[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.]

[name and address redacted]

RE: CMS Advisory Opinion No. CMS-AO-2013-02

Dear [name redacted]:

We write in response to your request for an advisory opinion regarding an arrangement under which [name redacted] ("Requestor") would provide without charge to physicians who make referrals to Requestor for designated health services payable by Medicare ("Referring Physicians") disposable [brand name redacted] biopsy brushes (the "Devices") for use in obtaining a biopsy of visible exocervical lesions (the "Arrangement"). Specifically, you seek a determination as to whether the provision of free Devices constitutes "remuneration" that gives rise to a "compensation arrangement" under section 1877(h)(1) of the Social Security Act (the "Act").

You certified that all of the information provided in your request, including all supplementary materials and documentation, is true and correct and constitutes a complete description of the relevant facts and arrangements between the parties. In issuing this opinion, we relied solely on the facts and information you presented to us and information available to the general public as noted herein. We have not undertaken an independent investigation of this information. If material facts have not been disclosed or have been misrepresented, this advisory opinion is without force and effect.

Based on the specific facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Arrangement would result in the provision of remuneration to Referring Physicians and, therefore, the Arrangement constitutes a compensation arrangement between Requestor and Referring Physicians within the meaning of section 1877(h)(1) of the Act. We do not address whether the Arrangement satisfies the requirements of an exception to the physician self-referral prohibition.

This opinion may not be relied on by any persons other than Requestor and is further qualified as set forth in section IV below and in 42 C.F.R. §§ 411.370 through 411.389.

I. FACTUAL BACKGROUND

Requestor is a for-profit corporation located in [state redacted]. Requestor provides clinical laboratory services to various health care providers, including Referring Physicians. The clinical laboratory services are billed by Requestor to various payors, including Medicare and Medicaid.

Under the Arrangement, Requestor would provide the Devices to Referring Physicians without charge. Requestor certified that the Device is a patented, sterile, disposable, single-use, cervical

biopsy device used to obtain tissue from areas of the cervix appearing to be abnormal during vaginal examinations. The Device is a brush biopsy and is intended as an alternative to the traditional punch biopsy, which pierces and removes tissue to obtain a sample for testing. It has been cleared for sale by the U.S. Food and Drug Administration ("FDA").[1] Referring Physicians use the Device to biopsy areas of the cervix, and tissue is sent to Requestor to test for abnormal precancerous conditions and cervical cancer. Requestor certified that the American Medical Association's Current Procedural Terminology ("CPT")[2] code reported to document the collection of specimens using the Device is the same as that used to document collection via punch biopsies (CPT code 57454, Colposcopy of the cervix including upper/adjacent vagina; with biopsy(s) of the cervix and endocervical curettage). According to Requestor, when the Device is used, its tip is broken off and sent to the laboratory in a small specimen bottle with formalin to preserve the specimen. The Device cannot be reused.

II. LEGAL ANALYSIS

A. Law

Under section 1877 of the Act and the regulations in 42 C.F.R. § 411.350 et seq. (collectively, the physician self-referral law), a physician may not refer a Medicare beneficiary for certain designated health services ("DHS") to an entity with which the physician (or an immediate family member of the physician) has a financial relationship, unless an exception applies. The physician self-referral law also prohibits an entity from submitting claims to Medicare, the beneficiary, or any other entity for DHS that are furnished as a result of a prohibited referral.[3]

In section 1877(h)(1)(A) of the Act, "compensation arrangement" is defined as "any arrangement involving any remuneration" between a physician (or an immediate family member of such physician) and an entity furnishing DHS. Section 1877(h)(1)(B) of the Act defines "remuneration" to include "any remuneration, directly or indirectly, in cash or in kind." However, under section 1877(h)(1)(C) of the Act, "remuneration" does not include "[t]he provision of items, devices, or supplies that are used solely to . . . collect, transport, process, or store specimens for the entity providing the item, device, or supply." Through rulemaking, we

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[1] Section 510(k) of the Federal Food, Drug, and Cosmetic Act requires certain device manufacturers to notify the FDA, at least 90 days in advance, of their intent to market medical devices. The FDA does not "approve" medical devices under the 510(k) process; rather, upon completion of the process, the medical device is "cleared" for sale. *See* www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketnotification510k/default.htm.

[2] CPT codes and descriptions only are copyright 2013 American Medical Association. All rights are reserved and applicable FARS/DFARS clauses apply.

