



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:** June 29, 2017

**Posted:** July 7, 2017

[Names and addresses redacted]

### **Re: OIG Advisory Opinion No. 17-02**

Dear Gentlemen:

We are writing in response to your request for an advisory opinion regarding a hospital outpatient facility's proposal to reduce or waive, on a non-routine, unadvertised basis, cost-sharing amounts owed by financially needy Medicare beneficiaries for items and services furnished in connection with a clinical research study (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 prohibiting inducements to beneficiaries, section 1128A(a)(5) of the Social Security Act (the "Act"), or under the exclusion authority at section 1128(b)(7) of 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: (i) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the Proposed Arrangement 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] or [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 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] or [name redacted], the requestors 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**

[Name redacted] (the “Hospital”) is a non-profit, full-service, 171-bed regional medical center that provides extensive inpatient and outpatient services. The Hospital operates [name redacted] (the “Center”) as a hospital outpatient facility. The Center furnishes comprehensive wound care services, primarily to patients with chronic, non-healing wounds.

[Name redacted] (the “Biomedical Company,” and together with the Hospital, “Requestors”) manufactures biodynamic therapies for wound care, including the [product redacted] (“Wound Care System”). The U.S. Food & Drug Administration cleared the Wound Care System, which is indicated for the management of ulcers and exuding wounds. In August 2012, the Centers for Medicare & Medicaid Services (“CMS”) issued a National Coverage Determination (“NCD”) decision memorandum approving the Medicare Coverage with Evidence Development (“CED”) framework for the use of autologous platelet-rich plasma for chronic, non-healing diabetic, pressure, or venous wounds.<sup>1</sup> CMS approved three separate protocols under the CED framework (each, a “Study”) to study the treatment of Medicare beneficiaries’ chronic, non-healing wounds

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<sup>1</sup> See Centers for Medicare & Medicaid Services, Medicare National Coverage Determinations Manual, CMS Pub. 100-03, Ch. 1, Sec. 270.3 (Rev. 190, Feb. 5, 2016), available at [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1\\_Part4.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/ncd103c1_Part4.pdf).

using the Wound Care System.<sup>2</sup> The Center was cleared to participate in the Medicare CED clinical study program for the Wound Care System in December 2016.

Under each Study, Medicare covers the Wound Care System and related items and services furnished to Study-enrolled beneficiaries.<sup>3</sup> Medicare beneficiaries who enroll in a Study are randomized 1:1 to receive either the Wound Care System therapy or the control therapy, and are responsible for any copayment owed for the items and services they receive in connection with the Study.

Medicare beneficiaries who are also Medicaid beneficiaries (dual-eligible beneficiaries) often do not owe copayments for Medicare Part A and Medicare Part B services because Medicaid may pay for cost-sharing for Medicare items and services to the extent consistent with the Medicaid State Plan. However, Medicaid does not necessarily cover items and services provided in connection with clinical research studies, even in the context of a CMS-approved CED study and, therefore, may not pay for the cost-sharing of dual-eligible beneficiaries. As a consequence, it is possible that the cost-sharing obligations incurred through Study participation would deter dual-eligible beneficiaries from Study participation.

Under the Proposed Arrangement, the Center would reduce or waive applicable cost-sharing amounts owed by financially needy beneficiaries for all Study-related items and services.<sup>4</sup> The Biomedical Company certified that it would not compensate or reimburse the Center or the Hospital in any manner for reduced or waived cost-sharing amounts owed by Medicare beneficiaries. As part of the process of obtaining a beneficiary's informed consent for a Study, the Study investigator, or another appropriate staff member at the Center, would inform the beneficiary that he or she may owe cost-sharing amounts in connection with the Study regardless of whether the beneficiary receives the Wound

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<sup>2</sup> CMS originally approved four separate protocols under the CED framework to study the treatment of Medicare beneficiaries' chronic, non-healing wounds using the Wound Care System in February 2013. The Biomedical Company currently operates its clinical studies under CMS-approved revisions to three of the protocols.

<sup>3</sup> The only Biomedical Company product covered by the NCD is the Wound Care System. However, Medicare may also cover related items and services, including standard wound debridement and physician services.

<sup>4</sup> Requestors certified that the Center would reduce or waive cost-sharing for a financially needy Medicare beneficiary regardless of whether the Medicare beneficiary receives the Wound Care System therapy or the control therapy. In addition, the Hospital certified that, to the extent that the Hospital (or the Center) would furnish Medicare-covered items or services outside of the Study, the Hospital would reduce or waive cost-sharing for any such items or services in accordance with its financial need policy.

Care System therapy or the control therapy. If, at that point, the beneficiary notifies the investigator or other staff member that he or she lacks the financial resources necessary to cover the applicable cost-sharing, the Center would make a reasonable inquiry, and determine on an individualized basis, whether the Medicare beneficiary satisfies objective financial need criteria.<sup>5</sup> The Hospital certified that it would not claim any amounts stemming from cost-sharing reductions or waivers under the Proposed Arrangement as bad debt on its Medicare cost report.

Requestors certified that neither the Hospital, the Center, the Biomedical Company, nor any other person would advertise the Proposed Arrangement's cost-sharing reductions or waivers, nor would the potential for such reductions or waivers be mentioned in any public notices about the Studies.

