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American Urological Association Statement to Practicing Physicians Advisory Council December 3, 2007

The AUA is pleased to submit the following statement regarding the physician fee schedule final rule and the ambulatory surgical center (ASC) final rule for consideration by the Practicing Physicians Advisory Council (PPAC) at its December 3, 2007 meeting. We urge the PPAC to support our recommendations below by making similar recommendations to CMS.

Brachytherapy performed in an ASC

The AUA sought clarification from CMS that it would exclude brachytherapy sources (seeds) from the definition of designated health service (DHS) when they are provided as part of a brachytherapy procedure in an Ambulatory Surgery Center (ASC). CMS declined to do so in the final rule, but stated that a new proposed rule would need to be issued to make such a change. Because of the ASC payment policy changes, as of January 1, 2008, urology-owned ASCs will no longer be able to provide brachytherapy services. Therefore, we suggest two alternatives to handle this problem until a final rule solving the problem is implemented. One alternative is for CMS to allow radiation oncologists to continue to bill for brachytherapy seeds after January 1, 2008. Alternatively, CMS should consider that there is no financial relationship created when an ASC passes through to the seed vendor all of the reimbursement received for the seeds.

The AUA believes that seeds should not be a DHS where they are a covered ancillary service that is integral to an ASC procedure. The Stark definition of DHS at 42 C.F.R. § 411.351 states, "DHS do not include services that are reimbursed by Medicare as part of a composite rate (for example, ambulatory surgical center services . . .)." According to the ASC Final Rule issued on August 2, 2007 (72 Red. Reg. 42470), beginning January 1, 2008, ASC services "means . . . the combined facility services and covered ancillary services that are furnished in an ASC in connection with covered surgical procedures." 42 C.F.R. § 416.2. Covered ancillary services are specifically defined as:

"items and services that are integral to a covered surgical procedure performed in an ASC as provided in § 416.164 (b), for which payment may be made under § 416.171 in addition to the payment for the facility services."

Id. The regulations specifically list brachytherapy sources as a covered ancillary service. 42 C.F.R. § 416.164 (b)(1). Accordingly, the plain language of the



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regulations indicates that brachytherapy seeds are not DHS when provided in an ASC during a brachytherapy procedure.

Furthermore, the preambles to the Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2008 Payment Rates and Proposed Changes to the Ambulatory Surgical Center Payment System and CY 2008 Payment Rates (OPPS Proposed Rule) 72 Fed. Reg. 42628 (August 2, 2007) and the ASC Final Rule make clear that brachytherapy sources are separately payable in an ASC as a covered ancillary service that is integral to an ASC procedure. First, the preamble to the OPPS Proposed Rule specifically sets forth the general payment policies for covered ancillary services under the revised ASC payment system. This preamble describes those services which are ancillary to ASC procedures.

The categories of covered ancillary services which are separately payable include brachytherapy sources, certain drugs and biologicals for which separate payment is allowed under the OPPS, and certain radiology services for which separate payment is allowed under the OPPS. See 72 Fed. Reg. 42780. Second, the preamble addresses payment policies for specific items and services. Under the description of brachytherapy sources the preamble clearly states that separate payment for brachytherapy seeds will be provided when they are implanted in conjunction with the covered surgical procedure billed by the ASC. CMS specifically acknowledges that the application of the brachytherapy sources is integrally related to the surgical procedures for insertion of brachytherapy needles and catheters. Id. Third, brachytherapy sources are assigned payment indicator “H2” which denotes a brachytherapy source paid separately when provided integral to a surgical procedure on the ASC list; payment based on OPPS rate. This clearly shows that CMS believes that brachytherapy sources are integral to the surgical procedure related to the insertion of the needles.

CMS also explains in the preamble the reason for the separate seed payment. Brachytherapy sources are paid separately from the facility fee payment due to a statutory requirement that there be separate payment groups for brachytherapy sources that relate to the number, radioisotope, and radioactive intensity, as well as for stranded and non-stranded sources under the OPPS. Since the OPPS procedure payments do not include payment for brachytherapy sources, the ASC payments also will not include payments for the brachytherapy sources, in order for their to be parallel and consistent payment policies for brachytherapy performed in an outpatient hospital setting or in an ASC setting.

Radiology services, as well as drugs and biologicals are also separately discussed in the same section of the preamble. For these services, the proposed regulation text of 42 C.F.R. 411.351 – Definitions has been revised to include in both the definition of outpatient prescription drugs, and radiology and certain other imaging services, an exclusion for those services that are “covered ancillary services as defined at § 416.164 (b) of this chapter, for which separate payment is made to an ambulatory surgical center.” There is no corresponding change to the definition of radiation therapy services to denote the exclusion of brachytherapy seeds from DHS.

Based on previous comments by CMS relating to separately payable services that are integrally related to ASC procedures, it appears that this inconsistency may have been unintentional.

