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Strictly Speaking: CMS Stark Law Guidance to Labs on Speculums and Other Supplies

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Clinical and pathology laboratories and their legal counsel have debated for years the legality of providing free speculums to clinicians to aid in collecting Pap smear specimens to send to the laboratory for testing. Proponents justified the practice on the grounds that (1) Pap specimens cannot be collected without speculums; (2) a speculum is needed to ensure collection of a viable and reliable Pap specimen; (3) speculums are relatively inexpensive; and (4) labs can readily correlate the volume of speculums provided with the number of Pap tests for which they are used. In its Stark law advisory opinion issued last year and posted at its website earlier this year, CMS directly rejected those justifications, and concluded that the Stark law prohibits the practice of providing inexpensive disposable single-use speculums to physicians who refer testing reimbursed by Medicare or Medicaid, unless a specific Stark law exception applies.

The Advisory Opinion underscores the government's strict interpretation of its strict liability Stark statute. Given the significant penalties for the failure to understand and meet the technical, and perhaps illogical, requirements of Stark, clinical and pathology laboratories are well advised to review their policies and practices relative to providing supplies and equipment to ordering physicians.

CMS Advisory Opinion CMS-AO-2010-01, issued in response to a formal request from an unnamed laboratory, reviewed the practice by the lab of providing to its physician customers, at no charge, two types of disposable, single-use speculums costing $.30 and $1.68. CMS explained that the Stark law does not prohibit labs from providing physicians with items, devices, or supplies used solely to collect, transport, process, or store specimens, or to order or communicate test results. CMS noted the lab's representation that the speculums were "*not often used when a specimen is not collected*" and that the lab monitored the number of specimens to limit the quantity of speculums provided. CMS nonetheless concluded that "*[b]ecause the specula are not used by the physicians solely to collect, transport, process, or store specimens referred to the [laboratory], the provision of specula to the Referring Physicians constitutes remuneration*" prohibited by the Stark law. CMS reasoned, "*Pap smear specimens are typically collected as part of an extensive gynecological examination of the patient. Such examination requires the use of a speculum, regardless of whether a Pap smear specimen is collected.*"

CMS makes clear that the pivotal question under the Stark law is not whether the supply or equipment in question is necessary for the referring physician to collect, transport, process, or store specimens to be sent to the laboratory. Rather, the test is whether the supply or equipment is used exclusively for these purposes, even if the requested lab tests cannot be performed or reported without it.

In prior commentary to the proposed Stark II regulations in 1998, CMS explained:

We interpret "solely" in this context to mean that these items are used solely for the purposes listed in the statute, such as cups used for urine collection or vials used to hold and transport blood to the entity that supplied the items or devices. [CMS does not] regard specialized equipment such as disposable or reusable aspiration or injection needles and snares as solely collection or storage devices. Instead, these items are also surgical tools that are routinely used as part of a medical or surgical procedure.

Two years later, CMS explained further in its commentary to the final Stark II regulations:

We wish to clarify our views on the "items, devices, and supplies" provision here. First, in enacting section 1877(h)(1)(C)(ii) of the Act, we believe that the Congress ... intended to include in this section items, supplies, and devices of low value, such as single use needles, vials, and specimen cups, that are primarily provided by laboratories to physicians to ensure proper collection of specimens for processing at the laboratory and that have little, if any, independent economic value to the physicians who receive them. In many cases, the cost of these items may already be included in the practice expense portion of the Medicare payment made to the physician.

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As to those single use, low value items, devices, and supplies that come within the scope of section 1877(h)(1)(C)(ii) of the Act, the fact that the number of supplies provided to a physician approximates the number of specimens sent by the physician to the laboratory providing the supplies is merely one indicator that the supplies have been provided in connection with specimen collection for the entity providing the supplies. The numerical correlation is not a statutory or regulatory requirement. However, the provision of an excessive number of supplies creates an inference that the supplies are not provided solely to collect, transport, process, or store specimens for the entity providing them.

While we recognize that sterile gloves are essential to the proper collection of specimens, we believe they are not items, devices, or supplies used solely to collect, transport, process, or store specimens. To be sure, sterile gloves are essential to the specimen collection process, but their main function is to prevent infection or contamination. Also, sterile gloves are fungible, general purpose supplies typically found in a physician's office and used for a wide

range of examinations and procedures. We believe it would be impractical for physicians' offices to monitor and regulate the use of gloves so as to limit their use to the collection of specimens for the laboratory that provided them. Accordingly, we believe the provision of free gloves is remuneration subject to the general prohibition of section 1877 of the Act, in the absence of an applicable exception.

Because the Stark law is a strict liability statute, lab practices that violate the Stark law, even if they can be justified as "reasonable" or "common sense" business practices, may result in denial or refunds of Medicare/Medicaid payments for prohibited referrals, monetary penalties of up to $15,000 per claim, fines of up to double the amount claimed, and exclusion from the Medicare/Medicaid Programs. The Stark law can also result in a violation of the federal False Claims Act, resulting in civil penalties of $5,500 to $11,000 per false claim and damages of 3 times the amount of each false claim, exclusion from federal programs, and imprisonment for up to 5 years.

