



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:** February 20, 2018

**Posted:** February 27, 2018

[Name and address redacted]

**Re: OIG Advisory Opinion No. 18-01**

Dear [Name redacted]:

We are writing in response to your request for an advisory opinion regarding the effect of your exclusion from Medicare, Medicaid, and all other Federal health care programs. Specifically, you have inquired whether a newly formed, for-profit corporation's proposal to employ you to market its services (the "Proposed Arrangement") would violate the terms of your exclusion and constitute grounds for the imposition of sanctions against you under the civil monetary penalty provision at section 1128A(a)(1)(D) of the Social Security Act (the "Act").

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 the Proposed Arrangement could violate your exclusion and could constitute grounds for the imposition of administrative sanctions against you under section 1128A(a)(1)(D) of the Act, the Office of Inspector General (“OIG”) would not impose such sanctions in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement 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**

As a result of your criminal conviction for health care fraud under 18 U.S.C. § 1347 and pursuant to a civil False Claims Act settlement, you agreed to be permanently excluded from participation in Medicare, Medicaid, and all other Federal health care programs. The effective date of your exclusion was [date redacted].

You have certified that you received a good faith employment offer from [name redacted] (the “Company”), a newly formed, for-profit corporation. The Company has informed you that its services will consist of offering long-term care pharmacies (the “LTC Pharmacies”) access to discounted rates for emergency medications<sup>1</sup> that the Company negotiates with local retail pharmacies. The prices the Company would charge for the medications the LTC Pharmacies obtain from the local retail pharmacies<sup>2</sup> would be the discounted rate the Company negotiated with the local retail pharmacies, plus a mark-up.

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<sup>1</sup> As described in your request for an advisory opinion, the term “emergency medications” refers to situations where the LTC Pharmacies may not be able to meet the needs of their customers through a normal ordering and delivery process, generally because their customers need an order filled on an emergency basis and the LTC Pharmacies are located some distance from their customers or are closed at the time their customers need a medication order filled.

<sup>2</sup> We have not been asked to opine on, and express no opinion regarding, the Company’s operations or its arrangements with the LTC Pharmacies or local retail pharmacies.

You have certified that neither you nor the Company would directly submit claims for items or services that are paid for by any Federal health care program, including any medications the LTC Pharmacies obtain from the local retail pharmacies. You have further certified that neither you nor the Company would directly or indirectly have any role in the LTC Pharmacies' or their customers'<sup>3</sup> submission of claims to any Federal health care program.<sup>4</sup> In addition, you have certified that neither you nor the Company would submit claims to Medicare, Medicaid, or any other Federal health care program for any items or services you provide in connection with the Proposed Arrangement.

Under the Proposed Arrangement, you would market the Company's services to the LTC Pharmacies and offer them the opportunity to contract with the Company to receive lower prices than they normally would pay when ordering emergency medications from a local retail pharmacy. You have certified that, because the LTC Pharmacies and their customers would determine the volume, type, and frequency of any medications they would need or order, neither you nor the Company would exercise any direct or indirect control over those determinations. The Company would pay you a fixed salary plus a commission based on the number of LTC Pharmacy accounts you secure for the Company. You have further certified that your compensation would not be determined based on the volume, value, frequency, price, or selection of any medications, including federally reimbursable medications, the LTC Pharmacies or their customers would order. You also have certified that neither you, nor any of your immediate family members,<sup>5</sup> nor any member of your

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<sup>3</sup> The LTC Pharmacies' customers include skilled nursing facilities, assisted living facilities, group homes, and correctional facilities.

<sup>4</sup> We rely on your certifications regarding the Company's conduct. If those certifications are inaccurate, this opinion is without force and effect.

<sup>5</sup> "Immediate family member means, a person's husband or wife; natural or adoptive parent; child or sibling; stepparent, stepchild, stepbrother or stepsister; father-, mother-, daughter-, son-, brother- or sister-in-law; grandparent or grandchild; or spouse of a grandparent or grandchild." 42 C.F.R. § 1001.2.

household,<sup>6</sup> have any direct or indirect ownership or control interest<sup>7</sup> in the Company or would obtain such ownership or control interest during the term of the Proposed Arrangement.

## II. LEGAL ANALYSIS

### A. Law

When an individual is excluded pursuant to section 1128 of the Act, no payment may be made by Medicare, Medicaid, or any other Federal health care program for any item or service furnished by that individual on or after the effective date of the exclusion. See sections 1862(e) and 1902(a)(39) of the Act. An excluded individual who submits, or causes to be submitted, claims to Medicare, Medicaid, or any other Federal health care program for items or services furnished during the exclusion period is subject to civil monetary penalty liability under section 1128A(a)(1)(D) of the Act.

### B. Analysis

Under the Proposed Arrangement, the Company would employ you to market its services to the LTC Pharmacies, which then would obtain emergency medications at discounted rates from local retail pharmacies. You have certified that the Company would not submit claims to Medicare, Medicaid, or any other Federal health care programs for any medications the LTC Pharmacies obtain from the local retail pharmacies or for any items or services you provide in connection with the Proposed Arrangement. We understand that the prices the

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<sup>6</sup> “Member of household means, with respect to a person, any individual with whom the person is sharing a common abode as part of a single-family unit, including domestic employees and others who live together as a family unit. A roomer or boarder is not considered a member of household.” Id.

