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August 29, 2008

Kerry Weems
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-1403-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW.
Washington, DC 20201

VIA COURIER

Re: CMS-1403-P entitled “Medicare program; Revisions to Payment Policies Under the Physician Fee Schedule and other Revisions to Part B for CY 2009.”

Dear Mr. Weems:

The College of American Pathologists (CAP) appreciates the opportunity to comment on the proposed rule CMS-1403-P entitled “Medicare program; Revisions to Payment Policies Under the Physician Fee Schedule and other Revisions to Part B for CY 2009.” We are also submitting comments on other issues contained in the proposed rule in a separate letter. The CAP is a national medical specialty society representing more than 17,000 physicians who practice anatomic and/or clinical pathology. CAP members practice their specialty in clinical laboratories, academic medical centers, research laboratories, community hospitals and federal and state health facilities.

“Physician Self-Referral and Anti-Markup Issues”:

The CAP has been a longstanding advocate for CMS’s efforts to promulgate regulations that implement the purposes of the Physician Self-Referral Act, 42 U.S.C. § 1395nn. The CAP, as an advocate for high-quality and cost-effective medical care, believes that ordering physicians should not have an economic self-interest in laboratory testing. When ordering physicians order on the basis of financial interest, tests are over-utilized, results are of a lower quality and efficiencies in laboratory medicine are reduced. In recent years, the CAP has seen a proliferation of schemes that allow physician groups to

profit from their self-referrals for anatomic pathology services. The CAP accordingly has alerted CMS of the need to take appropriate action. Unfortunately, actions taken to date have not quelled the growth in self-referral arrangements, particularly among urologists, gastroenterologists and dermatologists.

The CAP applauds CMS for once again proposing substantive changes to the Reassignment Rule and the Physician Self-Referral Regulations to address a number of the existing abuses in the billing and payment for pathology services. The CAP urges CMS to take prompt, definitive action to finalize bright-line tests specifying the level of involvement in laboratory testing required before a referring practice can bill for lab tests that they order. Any delay for further study only permits greater numbers of self-referral ventures to be established, making it ever harder to reign in abuses.

The CAP supports CMS's approach of addressing this issue in part through a broadening of the anti-markup provision. The CAP believes that self-referral arrangements can only be controlled by removing the economic self-interest of ordering physicians. However, the CAP wants to ensure that any anti-markup rule is drafted in a manner that recognizes that entities like pathology practices and independent laboratories that do not order lab tests not be hindered by any such rule.

In this regard, the CAP urges CMS to except from application of the anti-markup provision single specialty pathology physician groups and independent laboratories who generally do not order tests and utilize pathology/laboratory CPT codes for at least 75% of their billings. The CAP also urges CMS to exclude anatomic pathology from the in-office ancillary services exception to the physician self-referral regulations. Excluding anatomic pathology from ancillary services is the best method for preventing self-referral abuses without risk of inadvertent consequences to pathology groups. These recommendations are discussed below.

A. Changes to Reassignment and Physician Self-Referral Rules Related to Diagnostic Tests (Anti-Markup Provision)

CMS has long recognized that when physicians who order diagnostic testing also have an economic interest in billing and collecting for the tests ordered, the result often is program and patient abuse, over utilization and higher costs. Over the years, CMS and Congress have imposed rules and limitations to prohibit physician self-referral for tests. These rules initially prohibited physicians from billing for tests they did not perform (42 U.S.C. § 1395l(h)(5)). The result was a proliferation of joint venture laboratories owned in part by referring physicians. Congress then prohibited physicians from referring to labs in which the physician had an economic interest (42 U.S.C. § 1395nn). The result has been a proliferation of pod labs and in-practice labs that have little connection to the practice which claims the lab for billing purposes. The CAP believes that the next necessary step in regulations is to define requirements before a lab can be considered part of a group practice.

CMS has proposed using the vehicle of the anti-markup regulation as a reasonable basis for limiting the ability of an ordering practice to profit from laboratory tests. In the CY 2008 Physician Fee Schedule final rule, CMS revised the anti-markup provision to apply to the technical component (TC) and professional component (PC) of diagnostic tests that are ordered by the billing physician or other supplier when the TC or PC is outright purchased or when the TC or PC is not performed in the office of the billing physician or other supplier. That form of the anti-markup rule has been effective in addressing certain distant pod labs that perform services far removed from the ordering physician practice. However, practices intent on profiting from their referrals have simply moved the pods from an off-site location to some small space within the practice. Such practices have had little difficulty complying with the geographic requirement. As a result, little has changed: the laboratory has little connection with the practice that orders the testing other than geographic location. Ordering practices now contract with independent contractor pathologists with little connection to the practice and require that the pathologist read out the case on the premises of the ordering physician practice.

