaries, other than free use of the Platform, to induce them to use the Platform or receive items or services from any Enrolled Providers.

Lastly, Requestor designed the Platform to include other safeguards that mitigate the risk of fraud and abuse. For example, the Platform's listing of Enrolled Providers or Non-Enrolled Providers would not promote any specific items or services Users could obtain from such providers. When the Platform is able to generate a list of Enrolled Providers, the list would include all Enrolled Providers who meet the Users' search criteria, and the Platform would notify Users that the search results include only names of providers who pay a fee to be listed and that there may be other providers who meet the same search criteria, which reduces the likelihood that Users would think the Platform reflects the full scope of home-based health care providers available to them. If the Platform does not find any Enrolled Providers who meet the User's search criteria, the Platform would list Non-Enrolled Providers who do not pay any fee to Requestor. Requestor also would require Enrolled Providers to agree that neither the hyperlink to their websites nor their websites will prohibit or impede Users from directly returning to the Platform, which could improve the ability of Users to readily access the Platform and search for different Enrolled Providers. Further, Requestor would not permit providers of home-based health care services to be Advertisers, which could reduce any potential confusion as to whether Requestor endorses or favors any particular providers of home-based health care services.

With respect to the Beneficiary Inducements CMP, Requestor's provision of the Platform at no charge to Federal health care program beneficiaries could influence beneficiaries to select an Enrolled Provider, but for the reasons stated above, in an exercise of our discretion, we would not impose sanctions under the Beneficiary Inducements CMP in connection with the Proposed Arrangement.

III. CONCLUSION

Based on the relevant facts certified in your request for an advisory opinion and supplemental submissions, we conclude that: (i) although the Proposed Arrangement, if undertaken, would generate prohibited remuneration under the Federal anti-kickback statute if the requisite intent were present, the OIG would not impose administrative sanctions on Requestor in connection with the Proposed 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; and (ii) although the Proposed Arrangement, if undertaken, could generate prohibited remuneration under the Beneficiary Inducements CMP, the OIG would not impose administrative sanctions on Requestor in connection with the Proposed Arrangement under the Beneficiary Inducements CMP or section 1128(b)(7) of the Act, as that section relates to the commission of acts described in the Beneficiary Inducements CMP.

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 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 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, 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 Proposed 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 Proposed 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 Proposed 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,

/Robert K. DeConti/

Robert K. DeConti
Assistant Inspector General for Legal Affairs