<sup>7</sup> “Ownership or control interest means, with respect to an entity, a person who (1) Has a direct or an indirect ownership interest (or any combination thereof) of 5 percent or more in the entity; (2) Is the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the entity or any of the property assets thereof, if such interest is equal to or exceeds 5 percent of the total property and assets of the entity; (3) Is an officer or a director of the entity; (4) Is a partner in the entity if the entity is organized as a partnership; (5) Is an agent of the entity; or (6) Is a managing employee of the entity.” Id. “Ownership interest means an interest in: (1) The capital, the stock, or the profits of the entity, or (2) Any mortgage, deed, trust or note, or other obligation secured in whole or in part by the property or assets of the entity.” Id.

Company would charge to the LTC Pharmacies for the emergency medications they obtain from the local retail pharmacies would be the discounted rate the Company negotiated, plus a mark-up. We presume that this mark-up would include costs the Company incurred to negotiate the discounted medication rates with the local retail pharmacies, such as general business expenses and employee expenses, including the cost to employ you to market the Company's services.

For purposes of section 1128A of the Act, the term "items or services" includes, without limitation, any item, device, drug, biological, supply, or service (including management or administrative services). 42 C.F.R. § 1003.110. The term "furnished" refers to items or services provided or supplied, directly or indirectly, by an individual or entity. 42 C.F.R. § 1000.10. This includes items or services provided by individuals or entities that do not directly submit claims to any Federal health care programs, but that provide items or services to providers who submit claims to those programs. Id. The emergency medications obtained by the LTC Pharmacies from local retail pharmacies are "items or services" for which claims may be submitted to a Federal health care program.

Under the Proposed Arrangement, neither you nor the Company would submit claims to Medicare, Medicaid, or any other Federal health care program for items or services furnished by you. However, the LTC Pharmacies or their customers may submit claims to Medicare, Medicaid, or another Federal health care program for services furnished by you, as described below. In marketing the Company's services you would enable the LTC Pharmacies to obtain emergency medications at discounted rates from local retail pharmacies. If the amounts Medicare, Medicaid, or other Federal health care programs reimburse the LTC Pharmacies or their customers for the emergency medications include the LTC Pharmacies' acquisition costs (which costs, as noted above, would take into account the costs of your marketing services), then the Medicare, Medicaid, or other Federal health care programs may indirectly pay for the marketing services you provide to the Company. Therefore, you would be indirectly furnishing an item or service for which a claim is submitted to the Medicare, Medicaid, or other Federal health care programs. If you are furnishing services, even indirectly, for which a claim is submitted or caused to be submitted to the Federal health care programs, then the Proposed Arrangement would violate the terms of your exclusion and could constitute grounds for the imposition of administrative sanctions under section 1128A of the Act.

Your employment responsibilities would be limited to marketing the Company's services to the LTC Pharmacies. You have certified that neither you nor the Company would directly or indirectly have any role in the LTC Pharmacies' or their customers' submission of claims to Federal health care programs. You have further certified that neither you nor the Company would directly or indirectly exercise any control over the volume, type, or frequency of any medications the LTC Pharmacies or their customers would need or order

because the LTC Pharmacies or their customers would make those determinations. You have also certified that neither you, nor any of your immediate family members, nor any member of your household, have any direct or indirect ownership or control interest in the Company or would obtain such ownership or control interest during the term of the Proposed Arrangement, and that your compensation would not be determined based on the volume, value, frequency, price, or selection of any medications, including federally reimbursable medications, the LTC Pharmacies or their customers would order.

Accordingly, because your marketing services on behalf of the Company would be so far removed from the emergency medications the LTC Pharmacies or their customers would provide to program beneficiaries (and for which claims would be submitted), we conclude that the Proposed Arrangement (as described and certified in the request for an advisory opinion and supplemental submissions) poses minimal risk to Federal health care programs and beneficiaries, and the OIG would not subject you to administrative sanctions under section 1128A(a)(1)(D) of the Act in connection with the Proposed Arrangement.

### **III. CONCLUSION**

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that, although the Proposed Arrangement could violate the terms of your exclusion and could constitute grounds for the imposition of sanctions under section 1128A(a)(1)(D) of the Act, the OIG would not impose such sanctions in connection with the Proposed Arrangement. This opinion is limited to the Proposed Arrangement 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 Arrangement, including, without limitation, the physician self-referral law, section 1877 of the Act (or that provision's application to the Medicaid program at section 1903(s) of the Act).

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services.
- This advisory opinion is limited in scope to the specific arrangement described in this letter and has no applicability to other arrangements, even those which appear similar in nature or scope.
- No opinion is expressed herein regarding the liability of any party under the False Claims Act or other legal authorities for any improper billing, claims submission, cost reporting, or related conduct.

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

The OIG will not proceed against you 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 you 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