To address the problem of practices nominally bringing the pods in house, CMS has proposed two alternative approaches for revising the current anti-markup provision. Under the first proposal, the anti-markup provision would apply in all cases where the PC and TC of a diagnostic testing service is either purchased from an outside supplier or performed or supervised by a physician who does not “share a practice” with the billing physician or physician organization. A physician who is employed by or contracts with a single physician organization is considered to “share a practice” with that physician or physician organization. Under this proposal, a physician who is an employee or independent contractor of more than one billing physician or physician organization would not “share a practice” and be subject to the anti-markup provision. CMS’ second proposed alternative is to maintain the current anti-markup provision and its “in-office site of service” approach in determining whether a physician “shares a practice” with the billing physician or other supplier.

At the outset, CAP believes that CMS’s second proposal will do little to quell the growth in self-referral lab arrangements. Over the past year, urologists, gastroenterologists and dermatologists have had little difficulty adjusting to the anti-markup rule by simply setting up shop in some space where the practice performs other physician services and requiring an independent contractor pathologist to spend some time each week reading out cases in that space. The rules should clearly require a greater connection and integration with a practice before the practice can profit from lab tests ordered by the physicians in the group.

Accordingly, CAP strongly urges CMS to focus on its first proposal to apply the anti-markup provision to all TC and PC diagnostic tests that are ordered by the billing physician or other supplier unless the physician who performs and supervises the pathology services is dedicated solely to that physician organization. This would protect legitimate multi-specialty group practices that employ their pathologists on a full-time basis. At the same time, this proposed change would go a long way to close down the

“in-office” loophole where there is a lack of integration between the pathologist and the billing practice.

However, the CAP cautions CMS to draft the rule in a manner that does not have a detrimental affect on longstanding and legitimate pathology groups and other physician organizations. In this regard, the CAP is concerned that by defining a physician who does not share a practice as the dividing line, a pathologist who provides 99% of the pathologist services to a pathology practice and 1% of the pathologist’s services to an outside practice may be subject to the anti-markup provisions in *all* settings. While pathologists in general do not make referrals for the lab tests that they perform, they do occasionally make a determination on the need for a special stain or other detail in the performance of a test that ultimately is ordered by an outside physician.

In order to address this concern, the CAP urges CMS to clarify the anti-markup rule does not apply to a pathology practice where the initial order for the underlying test is made by a physician not affiliated with the pathology practice, without regard to any determinations that the pathology group might make for special stains or other professional judgments on how to best perform a test that was ordered by an outside physician.

The CAP also recommends an exception from the anti-markup provision for single specialty pathology physician groups and independent laboratories. The CAP suggests that such entities be defined as an entity in which all physicians within the group are pathologists and for which 75% of all CPT codes billed by the entity are pathology and laboratory CPT codes. The CAP agrees with CMS that it is necessary to extend the anti-markup provision to prevent abusive billing arrangements by ordering physicians who seek to profit from services that they order for their patients but do not personally perform or supervise. However, it is also important to consider unintended consequences that might result to many common laboratory and pathology practice arrangements. Because pure pathology groups do not control the ultimate orders for lab tests requested by other physicians, they should be clearly excepted from the anti-markup provision.

The CAP urges CMS to address this issue by providing an exception for single specialty pathology physician groups and independent laboratories. A reasonable definition for a single specialty pathology group is an entity for which at least 75% of the services performed by the entity fall into the CPT codes for pathology and laboratory services. This would clarify that dedicated pathology practices and independent laboratories are not subject to the anti-markup provision for certain purchased diagnostic tests and interpretations or the ordering of special stains to perform better the tests ordered by outside, independent physicians.

The foregoing clarification is consistent with existing rules under the Stark Law for referrals/orders made by pathologists for clinical diagnostic laboratory tests and pathological examination services. The Stark Law recognition that pathologists who order special stains, etc. should not be viewed as making a referral to an entity within the meaning of the Stark Law should carry over to the anti-markup provision. Congress has

recognized that the decisions of certain physicians who order certain services pursuant to a consultation with another physician, specifically pathologists, diagnostic radiologists and radiation oncologists, do not pose the same risk for abuse. Accordingly, the decisions of those physicians are not treated as restricted referrals to an entity with which they have a financial interest. The same considerations should be applied to permit an exception to the anti-markup rule in similar circumstances.

Another alternative that CMS could consider is to provide for an exception for any laboratory where at least 75% of the diagnostic services performed have been ordered by physicians outside of the group, lab, or entity that performed the services. This is an alternative bright-line test that would avoid the unintended consequences of applying the anti-markup rule to legitimate laboratory operations. It also would not protect other single specialty groups that seek to bring the lab in-house, since such practices would not come close to satisfying the 75% of tests be ordered from outside the group or lab test.