[3] In 1993, the physician self-referral prohibition was made applicable to the Medicaid program, effective January 1, 1995. 42 U.S.C. § 1396b(s).

have interpreted this statutory provision to exclude surgical items, devices, or supplies from the types of items, devices, or supplies that would not constitute remuneration.[4]

B. Analysis

We believe that the Device is a surgical item, device, or supply. To inform our analysis, we considered the FDA rules and regulations. We began our analysis by reviewing the FDA regulation that addresses certain surgical devices. In 21 C.F.R. § 878.4800(a), the FDA defines a "manual surgical instrument for general use" as a non-powered, hand-held, or hand manipulated device, either reusable or disposable, intended to be used in various general surgical procedures. This provision lists approximately 50 types of devices intended for use in various surgical procedures, including a biopsy brush. It also states that surgical instruments that have specialized uses are further classified in separate regulations in 21 C.F.R., Parts 868 through 892.[5] In these regulations, instruments are classified as Class I, II or III, which indicates the level of premarket notification or approval required by the FDA for the instrument.

Although informative, the FDA regulations are not dispositive for purposes of our analysis under the physician self-referral law. In order to determine conclusively whether the Device is a "surgical device" for purposes of the physician self-referral law, we considered the intended purpose of the Device and whether it is "routinely used as part of a surgical or medical procedure."[6]

First, we reviewed the 510(k) premarket notification submitted to the FDA to determine the intended purpose of the Device. The 510(k) premarket notification indicates that the Device is intended for use in obtaining a biopsy of visible exocervical lesions. The notification also indicates that the Device is a brush biopsy, which is an alternative to other forms of biopsy, such as the punch biopsy.[7] Next, we considered the medical procedures for which the Device is routinely used and which are billed to the Medicare program. Requestor certified that the CPT code reported when specimens are obtained using the Device is CPT code 57454 (Colposcopy of the cervix including upper/adjacent vagina; with biopsy(s) of the cervix and endocervical curettage), the same CPT code reported for punch biopsies. Because all biopsies are categorized by the American Medical Association as surgical procedures,[8] and in light of our review of the 510(k) premarket notification, we conclude that the Device is "routinely" (if not predominantly) used as part of a surgical procedure. Finally, we consulted with CMS medical officers, who confirmed that: (1) biopsies are surgical procedures; (2) the Device routinely is used to obtain a biopsy of a visible lesion of the cervix and, therefore, it is a "surgical" device; and (3) the

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[4] 42 C.F.R. § 411.351 (defining "remuneration"). For relevant preamble discussion, see 66 Fed. Reg. 856, 947-948 (Jan. 4, 2001) and 63 Fed. Reg. 1659, 1693-94 (Jan. 9, 1998).
[5] *See* 21 C.F.R. § 878.4800(a).
[6] 63 Fed. Reg. at 1693-94.
[7] *Id*.
[8] The American Medical Association, Current Procedural Terminology (CPT) 2013, Professional Edition, pp. 289, 295 (2013).

surgical procedure for which the Device is routinely used is substantially different from and goes well beyond the mere scraping of surface cells seen in a Pap smear.

After consideration of the factors described above, we conclude that the Device is a "surgical item, device,` or supply" for purposes of physician self-referral law. Therefore, the provision of the Device by Requestor at no cost to Referring Physicians would result in remuneration to Referring Physicians.

III. CONCLUSION

Based on the specific facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Arrangement would result in remuneration to Referring Physicians and thereby create a "compensation arrangement" that implicates the physician self-referral law. Our analysis is limited solely to the furnishing of the Device by Requestor to Referring Physicians. We have not considered, nor do we express an opinion about, any other relationships between Requestor and Referring Physicians. We make no determination regarding the applicability of, or compliance with, any exception to the physician self-referral prohibition.

IV. LIMITATIONS

The limitations applicable to this opinion include the following:

- This advisory opinion is issued only to 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 in any matter involving an entity or individual that is not a requestor of this opinion.

- This advisory opinion is applicable only to the statutory and regulatory 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 Requestor or Referring Physicians, including, without limitation, the Federal anti-kickback statute, section 1128(B)(b) of the Act.

- This advisory opinion will not bind or obligate any agency other than the U.S. Department of Health and Human Services. The Centers for Medicare & Medicaid Services reserve 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.

- 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 in 42 C.F.R. §§ 411.370 through 411.389.

Sincerely,

Elizabeth Richter
Acting Director, Center for Medicare

cc: [name redacted]