Indeed in the Phase I regulations CMS stated, that prosthetic devices implanted during an ASC procedure should be exempted from the definition of DHS. CMS stated that such devices should be excluded because, if surgeons refer to an ASC in which they have an ownership interest, there will, in many cases, be no exception that would apply to the financial relationship to the ASC. Implanted prosthetic devices, implanted prosthetics, and implanted DME are not included in the bundled ASC payment rate and thus would retain their character as DHS, even when implanted in ASC. As a practical matter, the absence of an exception for all of these items implanted in ASCs is likely to result in these procedures moving toward more costly hospital outpatient settings . . . we believe that the exclusion . . . will not increase the risk of over-utilization beyond what is already presented by the surgeon's Part B physician fee and is consistent with the congress' decision not to include Ambulatory Surgical Services as a specific designated health service." 66 Fed Reg. 856, 934 (January 4, 2001).

The AUA sees no reason to differentiate brachytherapy seeds, which are clearly covered ancillary services, from outpatient drugs, radiology services, or implanted prosthetics. The brachytherapy procedure is covered in an ASC, and brachytherapy seeds are integral to the procedure. Furthermore, the ASC final rule makes clear that CMS intends to treat brachytherapy seeds consistent with radiology and outpatient drugs. In response to comments, CMS stated that it was their intention to maintain consistent payment across hospital outpatient departments and ASC settings for covered ancillary services that are integral to covered surgical procedures performed in ASCs --

Therefore, consistent with our policy to pay separately for some drugs, biologicals, and radiology services as covered ancillary services, we also believe that adopting a payment policy consistent with the OPPS for payment of brachytherapy sources is reasonable and appropriate to ensure that the comprehensive brachytherapy service can be provided by ASCs.

72 Fed. Reg. 424.98

Exempting brachytherapy seeds from the definition of DHS is consistent with Congress' intent, CMS' payment policies, as well as CMS' Stark regulations with respect to integral ancillary services provided in an ASC. Any other outcome is counter to CMS' stated policy of desiring services to be performed in the best site available for such services. In the case of brachytherapy, that is often in the ASC setting.

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

The AUA believes that the final anti-markup rule in the 2008 Medicare Physician Fee Schedule is too broad and will prohibit arrangements that benefit patients, pose no risk of abuse and radically change the way physicians practice medicine. Furthermore, the final rule is vastly different than what CMS proposed. Thus, there was no ability to comment on these regulations. Much of the proposed rule focused on whether the person performing either the TC or PC of the test was a full-time employee of the group practice, rather than a part-time employee or an independent contractor. The Final Rule eliminates that distinction and simply imposes an anti-

markup provision on the TC and PC of diagnostic tests that are ordered by a billing physician or other supplier (or a related party) if the TC or PC is purchased from an “outside supplier” or if it is performed at a site other than the office of the billing physician or other supplier. 42 C.F.R. § 414.50.

The Final Rule applies the anti-markup provision to tests performed in the same building, but not in the same office space. For example, a urology practice that structured their practice to provide CT tests in compliance with the in-office ancillary services exception utilizing the “same building” criteria, may have located the CT machine on the first floor of a medical office building and their office practice on the third floor of the same building. Under the Final Rule, however, any CT test would be subject to the anti-markup provision because the CT is not located in the office where the physician practice provides substantially the full range of services (even though it is the same building where the physician provides non-DHS services).

Similarly, CMS, in all practicality, has vitiated the applicability of the definition of “centralized building” under the in-office ancillary services exception under Stark for diagnostic tests, even though Congress specifically created an exception in the Stark statute for DHS services provided in centralized buildings. While CMS has been clear that it is concerned about the use of centralized buildings for diagnostic testing where the tests are performed by independent contractors or part-time employees that provide services to many physician practices, CMS had not previously indicated in its proposed regulations that all diagnostic tests performed in centralized locations would be subject to the anti-markup provisions.

Throughout the Final Rule, CMS states that physicians can continue to purchase, and bill for, diagnostic tests — they just cannot profit from such tests. However, the definition of “net charge” realistically precludes most diagnostic testing arrangements that fall within the anti-markup prohibition. Under the anti-markup provisions, the amount at which a physician practice may bill Medicare for diagnostic tests may not exceed the lowest of the following amounts:

- (i) The performing supplier’s net charge to the billing physician or other supplier.
- (ii) The billing physician or other supplier’s actual charge.
- (iii) The fee schedule amount for the test that would be allowed if the performing supplier billed directly.

According to the Final Rule, the billed amount “must be determined without regard to any charge that is intended to reflect the cost of equipment or space leased to the performing supplier by or through the billing physician or other supplier.” One effect of this provision is that physician practices cannot take into account the cost or space of equipment when billing for the TC or PC of a diagnostic test that is not performed in their offices.

Thus, for practical purposes, diagnostic tests not performed in a physician practice’s office space may not be economically feasible. For example, if a urology group owns (or leases from a manufacturer) an CT that it locates in a “centralized building” or in the “same building,” but not the same office space as the physician practice, the physician practice would not be able to include any costs related to the CT equipment in its net charge to Medicare for the TC. Without receiving any reimbursement from Medicare for the equipment (or for the attendant overhead

related to the services), for which the physician practice directly incurs costs, it is improbable that any physician practice can sustain providing such services.

In sum, the final rule goes far beyond the intent of Congress, which enacted the anti-markup rule to apply to the technical component of purchased diagnostic tests. CMS's new rule applies even when a test is not purchased; where a physician group owns the equipment and employs the personnel providing the tests. CMS should not implement this rule at this time, but rather should reconsider and revise the anti-markup provision to apply only to truly purchased diagnostic tests, as Congress intended.