



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 associated with the individual or entity, unless otherwise approved by the requestor.]

Issued: November 30, 2012

Posted: December 7, 2012

[Name and address redacted]

Re: OIG Advisory Opinion No. 12-19

Ladies and Gentlemen:

We are writing in response to your request for an advisory opinion regarding four proposed arrangements involving a pharmacy company's provision of items and services to community homes in which its customers reside. The first and second proposed arrangements ("Proposed Arrangement A" and "Proposed Arrangement B," respectively) would primarily involve the pharmacy company providing pre-populated medication administration records ("MARs"), physician order forms, and treatment sheets to community homes for free either in paper format or via a web-based software program. Under the third and fourth proposed arrangements ("Proposed Arrangement C" and "Proposed Arrangement D," respectively) the pharmacy company would provide a sublicense for a different web-based software program to community homes that would allow the community homes to perform certain administrative functions and to maintain electronic medication administration records ("eMARs"). We refer to Proposed Arrangement A, Proposed Arrangement B, Proposed Arrangement C, and Proposed Arrangement D collectively as the "Proposed Arrangements." Specifically, you have inquired whether the Proposed Arrangements would constitute 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.

You have certified that all of the information provided in your request, including all supplemental submissions, is true and correct and constitutes a complete description of the relevant facts and agreements among the parties.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken an independent investigation of such information. This opinion is limited to the facts presented. If material facts have not been disclosed or have been misrepresented, this opinion is without force and effect.

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although Proposed Arrangement A, Proposed Arrangement B, and Proposed Arrangement C could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the Office of Inspector General (“OIG”) would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with Proposed Arrangement A, Proposed Arrangement B, or Proposed Arrangement C.

However, we conclude that Proposed Arrangement D could potentially generate prohibited remuneration under the anti-kickback statute and that the OIG could potentially impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with Proposed Arrangement D. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties’ intent, which determination is beyond the scope of the advisory opinion process.

This opinion is limited to the Proposed Arrangements and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions. This opinion may not be relied on by any persons other than [name redacted], the requestor of this opinion, and is further qualified as set out in Part IV below and in 42 C.F.R. Part 1008.

I. FACTUAL BACKGROUND

A. Background

[Name redacted] (the “Requestor”) provides pharmacy services to more than 3400 individuals with intellectual and developmental disabilities who reside in community homes (“Community Homes”) located in [state name redacted] and [state name redacted] (the “States”). The Requestor enters into agreements with certain Community Homes to

supply prescription medications to their residents. The Requestor certified that nothing in the Proposed Arrangements would require those agreements to be exclusive. The Requestor provides its services through its pharmacies. According to the Requestor, the Community Homes have the ability to select, or influence the selection of, the pharmacy serving their residents, some of whom are Federal health care program beneficiaries. The Requestor also certified that, although the residents (or the residents' families) may choose an alternate pharmacy, and the Community Homes are obligated to respect their residents' (and their families') choice, that choice is not frequently exercised. The Requestor certified that the Community Homes can neither prescribe, nor influence or control the prescription of, medications and that the Community Homes neither control nor influence the decisions of prescribing physicians.¹ The Requestor further certified that the Community Homes do not set formularies or otherwise limit or influence prescribing physicians' selection of prescription medications.

Both States in which the Community Homes served by the Requestor operate require that the Community Homes maintain a MAR documenting certain information about the medications provided to their residents. According to the Requestor, the Community Homes are required to maintain the MARs as a condition of licensure in both States, and licensure is a condition of participation in Medicaid.

B. Proposed Arrangements

The Requestor proposes to enter into the Proposed Arrangements with various Community Homes located in the States. One of the Proposed Arrangements would be available to all Community Homes in the two States in which the Requestor does business, while the others would be available only to those Community Homes that have residents who obtain prescription medications from the Requestor. The Requestor certified that, except for the limitation referenced in the preceding sentence, each Proposed Arrangement would be available regardless of the volume or value of prescription medications a particular Community Home's residents obtain from the Requestor. The Requestor further certified that no other remuneration would be offered or provided to any of the Community Homes in connection with the Proposed Arrangements.

¹ According to the Requestor, residents and their families have the right to choose their own physicians. While some Community Homes employ or otherwise obtain the services of medical directors, we have not been asked to opine on, and we offer no opinion concerning, those relationships.

