

[Name Redacted]

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[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: Advisory Opinion No. CMS-AO-2010-01**

Dear [Name Redacted]:

We are writing in response to your request for an advisory opinion regarding an arrangement (the “Arrangement”) under which [name redacted] (the “Requestor”) would provide disposable, single-use specula for use in the collection of Papanicolaou (“Pap”) smear specimens to physicians who refer Pap smears to the Requestor for testing (the “Referring Physicians”). Specifically, you seek a determination as to whether the Arrangement constitutes a compensation arrangement within the meaning of section 1877(h)(1)(A) of the Social Security Act (the “Act”).

You have certified that all of the information you have provided in your request, including all supplementary materials and documentation, is true and correct, and constitutes a complete description of the relevant facts and agreements among the parties. In issuing our opinion we have relied solely on the facts and information 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 facts certified in your request for an advisory opinion and for the reasons set forth below, we conclude that the Arrangement would result in a compensation arrangement between the Requestor and the Referring Physicians within the meaning of section 1877(h)(1)(A) 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 the Requestor of this opinion, 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**

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

The Requestor provides plastic, single-use disposable specula for use by physicians in the collection of Pap smear specimens. The specula are made available by the Requestor to all physicians who refer Pap smear specimens to it and who request such supplies. A significant majority of the specula provided are lighted and cost approximately \$1.68 each. The remainder of the specula provided are not lighted and cost approximately one-fifth as much as the lighted specula. As a means to ensure that the specula provided by the Requestor are used in connection with the collection of Pap smear specimens, the Requestor monitors the number of Pap smear specimens referred by physicians and adjusts the quantity of specula provided to a particular physician based on the number of Pap smear tests referred by that physician for testing by the Requestor.

Pap smear specimens are typically collected as part of an extensive gynecological examination of the patient. Such an examination requires the use of a speculum, regardless of whether a Pap smear specimen is collected. According to the Requestor, specula are fungible and it is possible that a Referring Physician could use a speculum provided by the Requestor to conduct an examination in which no Pap smear is collected (although the Requestor expects that the specula it provides to Referring Physicians are not often used when a specimen is not collected). In addition, the Requestor has no way to prevent the concurrent use of a speculum for the collection of a Pap smear specimen and the gynecological examination of a patient.

## II. LEGAL ANALYSIS

### A. Law

Under section 1877 of the Act (42 U.S.C. §1395nn), a physician may not refer a Medicare patient 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. Section 1877 also prohibits the entity furnishing the DHS from submitting claims to Medicare, the beneficiary, or any other entity for Medicare DHS that are furnished as a result of a prohibited referral.<sup>1</sup> Clinical laboratory services, such as those provided by the Requestor, are DHS.

In section 1877(h)(1)(A) of the Act, a compensation arrangement is defined as “any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity other than an arrangement involving only remuneration described in subparagraph (C).” Section 1877(h)(1)(C) of the Act defines “remuneration” to include “any remuneration, directly or indirectly, in cash or in kind.” Section 1877(h)(1)(C) also identifies certain types of remuneration which, if provided, would not create a compensation arrangement subject to the physician self-referral prohibition. Such remuneration includes “[t]he provision of items, devices, or supplies that are used solely to...collect, transport, process, or store specimens for the entity

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<sup>1</sup> In 1993, the physician self-referral prohibition was made applicable to the Medicaid program. 42 U.S.C. § 1396.

providing the item, device, or supply.” *See, also*, the definition of “remuneration” at 42 C.F.R. § 411.351.

### **B. Analysis**

Based on the facts certified by the Requestor, the Requestor furnishes specula to the Referring Physicians upon request and at no cost to the Referring Physicians. The Referring Physicians use the specula to collect Pap smear specimens for referral to the Requestor for testing, as well to conduct routine gynecological examinations of their patients. Because the specula are not used by the physicians solely to collect, transport, process, or store specimens referred to the Requestor, the provision of the specula to the Referring Physicians constitutes remuneration other than the type specified in section 1877(h)(1)(C) of the Act, and such remuneration meets the definition of “compensation arrangement” for purposes of the statute’s prohibition on physician self-referral as set forth in section 1877(h)(1)(A) of the Act.

### **III. CONCLUSION**

Based on the facts certified in your request for an advisory opinion and supplemental submissions, we conclude that the Arrangement constitutes a compensation arrangement under section 1877(h)(1)(A) of the Act. Our analysis is limited to the furnishing of specula by the Requestor to the Referring Physicians upon request. We make no determination as to compliance with the physician self-referral law, or an applicable exception thereto.

### **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 the 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 the Requestor, including, without limitation, the Federal anti-kickback statute, section 1128B(b) of the Act (42 U.S.C. §1320a-7b(b)).

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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. CMS 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.
- 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. §§411.370 through 411.389.

Sincerely,

Jonathan D. Blum  
Deputy Administrator  
Director, Center for Medicare