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<sup>5</sup> Under the Proposed Arrangement, the Center would determine beneficiaries' financial need in accordance with the Hospital's financial need policy. According to the Hospital's financial need policy, to qualify for financial assistance, individuals must complete an application and provide the following documentation: (i) payroll check stubs from the most recent three months, (ii) the most recent tax return (if payroll check stubs are unavailable), (iii) unemployment records, (iv) documentation of government benefits, and (v) any other financial documentation reasonably requested by the Hospital. In addition, the Hospital's financial need policy requires patients to certify that all information provided on the financial need application is true. The Hospital's financial need policy prescribes that monthly family income and savings will be used in determining financial assistance eligibility. Per the policy, the Hospital determines family income using the Census Bureau definition of "income" which includes only certain income components. According to the Hospital's financial need policy, the reduction or waiver of cost-sharing varies, on a sliding scale, by family income based on certain percentages of the Federal Poverty Level. As we have previously stated, we do not specify any particular method of determining "financial need" because it varies with the circumstances. *See, e.g.*, 65 Fed. Reg. 24,400, 24,404 (Apr. 26, 2000). In addition, we have not previously specified what constitutes a "good faith" determination, as a reasonable inquiry to make such a determination would vary with the circumstances as well. We nevertheless believe that the policies and procedures set forth in the Hospital's financial need policy, which the Center would use to determine financial need under the Proposed Arrangement, would result in the Center making a reasonable inquiry, and determining on an individualized basis, whether the Medicare beneficiary satisfies objective financial need criteria.

## 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. 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), 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.

Section 1128A(a)(5) of the Act (“Beneficiary Inducement 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 (including Medicaid) beneficiary that the benefactor knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner, or supplier of any item or service for which payment may be made, in whole or in part, by Medicare or a State health care program (including Medicaid). The OIG may also initiate administrative proceedings to exclude such party from the Federal health care programs. Section 1128A(i)(6) of the Act defines “remuneration” for the purposes of the Beneficiary Inducement CMP as including “the waiver of coinsurance and deductible amounts (or any part thereof).” However, Section 1128A(i)(6) of the Act contains certain exceptions from the definition of remuneration for the purposes of the Beneficiary Inducement CMP. In particular, the waiver of coinsurance and deductible amounts are excepted from the definition of remuneration if:

- (i) the waiver is not offered as part of any advertisement or solicitation;
- (ii) the person does not routinely waive coinsurance or deductible amounts; and
- (iii) the person [making the waiver]—
  - (I) waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need; or
  - (II) fails to collect coinsurance or deductible amounts after making reasonable collection efforts.

Section 1128A(i)(6)(A) of the Act.<sup>6</sup> Subsections (i), (ii), and at least one prong of subsection (iii) must be satisfied for the exception to apply.

## **B. Analysis**

The Proposed Arrangement implicates the Beneficiary Inducement CMP and the anti-kickback statute, because the Center would reduce or waive cost-sharing amounts for wound care therapy furnished in connection with the Studies for eligible Medicare beneficiaries. Our concerns regarding routine waivers of Medicare cost-sharing amounts are longstanding, and providers that routinely waive Medicare cost-sharing amounts for reasons unrelated to individualized, good faith assessments of financial hardship may be held liable under the anti-kickback statute. See, e.g., Special Fraud Alert: Routine Waiver of Copayments or Deductibles Under Medicare Part B, 59 Fed. Reg. 65,372, 65,374 (1994). Such waivers may constitute prohibited remuneration to induce referrals. However, if the Proposed Arrangement satisfies all of the criteria of the exception to the Beneficiary Inducement CMP’s definition of “remuneration” for waivers of cost-sharing amounts, it would not result in prohibited remuneration for the purposes of the Beneficiary Inducement CMP. For the following reasons, we conclude that the Proposed Arrangement satisfies all of the criteria of the exception for waivers of cost-sharing amounts.

First, Requestors certified that neither the Hospital, the Center, the Biomedical Company, nor any other person would offer the cost-sharing reduction or waiver as part of any advertisement or solicitation under the Proposed Arrangement. In addition, the investigator or another appropriate staff member at the Center would inform the potential Study participant of a possible cost-sharing reduction or waiver only after the potential Study participant indicated that he or she may lack the requisite financial resources to cover the cost-sharing amounts. Second, the reduction or waiver of cost-sharing amounts under the Proposed Arrangement would not be made routinely; rather, a reduction or waiver would be contingent on the Medicare beneficiary’s inability to pay the cost-sharing amounts owed, which the Center would determine on a case-by-case

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<sup>6</sup> The regulatory definition of “remuneration” includes the same exception. *See* 42 C.F.R. § 1003.110.

basis using a financial need application process substantiated through required documentation, in accordance with the Hospital's financial need policy. Third, the Center would reduce or waive the cost-sharing amounts after determining, in good faith, that the individual is in financial need. In particular, the Center would make all financial eligibility determinations using objective criteria based on the potential Study participant's family income level as measured against certain percentages of the Federal Poverty Level. Requestors have certified that individualized determinations of financial need would be made in a uniform manner, using an application process, and in accordance with the policies and procedures set forth in the Hospital's financial need policy.

Accordingly, the Proposed Arrangement satisfies all of the criteria of the exception for waivers of cost-sharing amounts and would not constitute remuneration under the Beneficiary Inducement CMP. In light of the same safeguards set forth above, we also conclude that we would not subject Requestors to administrative sanctions under the anti-kickback statute 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: (i) the Proposed Arrangement would not constitute grounds for the imposition of civil monetary penalties under section 1128A(a)(5) of the Act; and (ii) although the Proposed Arrangement 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] and [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 the Proposed Arrangement.

### **IV. LIMITATIONS**

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to [name redacted] and [name redacted], the requestors 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] or [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 [name redacted] or [name redacted] 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 [name redacted] or [name redacted] 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,

/Gregory E. Demske/

Gregory E. Demske  
Chief Counsel to the Inspector General