1. Proposed Arrangement A

The Requestor would make Proposed Arrangement A available to Community Homes that have residents who obtain prescription medications from the Requestor. Under Proposed Arrangement A, the Requestor would provide these Community Homes with free computer-generated paper copies of pre-populated MARs² for each resident who receives his or her prescription medications from the Requestor. The Community Homes would still be required to document the actual administration of each dose of medication, including the date, time, and the person administering the medication.

The Requestor would also provide free paper copies of a physician order form (the “Physician Order Form”) and a treatment sheet (“Treatment Sheet”). According to the Requestor, the Physician Order Form contains all of the information that the Requestor collects about an individual as part of its process for filling prescriptions, including allergies, medications, and diagnoses. The Community Homes may then present the Physician Order Forms to the prescribing physicians who review and sign the Physician Order Forms to reauthorize prescriptions. That reauthorization, in turn, permits the Requestor to dispense the medications. The Requestor certified that the Community Homes are required by state law to retain a copy of the signed Physician Order Forms for their records in order for their staffs to administer medications. According to the Requestor, the Treatment Sheets are a form of MAR that include medication administration information related to topical prescription medications. The States require that Community Homes maintain this medication administration information.³ As with the MARs, the Community Homes would still need to document the actual administration of each dose of topical prescription medication on the Treatment Sheets. The Requestor

² The pre-populated information would include the resident’s name, address, and date of birth, the prescribing physician’s name, the name of the medication, the date the medication was started, the diagnosis/condition for which the medication was prescribed, the medication strength, dosage form, dose, route of administration, frequency of administration, prescribed administration times, duration of the prescription, and any special precautions. The Requestor obtains this information from prescribing physicians and other sources as part of its process for filling prescriptions.

³ While some Community Homes do not use Treatment Sheets, and instead maintain all required medication administration information in one MAR document, other Community Homes choose to separately maintain administration information regarding topical medications on a separate document, a Treatment Sheet, because topical prescription medications may be stored and handled differently than oral medications and may be administered by different staff members.

would deliver the paper copies of the pre-populated MARs, Physician Order Forms, and Treatment Sheets once a month.

The Requestor acknowledges that, absent the Proposed Arrangements, the Community Homes would be required to prepare MARs, Physician Order Forms, and Treatment Sheets in order to meet their obligations under state law. According to the Requestor, the cost of providing the pre-populated materials would be nominal because the Requestor must gather the information contained in the materials to fill a prescription. Further, the Requestor states that providing the pre-populated materials could reduce medication errors resulting from the Community Homes' staff manually transcribing prescription information from pill bottles or other prescription medication packaging on to blank forms.

2. Proposed Arrangement B

The Requestor would make Proposed Arrangement B available to Community Homes that have residents who obtain prescription medications from the Requestor. Under Proposed Arrangement B, the Requestor would offer these Community Homes free, limited access to [name redacted] ("Software Y") in connection with each resident who receives his or her prescription medications from the Requestor. Software Y is a secure, web-based software program that allows users to re-order medications, print medical records, and communicate directly with the Requestor's pharmacists. The Community Homes' access to Software Y would be limited to the following functions: printing pre-populated MARs, Physician Order Forms, and Treatment Sheets; composing messages to, and reading messages from, the Requestor; reviewing the resident profile that is maintained by the Requestor; reordering and refilling prescriptions; checking on the status of the ordered prescriptions; and changing the user's password. If the end-user is a nurse, then the following additional functions would also be available: changing resident demographics, adding and removing resident drug allergy information, and adding and removing resident medical condition information. The Requestor certified that it requires this updated information to ensure that it is safely dispensing the prescription medications. The Community Homes would have access to these limited Software Y functions 24 hours a day, 7 days a week. Thus, if information on one of the pre-populated materials changed in the middle of a month, the Community Homes' staff would be able to access and print the updated materials. In the absence of this ability to access and print updated materials, the Community Homes' staff would have to manually update the existing materials to reflect any changes.

The licensor of Software Y charges a one-time fee based on the number of pharmacies using the software. For the Requestor, that one-time fee totaled [amount redacted] for all of its pharmacies. The Requestor would incur no additional costs to add users or to give the Community Homes access. Software Y is only available for purchase by pharmacies. The Requestor certified that Software Y is not “interoperable” within the meaning of 42 C.F.R. § 1001.952(y).

