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LEGISLATIVE NEWS

AFROC Spearheads Effort to Increase Payment for Radiation Oncology Practice Expenses

The results of a call-back survey undertaken as the result of an initiative spearheaded by AFROC has the potential to increase Medicare payment for the indirect costs of radiation oncology services overall. It is anticipated that the study will increase overall Medicare payment for radiation oncology indirect expenses—such as administrative costs and overhead—by up to 6%.

In the final 2010 Physician Fee Schedule Rule, CMS utilized a revised PE/HR for radiation oncology services that was based in part on a “blend” of the PE/HR for hospital-based radiation oncologists and the PE/HR for the Freestanding Radiation Oncology (FSRO) Centers, as determined through a survey jointly sponsored by AFROC, ASTRO, and ACRO. However, in determining the PE/HR for freestanding centers, CMS improperly weighted survey results based on practice size—even though the survey did not actually capture any data on the practice size of the survey respondents.

AFROC spearheaded an effort, joined by ASTRO and ACRO, to call back the respondents to the survey to determine their actual practice size and to re-weight the survey results based on actual practice size data. Preliminary results indicate that this corrected re-weighting would result in a \$236.00 increase in the total PE/HR for the 67 freestanding centers whose costs were ultimately included in the PE analysis. When these results are “blended” with hospital-based data, the PE/HR for radiation oncology as a whole would increase by over \$100/hr.

At this stage, it is unclear how these results will impact the rates for radiation oncology services; however, increases—especially for professional component practice expense payments—are anticipated.

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If you are interested, please contact the AFROC office at info@afroc.org.
Let's make the 2011 Annual Conference a success!

Claims That Fail to Include Name and NPI of Referring Physicians Subject to Denial after July 6

In May, the Centers for Medicare & Medicaid Services (CMS) published an interim final rule requiring any physician who refers or orders services covered by Medicare Part B to be enrolled with Medicare in the Provider Enrollment, Chain, and Ownership System (PECOS) by July 6, 2010. While the preamble to the rule focuses on referrals for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS); home health; and laboratory, imaging and "specialist" services (which are not defined by CMS), the regulation by its terms requires claims for all Part B services that are "referred" to include the legal name of the referring physician and the physician's national provider identifier (NPI) on the claim.

This includes any physician who has not submitted an updated enrollment application to Medicare in the past six years or who has not reported changes in his or her enrollment information during this time. Physicians must list on their claims the legal name and national provider identifier (NPI) of the physicians who referred the services; if the referring/ordering

physicians are not enrolled in PECOS by July 6, or if the claims do not include the required information, the claims may be rejected.

This interim final rule may impact radiation oncologists in two ways. First, to the extent that a radiation oncologist refers a patient for other services covered by Medicare, including for example laboratory and imaging services, the entity providing the services may be required to include the radiation oncologist's legal name and NPI on its claims to Medicare. For that reason, it is critical that all radiation oncologists be enrolled in PECOS by the July 6 deadline to ensure coverage for medically necessary services ordered for their patients. Second, since cancer patients are generally referred for radiation oncology services by another physician, radiation oncologists are apparently required to include the legal name and NPI of the referral source on their claims, effective July 6, or run the risk that the Medicare contractor may deny payment for the radiation oncology services.

This rule is extremely ambiguous in a number of respects. For example, it is unclear for how long the referring physician name and NPI must be included on the claims, nor is it clear how Medicare contractors will distinguish between claims that erroneously fail to include the name

and NPI of the referring physician from claims for services provided to patients who are self-referred. AFROC has submitted comments to CMS requesting the agency to limit application of the rule to claims for services, such as clinical laboratory and diagnostic imaging, which require a physician referral in order to be covered.

In the interim, it is critical that physicians enrolled in Medicare before November 2003 and who have not updated their Medicare enrollment information since then enroll in PECOS. For instructions, go to www.cms.hhs.gov/MedicareProviderSupEnroll and click on "Tips to Facilitate the Medicare Enrollment Process" under "Downloads." Physicians enrolled in Medicare after November 2003, or those that have updated



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Medicare enrollment information since November 2003, are already in the PECOS system. If you are unsure of whether or not you are enrolled in PECOS, check "[Ordering Referring Report](#)" on the CMS website.

