Dear [name redacted]:

We are writing in response to your request for an advisory opinion concerning a proposed program to provide free medical-alert pagers and pager monitoring service to homebound patients during the period that they are receiving your company’s home health services (the “Benefit”). Specifically, you have inquired whether the Benefit would constitute grounds for the imposition of sanctions under the civil monetary penalty (“CMP”) provision for violations of the prohibition against inducements to beneficiaries under section 1128A(a)(5) of the Social Security Act (the “Act”), as well as under the CMP and exclusion authorities at sections 1128A(a)(7) and 1128(b)(7) of the Act, respectively, as these sections relate to the commission of acts described in the anti-kickback statute, section 1128B(b) of the Act.

You have certified that all of the information provided in your request letter, including all supplementary information, is true and correct and constitutes a complete description of the material facts regarding the Benefit.

In issuing this opinion, we have relied solely on the facts and information presented to us. We have not undertaken any 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 the Benefit would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act, and, while the Benefit 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 [Company S] in connection with the Benefit 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).

This opinion is limited to the Benefit and, therefore, we express no opinion about any ancillary agreements or arrangements disclosed or referenced in your request letter or supplemental submissions.

This opinion may not be relied on by any persons other than [Company S], 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

[Company S] (the “Requestor”) is a for-profit provider of home health care services. Its patients are covered by private insurers and federal health care programs, including Medicaid and Medicare. The Requestor proposes to provide the Benefit to homebound patients during the period that they are receiving its home health services. The provision of free medical-alert pagers and pager monitoring service to the Requestor’s homebound patients will facilitate a rapid response to those who have fallen, are injured, or otherwise need emergency assistance, thereby forestalling the need for more expensive care and services. The Requestor estimates that the retail value of the Benefit would be between $20 to $30 monthly and $240 and $360 per year. The Requestor initially plans to provide the Benefit through a third-party service, but eventually will provide the service itself.

II. LEGAL ANALYSIS

The provision of free services to patients covered by Medicare and Medicaid implicates section 1128A(a)(5) of the Act, enacted as part of the Health Insurance Portability and Accountability Act of 1996. Section 1128A(a)(5) of the Act prohibits a person from offering or transferring remuneration to a beneficiary that such person knows or should know is likely to influence the beneficiary to order from a particular provider, practitioner, or supplier items or services for which payment may be made by Medicare or Medicaid. Violations are punishable by CMPs.

For purposes of section 1128A(a)(5), “remuneration” includes transfers of items or
services for free or for other than fair market value. See section 1128A(i)(6) of the Act. For purposes of enforcement, the OIG has set a threshold of $10 per item and $50 in the aggregate, per patient, per year. Items or services valued in excess of this threshold implicate the statute. No statutory exception applies to the Benefit.

Standing alone, the Benefit would implicate section 1128A(a)(5) of the Act. Notwithstanding, in this instance, the Centers for Medicare and Medicaid Services (CMS) – construing congressional intent in 42 U.S.C. 1395fff(e)(1) – has provided that, as part of the benefits for which payment may be made by Medicare, a home health agency “may adopt telehealth technologies that it believes promote efficiencies or improve quality of care,” HIM 201.13, although the use of such technologies may not substitute for services ordered by a physician. By ensuring prompt emergency assistance and potentially forestalling the need for more expensive care and services, the provision of the Benefit is reasonably related to the delivery of home health services and to the fostering of efficiency and quality of care. Given CMS’ express encouragement of innovative telehealth technologies in the delivery of home health care, we conclude that the provision of the Benefit by the Requestor in the context of home health services would not be an impermissible inducement under section 1128A(a)(5) of the Act.

III. CONCLUSION

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Benefit would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act, and, while the Benefit 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 [Company S] in connection with the Benefit 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).

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [Company S], the requestor of this opinion. This advisory opinion has no application, and cannot be relied upon, by any other individual or entity.

- This advisory opinion may not be introduced into evidence in any matter involving an entity or individual that is not a requestor to this opinion.

- 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 Benefit, including, without limitation, the physician self-referral law, section 1877 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 [Company S] with respect to any action that is part of the Benefit 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 Benefit 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, rescind, modify, or terminate this opinion. In the event that this advisory opinion is modified or terminated, the OIG will not proceed against [Company S] with respect to any action 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,

/s/

Lewis Morris
Chief Counsel to the Inspector General