The CAP does not believe that CMS' second proposed alternative to the current anti-markup provision would effectively curtail the growing problem of referring physician practices avoiding regulatory restrictions through the simple expedient of bringing histology laboratories in-house and/or requiring a part-time pathologist to read out cases in the space of the practice. The limitation of the current anti-markup provision is that it focuses only on *where* the laboratory service is performed and not *who* is performing the service. This second proposed alternative anti-markup provision still would permit specialty physician practices to profit from their referrals by bringing Pods in-house to a office space where the group provides physician services. Thus, CMS' second proposed alternative will not stop the problem of self-referral over-utilization and abuse of the Medicare program.

The CAP also believes that CMS' two alternative proposals addressing whether the TC of a diagnostic test is considered a purchased test from an outside supplier are inadequate. CMS is proposing that if *either* the technician performing the test is an employee, *or* the physician supervising the test is an employee of the practice that the test could be considered to be provided by the practice. The CAP, however, believes that consistency with other regulatory provisions and policy considerations should mandate that *both* the performing technician and the supervising physician be employees of the billing practice. In this regard, note that Medicare regulations often require that an entity can only bill for the services of certain health professionals if those professionals are employed by the group. Thus, 42 C.F.R. § 410.74 provides that a physician practice can only bill for the services of the physician assistant if the physician assistant is an employee of the practice, and is supervised by a physician member of the group. Practices cannot bill for the services of physician assistants who are independent contractors. The same policy considerations that limit physician billing to employees of the practice should lead to the same conclusions here: a practice should only be able to bill for technical component services that are both provided by and supervised by employees of the practice.

The CAP recommends that CMS consider adopting a regulation that imposes the following requirements before a practice can bill for the technical component of laboratory tests:

- The TC should be performed on the premises of the billing physician practice;
- The TC must be performed by technicians who are employed by the practice and not independent contractors;
- The TC must be directly and actively supervised by a physician who is employed by the practice who is on premises on a regular basis when the services are performed;
- The billing practice must hold the CLIA certificate and be responsible for all aspects of the quality of the services;
- The CLIA Medical Director of the histology laboratory must be a physician who satisfies the requirements for being a physician dedicated solely to the billing physician practice.

CMS also is soliciting comments on how to implement the anti-markup provision for purchased diagnostic tests and interpretations. One key issue in this regard is how to measure the net charge for pathology interpretations. Because some physician groups arrange for pathologists to perform services on a per diem or other time basis, it may be difficult to determine the net per test charge on which to apply the anti-markup provision. The CAP recommends that CMS require as a condition for reassignment of a purchased interpretation that the parties mutually agree on a net charge for each unit of service for purposes of the anti-markup provision. Under this condition, per diem or other time-based arrangements, which are more susceptible to markups, would not be permitted under the reassignment rule for purchased interpretations. Because the net charge payment limitation has been an effective program safeguard for purchased tests, a similar requirement for purchased interpretations is likely to be the most effective mechanism to prevent markups. Also, by imposing a bright line test based on a net charge, contractors will have a greater ability to monitor and sanction abusive markup practices.

B. In-Office Ancillary Services Exception

For a number of years, CMS has solicited comments on the need for a regulation defining what services could qualify as in-office ancillary services. Services that did not meet the definition of in-office ancillary services would not qualify for the in-office ancillary services exception to the Stark Act. CMS has recognized that Congress created the in-office ancillary services exception to allow for the provision of certain services necessary to the diagnosis or treatment of the medical condition that brought the patient to the physician's office. These include such things as a urine analysis or blood glucose test,

which are collected and analyzed by the treating physician while the patient waits. CMS has suggested a number of potential ways to distinguish tests that would qualify for the in-office ancillary services exception.

The CAP endorses CMS's efforts to define in-office ancillary services, ancillary services should be limited to services that can be performed and where the results are available at the time that the patient is in the office. Services that meet that criteria are "ancillary" in the sense that they are an appropriate adjunct to the physician services provided at the time of the office visit. The CAP urges CMS to recognize that anatomic pathology services not be considered in-office ancillary services. Anatomic pathology services are very different from the routine clinical laboratory tests that were contemplated when Congress provided for the in-office ancillary services exception.

As CMS considers revising the parameters of the in-office ancillary services exception, CAP urges CMS to consider a test that looks to whether designated health services can be completed on a "time based approach." If services cannot be completed within the time of the patient's visit, the in-office ancillary services exception should not apply. There is no medical reason for performing laboratory tests in the physician's office that cannot be completed at the time of the office visit. The only reason why a practice seeks to perform such tests is to profit from the tests that the physician orders.