The need for strict compliance with the Stark law is illustrated by the March 2011 settlement between the OIG and Fairview Northland Regional Health Care in Minnesota. After it self-disclosed conduct to the OIG, the medical center agreed to pay $50,000 for allegedly violating the Civil Monetary Penalties Law provisions applicable to physician self-referrals and kickbacks. The OIG alleged that the hospital entered into an *unwritten lease agreement* with a physician practice. Stark requires that a lease with a referring physician be in writing, signed by both parties, for a term of at least one year, at a fair market value rental rate. The case underscores that the OIG cares about technical as well as substantive compliance with the Stark law.

Once laboratories understand the restrictions of the Stark law and regulations relating to the provision of supplies to physicians, two very significant practical challenges remain: (1) convincing physician clients that the lab is not simply trying to reduce its own costs at the doctor's expense; and (2) combating the practices of competitor labs that do not understand the Stark rules or do not care about the consequences of violating the law. The CMS Advisory Opinion concerning speculums may be another helpful document to share with customers, and perhaps with competitors. Another step taken by laboratories in California several years ago was to work within their trade association to seek legal guidance regarding prohibited supplies. In 2001, the California Clinical Laboratory Association (CCLA) first sought a legal opinion regarding the Stark law restrictions on client supplies, and then approved a resolution adopting that opinion. The CCLA guidance listed the following supplies as prohibited by the Stark law: alcohol pads K-Y or other lubricating jelly antibacterial soap microscope slides aspiration needles (reusable or disposable) parafilm band aids phlebotomy chairs baggies or zip lock bags plain paper for copier betadine swabs Q-tips biopsy needles reagents for in-office testing butterfly needles refrigerators catheter kits rubber bands coban wrap pressure bandage for wounds snares cotton balls speculums cover slips syringes examination gowns table paper facial tissues test kits gauze test tube racks germicidal

soap tongue blades gloves tourniquets hazardous material labels urine cups (non-sterile, without lid) hemocult developer urine dip sticks hypoallergenic tape injection needles (reusable or disposable; large and small)

Although some competitors and physicians in California continue to disregard this guidance, compliance-minded California laboratories have been able to use the guidance to help "level the playing field." At that time, CCLA also encouraged other industry trade associations to consider similar steps. CCLA also requested the OIG to provide the industry with formal guidance, through commentary, Fraud Alert, regulation or otherwise, to provide a clearer and more detailed standard for all laboratories inside and outside of California to follow—and utilize to convince physicians to follow. Although no such catalogue has been issued, both the OIG speculum opinion and the guidance cited in this article substantiate the list provided by the CCLA list.

As an additional caution, laboratories also must recall that the provision of supplies and equipment to lab customers implicates the federal anti-kickback statute. The general rule under the anti-kickback statute is that the statute is implicated any time a laboratory gives supplies to its clients for free or at less than fair market value—note that the statute contains no exemption for *de minimus* forms of remuneration. However, the HHS OIG in its 1994 Fraud Alert, clarified that the statute may not be implicated when a laboratory provides its clients with certain types of supplies that are integral to, and solely used for, performance of the outside laboratory's work:

The following are additional examples of inducements offered by clinical laboratories which may implicate the anti-kickback statute:

Provision of computers or fax machines, unless such equipment is integral to, and exclusively used for, performance of the outside laboratory's work.

OIG has made additional statements concerning free supplies since that time. Based upon these instructions from OIG, the general rule seems to be that a laboratory services provider can provide free supplies to the extent (1) they are not *provided to the physicians by the laboratories in exchange for referrals*; (2) they are *integral to, and exclusively used for, performance of the outside laboratory's work*; and (3) they do not *have a clear independent value to physicians*.

In conclusion, laboratories are strongly encouraged as part of their now mandatory compliance programs to adopt careful guidelines in connection with their offering and providing of supplies to physician clients. Some suggested guidelines include:

1. In no case should the provision of supplies to the physician client be offered to induce referrals of the physician client's testing business—thus, the lab should not use the provision of supplies as a sales or marketing pitch.

2. Supplies must be used by physicians solely to collect, transport, process, or store specimens referred to the laboratory.
3. The lab should adopt and adhere to a detailed list of permitted and/or prohibited supplies—the CCLA list is a very good place to start.
4. No supplies provided by the lab should be used for the collection, transportation, processing, storage or preparation of specimens for testing to be performed and/or billed by the physician client. The lab should take care to ascertain whether the physician client performs in-office testing, and regulate the provision of lab supplies accordingly.
5. The lab should maintain and document its procedures to police unauthorized use of the supplies. At a minimum, quantities of supplies must be carefully monitored and correlated to the volume of specimens typically sent to the laboratory for processing.