Sustainable Growth Rate Reduction Remains in Limbo

On June 18, 2010, Senators finally passed legislation to avert a 21.3 percent cut to Medicare physician payments, but not before CMS announced that it was putting the pay cut into effect. The Senate passed by unanimous consent a six-month, 2.2 percent pay increase for physicians, intended to avert the cut until December; however, the House had already recessed for the week and for that reason, the Senate move was too late to avert the pay cut. At this time, the House is refusing to pass the measure without certain jobs provisions that were excluded by the Senate. Many physicians are considering limiting new Medicare patients in reaction to Congress' repeated failure to take action on a long term "fix."

MedCAC Contemplates Lack of Clinical Evidence Supporting Radiation Treatment for Prostate Cancer

On April 21, 2010, the Medical Evidence Development and Coverage Advisory Committee (MEDCAC) held a meeting focused on the currently available evidence regarding the risks, benefits, and outcomes of radiation therapy, inclusive of external beam radiotherapy (EBRT) and brachytherapy, for the treatment of localized prostate cancer. AFROC attended the meeting, but did not submit comments. The meeting was well-attended and covered by the press.

The meeting focused to a large extent on a draft report prepared by the Agency for Healthcare Research and Quality (AHRQ), which can be found at <http://www.cms.gov/coveragegeninfo/downloads/id69ta.pdf>. The draft report concluded that definitive benefits of radiation treatments compared to no treatment or no initial treatment for localized prostate cancer could not be determined

because available data was insufficient to make this determination. The draft report also concluded that, for comparative effectiveness between different forms of radiation treatments (BT, EBRT, SBRT), available data also could not determine if one form of radiation therapy is superior to another form in terms of overall or disease-specific survival.

The purpose of the MedCAC meeting was to provide input to CMS regarding a number of questions that were posed by CMS regarding the extent of the clinical evidence available to support radiation treatment for prostate cancer. Presenters at the meeting addressed a broad array of radiation technologies for the treatment of prostate cancer, including not only external beam radiation therapy (including IMRT), brachytherapy (both low dose and high dose), CyberKnife, and proton beam. Representatives of the CyberKnife Coalition made a particularly strong showing at the meeting, and a number of patients who chose CyberKnife for the treatment of their prostate cancer spoke during the comment period.

However, for the purpose of providing feedback to CMS, the MedCAC collapsed all forms of radiation treatment into a single category, fundamentally determining that there was little evidence supporting the use of any kind of radiation treatment, as compared with "watchful waiting" (which was called "no initial treatment" for MedCAC voting purposes.) Significantly, a number of presenters referred to large scale European studies whose results may become available soon, which may shed light on the basic questions posed by CMS to the MedCAC.

While the views of the MedCAC members varied significantly on some issues, there was general agreement that additional research is needed into the fundamental utility of radiation treatment and, more specifically, into ways to determine which patient subgroups are likely to benefit from treatment (and, further, to distinguish which patient groups are more likely to benefit from each of the various forms of treatment). While some members of the MedCAC favored the development of the necessary evidence solely through randomized clinical trials, others

recognized the importance of “experiential” evidence, which would be gathered through a registry. At the meeting ASTRO announced that it is planning a prostate cancer registry, which could be used for this purpose.