3. Proposed Arrangement C

The Requestor has entered into a licensing agreement with [name redacted] (the “Developer”) that grants the Requestor the exclusive right to sell sublicenses for [name redacted] (“Software Z”) to Community Homes in certain territories, including the States.⁴ Software Z is a web-based software program that offers a number of functions, including bundled products that facilitate scheduling and administration of medications, and provides an eMAR that complies with state regulatory requirements. Specifically, Software Z integrates pharmacies’ information and order fulfillment processes with software end-users’ medication administration work responsibilities (e.g., documenting medication administration, tracking vital signs, and storing medical observations). Software Z also offers a real-time prompting system that automatically transfers prescription information from a pharmacy to an end-user and prompts end-user staff to administer scheduled medications. That same function could be used by the end-user to schedule, and prompt staff to engage in, other tasks and events like providing patients and residents with other treatments or exercise, taking vital signs, and other calendar-based events. End-user nurses and management could be alerted when medication administration or other tasks and events are omitted or performed early or late. The Requestor certified that Software Z is not “interoperable” within the meaning of 42 C.F.R. § 1001.952(y). According to the Requestor, the data that an end-user would create and maintain in Software Z would not be readily transferable to another system, and losing access to Software Z would result in losing electronic access to the MAR documentation and other data stored in Software Z.

The Requestor would make Proposed Arrangement C available to any Community Home, regardless of whether its residents obtain prescription medications from the Requestor or another pharmacy. Under Proposed Arrangement C, these Community Homes would be able to purchase a sublicense for Software Z from the Requestor. The Requestor would

⁴The Requestor is the exclusive sublicensor of Software Z to Community Homes in both States. We have not been asked to opine on, and we express no opinion regarding, the arrangement between the Requestor and the Developer.

offer sublicenses to all Community Home at the same price and under the same purchase terms. The Requestor would charge a one-time [amount redacted] setup fee⁵ in addition to a monthly per-resident fee. The Requestor certified that the fees it would charge Community Homes for Software Z access would be fair market value and would not vary based on whether the Community Homes' residents receive prescription medications from the Requestor or another pharmacy, or the volume or value of resident prescriptions, if any. The monthly per-resident fee charged by the Requestor would be lower than the monthly per-resident fee the Developer normally charges Community Homes for Software Z, but would not be below the cost to the Requestor.

4. Proposed Arrangement D

The Requestor would make Proposed Arrangement D available to Community Homes that have residents who obtain prescription medications from the Requestor. Under Proposed Arrangement D, the Requestor would offer these Community Homes a free sublicense for Software Z for their own use in connection with each such resident. The Requestor certified that its cost to provide the free sublicenses would be significant and exceed its nominal cost of providing the pre-populated materials described in connection with Proposed Arrangement A.

II. LEGAL ANALYSIS

A. Law

The anti-kickback statute makes it a criminal offense to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a Federal health care program. See section 1128B(b) of the Act. Where remuneration is paid purposefully to induce or reward referrals of items or services payable by a Federal health care program, the anti-kickback statute is violated. By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible “kickback” transaction. For purposes of the anti-kickback statute, “remuneration” includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind.

The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals. See, e.g., United States v. Borrasi, 639 F.3d 774 (7th Cir. 2011); United States

⁵ The setup fee would be charged per agency that operates the Community Homes, rather than per Community Home. According to the Requestor, a single agency may operate multiple Community Homes.

v. McClatchey, 217 F.3d 823 (10th Cir. 2000); United States v. Davis, 132 F.3d 1092 (5th Cir. 1998); United States v. Kats, 871 F.2d 105 (9th Cir. 1989); United States v. Greber, 760 F.2d 68 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985). Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from Federal health care programs, including Medicare and Medicaid. Where a party commits an act described in section 1128B(b) of the Act, the OIG may initiate administrative proceedings to impose civil monetary penalties on such party under section 1128A(a)(7) of the Act. The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs under section 1128(b)(7) of the Act.