Anatomic pathology services are a case in point regarding the misuse of the ancillary services exception. Unlike routine clinical lab tests, anatomic pathology involves high complexity testing that is subject to quality and other standards of the Clinical Laboratory Improvement Amendments ("CLIA"). Most physicians, other than pathologists, are not qualified to furnish or supervise the testing services under CLIA standards. In contrast, routine clinical lab tests often are waived under CLIA, or in any event require far less medical supervision and have lower CLIA requirements. There are real quality issues associated with the provision of anatomic pathology services by non-specialists, and no medical reason to sacrifice quality to achieve expediency.

CMS has been searching for appropriate means to rein in the abuses of self-referral labs for years. The abuses posed by self-referral labs are apparent: specimens collected from the patient, and then performed as a wholly separate exercise, with a test turn-around time that is no shorter, and in many cases longer, than when the same test is performed by an independent laboratory. Whether the self-referral lab is a pod lab or an in-house captive laboratory is economically indistinguishable. Both raise the same concerns for patient and program abuse.

If CMS limits its efforts to curb self-referral ventures to restrictions on the building where tests are performed or the employment status of technicians, it will not stop problematic self-referrals. Ordering physicians will simply change the outward structure so that the services are performed in a manner that will preserve their ability to profit from referrals. The only effective way to curb these self-referral arrangements is to revise the definition of ancillary services to exclude services that cannot be performed at the time of the patient visit.

The CAP is aware of arguments that self-referring physicians make that their in-house laboratory pathology arrangements provide enhanced patient care. The CAP does not believe that self-referral arrangements structured to comply with a Stark regulatory loophole enhance patient care. Indeed, the CAP is aware that in some cases, the structure of the arrangement may even evade CLIA certification for the performance of the technical component or other aspects of service. The balkanization of the anatomic pathology service into the provision of an unregulated histology component, or the purchase of the histology component from an outside vendor, and the separate reading of slides by a physician with little if any day to day on-premises review and responsibility for accessing cases and histology hardly benefits patient care. The CAP urges CMS to adopt a definition of in-office ancillary services that excludes the highly complex tests that should be performed by an integrated independent laboratory.

Alternatively, the CAP suggests that if CMS does not exclude anatomic pathology from the ancillary services category, it at least impose some reasonable requirements before a practice is permitted to bill. These would include permitting a practice to bill for a test only if (1) the practice directly performs all aspects of the test (histology and the professional component) in a fully CLIA certified laboratory owned by the practice; (2) the CLIA certified laboratory is responsible for all portions of the service; and (3) the medical director of the laboratory is a pathologist or dermatopathologist who is a member of the group practice.

C. Direct Billing

CMS is also soliciting comments on whether in addition to, or in lieu of, the anti-markup provision, they should prohibit reassignment in certain situations and require the physician supervising the TC or performing the PC to bill Medicare directly. The CAP supports the establishment of direct billing for anatomic and clinical pathology services for all payers, public and private. The CAP believes payment for anatomic and clinical pathology services should be made only to the person or entity that has performed or supervised the service, except for referrals between laboratories independent of a physician's office. This policy, known as "direct billing," is consistent with American Medical Association's ethics principles.

In a practice known as client billing, a treating physician realizes a profit by charging a patient an inflated price for a laboratory service the physician received at a discount. Client billing gives providers an incentive to choose a laboratory based on the level of discount and profit potential from re-billing, rather than quality. It also creates an incentive to order more tests than necessary, as each service ordered results in an incremental increase in profit.

Imposing a direct billing requirement helps ensure that financial considerations do not influence physicians' choice of pathology services for their patients. With direct billing, ordering physicians can focus on quality alone when choosing laboratory services for

their patients. Direct billing does not restrict who may perform a service-only who may bill for it. Therefore, any qualified physician who performs or directly supervises a pathology service may bill for the service. Direct billing helps ensure compliance with federal laws that prohibit certain unlawful economic arrangements between physicians and the clinical laboratories to which they refer patient testing.

D. Effective Date of Regulatory Changes

CMS requests comment on whether the new provision should go into effect on January 1, 2009, as scheduled, or whether proposals contained in the rule should be delayed until some time later. CMS has been considering rules to stop abuse within billing and payment for pathology services for several years. Some interim changes have been made along the way but CMS has deferred the effective date of some of these changes. Such delays have permitted the growth of these abusive contractual joint ventures. Making the proposed anti-markup provision effective as soon as possible will not affect the ability of patients to obtain necessary services and will have the intended consequences of diminishing over-utilization of laboratory services and ultimately Medicare program expenses.

The CAP urges CMS to take definitive action on or before January 1, 2009 and not delay the effective date of any portion of this final rule.

The College of American Pathologists is pleased to have the opportunity to comment on these regulations and appreciates your considerations of these comments. Any questions regarding proposed changes should be directed to Traci Bone at 202-354-7133 (tbone@cap.org).

Sincerely,

Jared N. Schwartz MD PhD FCAP

Jared N. Schwartz, MD, PhD, FCAP
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