Proposed Modification of Medicare Coverage Policy for PET May Open Door to Use of PET for Tumor Localization

On May 6, 2010, CMS published a proposed modification of its coverage policy for FDG PET, which may open the door to the use of PET/CT for tumor localization. Specifically, CMS was asked to reconsider the April 3, 2009 National Coverage Determinations (NCD) provision at Section 220.6.17 of the NCD Manual, which established an absolute frequency limitation of only one FDG PET study to determine the location and/or extent of the tumor for certain purposes related to the initial treatment strategy. After review, CMS indicated that it believes that the current absolute restriction of coverage to one FDG PET is not supported by the available evidence and therefore proposed to amend 220.6.17 of the National Coverage Determinations Manual. Under the CMS proposal:

- The NCD will be changed to remove the current absolute restriction of coverage to ‘only one’ FDG PET scan to determine the location and/or extent of the tumor for the therapeutic purposes related to the initial treatment strategy;
- CMS will continue to nationally cover one FDG PET scan to determine the location and/or extent of the tumor for the therapeutic purposes related to the initial treatment strategy; and
- Local Medicare administrative contractors will have discretion to cover (or not cover) within their jurisdictions any additional FDG PET scan for the therapeutic purposes related to the initial treatment strategy as described above.

Under the proposed policy, for any individual beneficiary the usefulness of any additional FDG

PET scan for initial treatment planning might be affected by the beneficiary’s specific medical problem, the availability of results of other diagnostic tests and the expertise of the interpreting physician. CMS indicated that it was delegating to local administrative contractors the discretion to make determinations about any additional FDG PET scan for initial treatment planning within their jurisdictions.

A final decision regarding this proposed change is anticipated on August 4, 2010.

ASTRO Softens Position on Physician Supervision

Under pressure from members, ASTRO posted an updated FAQ on physician supervision, dated June 21, 2010. The statement indicates that it is ASTRO’s position that the same policy applies to freestanding and hospital-based radiation oncology centers. With respect to freestanding centers, the current ASTRO FAQ document includes the following interchange:

Q: I practice in a free standing radiation center and I am not clear on whether the physician supervision requirements allow for any MD or whether the radiation oncologist is the only one that can provide the supervision of radiation therapy services, as well as the “incident to” services.

A: ASTRO believes CMS requirements for physician supervision are the same irrespective of place of service, meaning that the supervising physician needs to be able to immediately step in and perform the procedure not just in the event of an emergency but to also be able to furnish assistance and direction throughout the performance of the procedure. Therefore it is ASTRO’s view that the Radiation Oncologist is always considered a clinically appropriate physician but there may be others who meet these requirements.

A prior posting indicated that ASTRO believed that only a radiation oncologist is qualified to supervise radiation oncology services, regardless of the setting where the services are performed.

FDA Targets Equipment Safety

On June 9 and 10, the Food and Drug Administration (FDA) held a public meeting on Device Improvements to Reduce the Number of Under-Doses, Over-Doses, and Misaligned Exposures from Therapeutic Radiation. Speakers at the meeting included radiation oncology experts from clinical practice, teaching institutions, and major manufacturers of radiation therapy equipment. Topics addressed included not only device improvements and reporting, but also user training, and quality assurance. The FDA has also announced an “Initiative to Reduce Unnecessary Radiation Exposure from Medical Imaging.” The emphasis by the FDA, Congress, and the media on radiation safety may well spur legislation, including potentially increased focus on legislation that would mandate licensure or other federal regulation of radiation technologists.

MedPAC Targets “Group Practice” Exception to the Stark Law

In its June report, MedPAC again targets the “group practice” (officially, the “in-office ancillary services”) exception to the federal physician self-referral law (the “Stark Law”). While MedPAC’s discussion focuses primarily on in-office imaging, it also addresses the use of the group practice exception by specialty groups other than radiation oncologists (e.g. urologists and medical oncologists), noting that the provision of radiation oncology services by referring physician groups has been growing in absolute terms, although the proportion of radiation oncology services provided by referring physician practices appears to be relatively stable. MedPAC is expected to include a discussion of eliminating the group practice exception for radiation therapy and physician therapy—as well as other options—in its March 2011 report (which, unlike the June report, is expected to include recommendations to Congress).

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Check out the website for updated information:
www.afroc.org

Practice Platinum, Gold & Silver Members Update

As of June 28, 2010:

Platinum Members:

- Minneapolis Radiation Oncology
Minneapolis, Minnesota
- 21st Century Oncology
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- Oncure Medical Corporation
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