The Department of Health and Human Services has promulgated safe harbor regulations that define practices that are not subject to the anti-kickback statute because such practices would be unlikely to result in fraud or abuse. See 42 C.F.R. § 1001.952. The safe harbors set forth specific conditions that, if met, assure entities involved of not being prosecuted or sanctioned for the arrangement qualifying for the safe harbor. However, safe harbor protection is afforded only to those arrangements that precisely meet all of the conditions set forth in the safe harbor. The safe harbor related to electronic health records, 42 C.F.R. § 1001.952(y), is potentially applicable to Proposed Arrangement B, Proposed Arrangement C, and Proposed Arrangement D.

B. Analysis

The Proposed Arrangements implicate the anti-kickback statute because, under each of the Proposed Arrangements and as explained more fully below, the Requestor potentially would provide remuneration to Community Homes that have the ability to select, or influence the selection of, the pharmacy serving their residents, some of whom are Federal health care program beneficiaries.

Although the electronic health records safe harbor potentially applies to Proposed Arrangement B, Proposed Arrangement C, and Proposed Arrangement D, each fails to meet the conditions of the safe harbor because, among other reasons, neither Software Y nor Software Z is interoperable within the meaning of the safe harbor regulation. However, the absence of safe harbor protection is not fatal. Instead, these Proposed Arrangements must be subject to case-by-case evaluation.

As a preliminary matter, we note that our position on the provision of free or below-market items or services to actual or potential referral sources is longstanding and clear: such arrangements are suspect and may violate the anti-kickback statute, depending on the circumstances. It is in this context that we consider each of the Proposed Arrangements in turn.

1. Proposed Arrangement A

Under Proposed Arrangement A, the Requestor would provide Community Homes that have residents who obtain prescription medications from the Requestor with free paper copies of pre-populated MARs, Physician Order Forms, and Treatment Sheets once a month for each resident receiving his or her prescription medications from the Requestor. In doing so, the Requestor would relieve the Community Homes of the need to prepare the materials in order to meet their obligations under state law. Accordingly, under Proposed Arrangement A, the Community Homes could avoid incurring certain administrative costs associated with their staff having to collect and transfer information from prescription medication packaging (e.g., pill bottles) and other sources to create and pre-populate the materials. Such a benefit would have clear independent value to the Community Homes, so we must consider the extent to which Proposed Arrangement A presents a risk of any of the harms typically associated with kickbacks—namely, distorted medical decision making, overutilization, increased Federal health care program costs, and unfair competition.

Community Homes can neither prescribe, nor influence or control the prescription of, any medication. They do not control or influence the decisions of prescribing physicians, and do not set formularies or otherwise limit or influence prescribing physicians' selection of prescription medications. This means that, under these particular facts, the Community Homes are unlikely to be able to increase the number or type of their residents' prescriptions. Accordingly, the risk of distorted medical decision making, overutilization, and increased Federal health care program costs is reduced under Proposed Arrangement A and, in fact, under all the Proposed Arrangements.

The fact that the Community Homes are able to select, or influence the selection of, the pharmacy serving their residents does, however, present a risk of unfair competition. This risk of unfair competition is mitigated under Proposed Arrangement A. For example, the Requestor certified that its cost of providing the pre-populated materials would be nominal and that it already gathers the information that would be contained in the materials to fill a prescription. Further, the Requestor's competitors likely would be able to offer a similar benefit at a nominal cost. While the cost of providing in-kind remuneration and the ability of competitors to provide similar remuneration are not normally factors in determining whether an anti-kickback violation exists, we find them relevant to our consideration of whether Proposed Arrangement A presents more than a minimal risk of unfair competition, and we conclude that it does not.

Our conclusion regarding the fraud and abuse risks posed by Proposed Arrangement A derives from the particular facts presented; we would likely reach a different conclusion were we to consider, for example, a similar arrangement wherein any of the underlying risks was more than minimal. Our analysis of Proposed Arrangement D, below, is instructive on this point in that the particular facts of Proposed Arrangement D would not sufficiently mitigate the risk of unfair competition, and we reach a different conclusion.

We also note that Proposed Arrangement A would likely enhance patient safety and quality of care. By providing the pre-populated materials directly from the Requestor's pharmacies' computer system, Proposed Arrangement A allows the Community Homes' staff to skip the step of transferring prescription information from the medication packaging to the form, thereby removing one of the opportunities for transcription errors in the medication administration process. Thus, Proposed Arrangement A gives rise to an additional benefit to patient safety and quality that would not be available but for the existence of this Proposed Arrangement. It is distinguishable, however, from situations where parties merely shift costs associated with meeting an obligation, without creating or providing an additional benefit to patients. In those situations—such as when a pharmacy provides free or below-market consulting pharmacist services to a nursing facility that is required to obtain or provide such services for its residents—the patient benefit results from meeting the underlying obligation and would inure to the patient even in the absence of the cost-shifting arrangement.

