

[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-2013-01

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”) liquid-based Pap smear specimen collection kits (the “Devices”) for use in obtaining cells for screening to detect abnormal growth of cervical cells (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. 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 not result in “remuneration” to Referring Physicians and, therefore, the Arrangement would not create a compensation arrangement between Requestor and Referring Physicians within the meaning of section 1877(h)(1) of the Act.

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 limited liability company located in [state redacted]. Requestor provides clinical laboratory services to various health care providers, including Referring Physicians. The clinical laboratory services are generally billed by Requestor to various payors, including Medicare and Medicaid. Requestor creates the Devices by packaging one or two

collection tools with a vial of fixative and labeling the kit with Requestor's name and/or brand.¹ Requestor certified that all component parts of the Device are patented, U.S. Food and Drug Administration ("FDA") cleared, disposable, single-use instruments used to collect specimens for Pap smear examination or liquid-based cytology.² Under the Arrangement, Requestor would provide the Devices to Referring Physicians without charge.

A Pap smear examines cells from both the ectocervix and endocervix. Generally, ectocervical cells are collected using a spatula, while endocervical cells are collected using a brush. In the alternative, a single combination collection tool may be used to obtain both ectocervical and endocervical cells at the same time. In its request for an advisory opinion, Requestor provided examples of the contents of the Devices: (1) where the Device contains separate ectocervical and endocervical collection tools, both a plastic disposable spatula and a brush are included; and (2) where the Device contains a single tool that collects both ectocervical and endocervical samples, a combination spatula/brush tool is included. Regardless of whether a Device contains two collection tools and a vial of fixative or one collection tool and a vial of fixative, all component parts of the Device are expended in the Pap smear sample collection process.

Requestor certified that it tracks the number of Devices that are provided to Referring Physicians, and through its monitoring procedures, ensures that the number of Devices received by Referring Physicians approximates the number of specimens sent to the Requestor by the Referring Physicians. Finally, Requestor certified that HCPCS code Q0091 (Screening Papanicolaou smear; obtaining, preparing and conveyance of cervical or vaginal smear to laboratory) is reported when Pap smear specimens for screening purposes are obtained using the Device.

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

¹ Requestor certified that it obtains the individual components of the Pap smear collection kits from their various manufacturers.

² Per Centers for Medicare & Medicaid Services ("CMS") medical officers, in liquid-based cytology, the specimen cells are collected in a manner similar to the Pap smear. However, rather than smearing the sample onto a microscope slide (as with the Pap smear), the head of the collection tool, where the cells are lodged, is broken off into a small vial containing preservative fluid, or rinsed directly into the preservative fluid. For purposes of this advisory opinion, we refer to both a Pap smear and liquid-based cytology as "Pap smear."

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 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

In determining whether the Devices constitute “remuneration,” we must first determine if they are “surgical items, devices, or supplies” that would not qualify for the exception to the definition of “remuneration.” If the Devices are not surgical items, devices, or supplies, we must determine if they are “used solely to . . . collect, transport, process, or store specimens for the entity providing the item, device, or supply.” We address each issue in turn.

1. Nature of the Devices

To inform our analysis regarding the surgical nature of the Devices, 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 spatula. 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, which classify instruments as Class I, II or III to indicate the level of premarket notification or approval required by the FDA for the instrument. Each of the component collection tools identified by Requestor is classified under 21 C.F.R. § 884.4530 as a cervical, cytological spatula.

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 Devices are a “surgical items, devices, or supplies” for purposes of the physician self-referral law, we considered the intended purpose of the Devices and whether they are “routinely used as part of a

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).

⁴ 42 C.F.R. § 411.351 (defining “remuneration”). For relevant preamble discussion, see 66 Fed. Reg. 856, 946-947 (Jan. 4, 2001) (“Phase I”) and 63 Fed. Reg. 1659, 1693-94 (Jan. 9, 1998).

surgical or medical procedure.”⁵ First, we reviewed publicly available marketing materials and the premarket notifications made by the manufacturers of the Devices’ component collection tools. Those materials revealed that the collection tools (and, thus, the Devices) are intended for use during the Pap smear specimen collection process to collect ectocervical and endocervical cells from the patient’s cervix for screening for abnormal growth of cervical cells.