In the particular circumstances presented here, Proposed Arrangement A would present a minimal risk of the harms typically associated with kickbacks, while potentially providing a significant patient benefit. Accordingly, we conclude that Proposed Arrangement A would be unlikely to result in fraud or abuse under the anti-kickback statute, and we would not seek to impose administrative sanctions.

2. Proposed Arrangement B

Under Proposed Arrangement B, the Requestor would provide the Community Homes that have residents who obtain prescription medications from the Requestor with free, limited access to Software Y for each resident receiving his or her prescription medications from the Requestor. The Software Y functions available to the Community Homes under Proposed Arrangement B would fall into two primary categories: (1) functions related to printing pre-populated MARs, Physician Order Forms, and Treatment Sheets; and (2) communication and other functions related to the services the Requestor provides. With respect to the first category, our analysis is the same as described in connection with Proposed Arrangement A; the only meaningful distinctions between

Proposed Arrangement A and the first category of functions under Proposed Arrangement B are the frequency with which the Community Homes may obtain updated materials (monthly versus on-demand) and the method of receiving those materials (delivery of a hard copy versus via Software Y). Under Proposed Arrangement A, if the information included on the pre-populated materials changed after the Requestor had sent them to a Community Home for a particular month—for example a change in drug administration frequency—then the Community Home staff would have to manually modify the applicable materials to reflect that change. Under Proposed Arrangement B, the Community Home would be able to access and print the updated materials reflecting that change, thus relieving the Community Homes of the administrative costs associated with manually making the change. While relieving the Community Homes of this administrative burden would increase the benefit offered by the Requestor to the Community Homes, we do not believe that this additional benefit would appreciably increase the risk posed by the first category of functions under Proposed Arrangement B over Proposed Arrangement A. Further, with respect to the pre-populated materials, Software Y serves as nothing more than a mechanism for delivery.⁶ In this particular situation, we do not believe that delivering the pre-populated materials via an electronic medium, rather than as a hardcopy, raises any additional risks of fraud or abuse.

Next, we turn to the second category of functions. While it remains the OIG's position, as mentioned above, that free or below-market items and services are suspect, the OIG has distinguished between situations in which a provider offers free items and services that are integrally related to that provider's services, and those that are not. 56 Fed. Reg. 35,952, 35,978 (July 29, 1991) (preamble to the 1991 safe harbor regulations). When the item or service offered can be used only as part of the underlying service being provided, it appears that the free items or services have no independent value apart from the underlying service. *Id.* Upon review of the additional functions within the second category, we conclude that they would be integrally related to the Requestor's services, such that they would have no independent value to the Community Homes apart from the services the Requestor provides.

For all of the above-stated reasons, we conclude that, in the particular circumstances presented here, Proposed Arrangement B would be unlikely to result in fraud or abuse

⁶ The functions related to accessing and printing the pre-populated materials do not involve the creation or storage of data in Software Y by the Community Homes and, therefore, the lack of interoperability of these functions does not raise the same risk of data lock-in that often arises in situations involving the offer of non-interoperable technology.

under the anti-kickback statute, and we would not seek to impose administrative sanctions.

3. Proposed Arrangement C

Under Proposed Arrangement C, the Requestor would offer to sell sublicenses for Software Z to Community Homes at a price below the price that the Developer normally would charge the Community Homes. The Requestor would offer the same price and purchase terms across-the-board to all Community Homes, regardless of whether their residents received prescription medications from the Requestor or another pharmacy. The Requestor's pricing structure appears to involve a general across-the-board price reduction, as opposed to a discount offered only to customer Community Homes. Further, Proposed Arrangement C would have safeguards built into it, including the fact that the Requestor's sales price would reflect fair market value and that the reduced fee would not be below the Requestor's cost. Accordingly, we conclude that, in the particular circumstances presented here, Proposed Arrangement C would be unlikely to result in fraud or abuse under the anti-kickback statute, and we would not seek to impose administrative sanctions.

4. Proposed Arrangement D

Under Proposed Arrangement D, the Requestor would provide Community Homes that have residents who obtain prescription medications from the Requestor with a free sublicense for Software Z for use in connection with such residents. As a threshold matter, we believe that free sublicenses for Software Z would have clear independent value to the Community Homes, as they would acquire the right to use Software Z for their own use without incurring the corresponding costs of obtaining that right. While the inability of the Community Homes to influence the number and type of residents' prescriptions results in a low risk of distorted medical decision making, overutilization, and increased Federal health care program costs, Proposed Arrangement D presents an increased risk of unfair competition for a number of reasons.

First, the Requestor certified that its cost to provide the free sublicenses would be significant, and would exceed the nominal cost of the pre-populated materials it would provide under Proposed Arrangement A. Further, we believe that the cost to competitor pharmacies to provide access to software with similar functionalities would be significant, without any apparent nominal cost alternatives to providing a similar benefit. Accordingly, providing a Software Z sublicense for free potentially would give the Requestor a significant advantage over its competitors, who may not be in a position to offer a similar benefit but whose direct services to patients may be better.

Second, Software Z is not interoperable. Data that a Community Home would create and store in Software Z, including MAR documentation, would not be readily transferable to other systems, resulting in Community Home data lock-in and, thereby, referral lock-in.⁷ Losing access to Software Z would result in the Community Homes losing electronic access to their data stored in Software Z, including the MAR documentation that they are required to maintain. Thus, if a Community Home resident began receiving medications from the Requestor and later decided to receive medications from another pharmacy, then the Community Home could face having to either transition that resident's data to another system or assume the full payment for a Software Z sublicense. This situation could give rise to a significant incentive for the Community Homes to steer patients to the Requestor rather than one of its competitor.

Given these risks, and the Requestor's acknowledgement that the Community Homes are in a position to select, or influence the selection of, the pharmacy serving their residents, in the particular circumstances presented here, Proposed Arrangement D would present a significant risk of unfair competition, which could lead to the selection of a pharmacy that offers the best benefit to the Community Home, rather than the best direct services to patients. Notwithstanding some similarities between Proposed Arrangement A and Proposed Arrangement D, including the patient safety benefit derived from removing one of the possible opportunities for transcription errors, the significant risk of unfair competition under Proposed Arrangement D distinguishes the two proposals in a meaningful way and leads us to reach different conclusions. Therefore, we conclude that Proposed Arrangement D could result in fraud and abuse under the anti-kickback statute and we could potentially seek to impose administrative sanctions.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although Proposed Arrangement A, Proposed Arrangement B, and Proposed Arrangement C could potentially generate prohibited remuneration under the anti-kickback statute if the requisite intent to induce or reward referrals of Federal health care program business were present, the OIG would not impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with Proposed Arrangement A, Proposed Arrangement B, or Proposed Arrangement C.

⁷ We note that Proposed Arrangement B may involve a Community Home entering data into Software Y when the end user is a nurse. However, that data, which is necessary for the Requestor to safely dispense the prescription medications, is distinguishable from the data that the Community Homes would enter and maintain in Software Z for their own use. The former situation would not raise the same risks related to locking in the Community Homes' data that are presented in the latter situation.

However, we conclude that Proposed Arrangement D could potentially generate prohibited remuneration under the anti-kickback statute and that the OIG could potentially impose administrative sanctions on [name redacted] under sections 1128(b)(7) or 1128A(a)(7) of the Act (as those sections relate to the commission of acts described in section 1128B(b) of the Act) in connection with Proposed Arrangement D. Any definitive conclusion regarding the existence of an anti-kickback violation requires a determination of the parties' intent, which determination is beyond the scope of the advisory opinion process.

This opinion is limited to the Proposed Arrangements and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request for an advisory opinion or supplemental submissions.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

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

- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

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

The OIG will not proceed against [name redacted] with respect to any action that is part of Proposed Arrangement A, Proposed Arrangement B, or Proposed Arrangement C 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 Proposed Arrangement A, Proposed Arrangement B, and Proposed Arrangement C in practice comport 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 [name redacted] with respect to any action that is part of the Proposed Arrangement A, Proposed Arrangement B, or Proposed Arrangement C 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,

/Gregory E. Demske/

Gregory E. Demske
Chief Counsel to the Inspector General