Next, we considered the medical procedures for which the Devices are generally used and how such procedures are billed to the Medicare program. Requestor certified that the HCPCS code Q0091 (Screening Papanicolaou smear; obtaining, preparing and conveyance of cervical or vaginal smear to laboratory) is reported when Pap smear specimens are obtained using either Device.⁶ The American Medical Association’s Current Procedural Terminology (CPT) Manual, which provides billing codes for medical procedures, categorizes Pap smears as screening procedures, a category separate and distinct from surgical procedures.⁷ Finally, we confirmed with CMS medical officers our conclusion that: (1) Pap smears, the use for which the Devices are intended, are not surgical procedures; and (2) because the Devices are used for a screening examination, rather than surgical procedure, they are not “surgical” devices.

After consideration of the factors described above, we conclude that the Devices are not “surgical items, devices, or supplies” for purposes of the physician self-referral law.

2. Use of the Devices

Although we conclude that the Devices are not surgical in nature, our response also requires consideration whether the Devices are used solely to collect, transport, process, or store specimens for Requestor. As we noted in the Phase I preamble, we believe that the Congress intended to exclude from the definition of “remuneration” items, devices, and supplies that are of low value and provided primarily to ensure proper collection of specimens for processing at the laboratory.⁸ We also stated that the provision of an excessive number of collection supplies creates an inference that the supplies are not provided “solely” to collect, transport, process, or store specimens for the entity that furnished them.⁹ Finally, we indicated that reusable items may have value unrelated to the collection of specimens for processing by the laboratory.¹⁰

Requestor certified that the Devices have no practical use other than to collect laboratory specimens. Information publicly available from the manufacturers of the component parts of the Devices identified by Requestor indicate that the collection tools are all disposable and intended

⁵ 63 Fed. Reg. at 1694.

⁶ See Medicare Claims Processing Manual, Internet Only Publication 100-4, Chapter 18 (Preventive and Screening Services), Section 30.5 (Screening Pap Smears/HCPCS Codes for Billing).

⁷ The American Medical Association, Current Procedural Terminology (CPT) 2013, Professional Edition, p. 443 (2013).

⁸ 66 Fed. Reg. at 947.

⁹ *Id.* at 948.

¹⁰ *Id.* at 947.

for a single use only. Requestor also certified that it has a system in place to ensure that Referring Physicians receive only the quantity of Devices appropriate for their practice needs, compare the number of specimen vials returned to the number of Devices distributed to Referring Physicians, and address potential instances of separation of the Devices into their individual component parts for use other than to collect Pap smear specimens. Finally, Requestor certified that none of the component parts of a Device can be reused, as they would be contaminated by the initial use.

Based on the Requestor's certifications and the publicly available information noted, we conclude that the Devices, when composed exclusively of single-use collection tools (and a vial of fixative), are used solely to collect, transport, process, or store specimens for Requestor within the meaning of section 1877(h)(1)(C)(ii) of the Act and 42 C.F.R. § 411.351. We caution that the provision of a kit containing a collection tool that is not a "single-use" item, device, or supply may result in a different conclusion.

In summary, given the nature and use of the Devices, we find that the Requestor's provision of the Devices at no cost to Referring Physicians is not remuneration for purposes of section 1877(h) of the Act.

III. CONCLUSION

Based on the specific facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Arrangement does not result in remuneration to Referring Physicians and, therefore, does not create a "compensation arrangement" that implicates the physician self-referral law. Our analysis is limited solely to the furnishing of the Devices by Requestor to Referring Physicians. We have not considered, nor do we express an opinion about, any other relationships between Requestor and Referring Physicians.

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.

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- 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]