

AFROC



ASSOCIATION OF FREESTANDING RADIATION ONCOLOGY CENTERS

Our Voice in Washington

The Source

June 2005

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2005 DUES

AFROC is the only organization that solely focuses on the regulatory, legislative, and socioeconomic issues of freestanding radiation oncology centers and is **your only voice in Washington**. Your continued participation is critical to its future and to the future of your freestanding radiation center.

Second invoices for 2005 dues have been mailed. It is estimated that 95% of your dues can be taken as a business expense. Thank you.

Check out
AFROC's website
www.afroc.org

LEGISLATIVE NEWS

Congress and the Centers for Medicare and Medicaid Services (CMS) are busy this spring and summer with multiple issues impacting freestanding centers.

In Congress, the enactment of a budget resolution could set the stage for a possible Medicare bill, a bill that could include a "fix" to the looming cut in physician payments scheduled to occur in 2006 if Congress does not act. Stand-alone legislation to increase payments over 2005 levels has been introduced as well. The budget resolution also calls for Medicaid cuts, which could impact negatively on benefits and reimbursement at the state-level.

In the Department of Health and Human Services, there are developments within CMS that could impact treatment decisions regarding non-Hodgkin's lymphoma and a new structure for appeals of denied claims.

BUDGET RESOLUTION "RECONCILIATION" INSTRUCTIONS COULD LEAD TO MEDICAID CUTS AND MEDICARE BILL

On April 28, 2005, Congress approved a fiscal year (FY) 2006 budget resolution and, for the first time since 1997, included reconciliation instructions to several Committees with jurisdiction over mandatory spending programs like Medicare and Medicaid. Reconciliation instructions are a budgetary mechanism to force spending changes in programs not subject to the annual Congressional appropriations process.

If you are planning to attend the Annual ASTRO Meeting in Denver, Colorado in October, do not miss the AFROC reception and update by Diane Millman on Sunday, October 16th from 6:00 to 8:00 pm.

This will be your chance to ask questions regarding Medicare reimbursement and legislative developments that impact your freestanding radiation oncology practice.

Watch this space for more details.

The House of Representatives narrowly approved the “conference report” by a vote of 214-211. The Senate approved the same measure by a vote of 52-47, with Senators DeWine (R-OH), Chaffee (R-RI) and Voinovich (R-OH) voting against it.

The \$2.56 trillion budget estimates that mandatory spending will reach \$1.669 trillion in the coming fiscal year, and puts a virtual freeze on discretionary spending. The reconciliation instructions direct authorizing Committees, such as the Senate Finance, the House Ways and Means Committee, and the House Energy and Commerce Committees—all committees with jurisdiction over Medicare and Medicaid—to find savings of \$35 billion from mandatory program spending over the next five years.

The Senate Finance Committee, which has jurisdiction over both Medicaid and Medicare, must find \$10 billion in savings over the next five years. The House Energy and Commerce Committee has been charged with finding almost \$15 billion in savings from programs such as Medicaid, possibly Medicare, and telecom-related programs. The House Ways and Means Committee must find \$1 billion in savings from programs such as Supplemental Security Income (SSI), TANF, Social Services Block Grants, the Earned Income Tax Credit and possibly Medicare. The Committees targeted in reconciliation will spend the next several months developing policies to achieve these mandated savings with a reconciliation bill expected in September, 2005.

Throughout the budget process, debate focused on cuts to the Medicaid program. While numbers between \$14 and \$20 billion were originally considered by the Budget Committees, the final reconciliation number directed at the Finance Committee only allows up to \$10 billion in cuts.

As a result of the reconciliation bill, House and Senate leaders are under pressure to consider changes to the Medicare program as well. Though neither party would support significant cuts to the Medicare program to offset the Medicaid cuts, several major Medicare proposals, such as a boost in physician payments, could necessitate cuts elsewhere.

The Sustainable Growth Rate, or SGR, automatically sets payment increases or decreases based on long-term average growth in overall expenditures for physician services. Because payments for physicians’ services have been higher than the target, the SGR formula has required reductions in each year since 2000; however, each year except 2001, Congress stepped in to not only preclude the reductions but to provide modest increases. With those years of statutory increases adding to the target expenditures rate, negative updates are forecast through 2011, without Congressional intervention.

Health care observers are hopeful that if a Medicare bill is considered, a provision would be inserted that would ameliorate the projected 4.3% cut in the physician fee schedule for 2006. Legislation has been

introduced in the House of Representatives that would increase payments by 2.7% over 2005 levels for calendar year 2006. However, it is unlikely that Congress will enact legislation that will fix the SGR formula over the long term—since the ten year cost of such legislation would exceed \$150 billion.

Such a large correction, which must be accounted for in the reconciliation process, is unlikely to garner much support. Even a one-year fix would necessitate substantial savings in other areas of Medicare. The Bush Administration has declared the new prescription drug benefit “off-limits” for cuts, so other Part B benefits would be on the chopping block. Some have suggested that reimbursements for drugs and biologicals under Part B may continue to be a target for budget-cutters, despite the substantial reductions in payment for such drugs this year.

AFROC will continue to monitor developments and will keep you apprised of further developments as the debate unfolds.

PROPOSED PHYSICIAN FEE SCHEDULE DUE TO BE PUBLISHED IN JULY

As indicated in our prior newsletter, AFROC has submitted the results of its practice expense study of freestanding radiation oncology centers. We have recently learned that CMS’s contractor, the Lewin Group, has analyzed the AFROC survey and forwarded its recommendations to CMS for consideration in conjunction with the proposed CY 2006 Physician Fee Schedule, which is to be published in the Federal Register in July. If CMS uses the survey data submitted by AFROC and other organizations in the proposed rule, the result could be a substantial redistribution of payments for physician practice expenses among the various specialties, with radiology, cardiology, and radiation oncology potentially experiencing the greatest changes.

NEW BRACHYTHERAPY CODES ISSUED IN ASC INTERIM FINAL RULE

According to an interim final rule published in the May 4, 2005, Federal Register, CMS will add two breast brachytherapy codes to the list of Ambulatory Surgical Center (ASC) covered services. The rule, which will be become final on July 5, 2005, is subject to comments.

The new brachytherapy codes effective July 5, 2005 include the following:

CPT 19296: Placement of radiotherapy afterloading balloon catheter into the breast for interstitial radioelement application following partial mastectomy, include image guidance; on date separate from partial mastectomy.

CPT 19298: Placement of radiotherapy afterloading

brachytherapy catheters (multiple tube and button type) into the breast for interstitial radioelement application following (at the time of or subsequent to) partial mastectomy, includes image guidance.

Procedure codes 57155, "Insertion of uterine tandems and/or vaginal ovoids for clinical brachytherapy" and 58346, "Insertion of Heyman capsules for clinical brachytherapy" were also added.

In the interim rule, CMS stated that "we agree that uterine and breast brachytherapy are appropriate services for the ASC setting." CMS also stated that:

"[W]hile we are adding these procedure codes to the list, these codes alone do not compromise a brachytherapy procedure. Similar to the performance of prostate brachytherapy, the codes for uterine and breast brachytherapy are among several procedures that may be furnished in the performance of uterine or breast brachytherapy and do not include the application of seeds. We are currently trying to resolve a number of payment options related to the performance of prostate brachytherapy and the extent to which those services could be paid for when furnished in an ASC under existing regulations related both to ASCs and other payment systems such as the Medicare physician fee schedule. The issues are very complex, and we are still exploring various options. Until we address them comprehensively through national instructions, payment for uterine and breast brachytherapy performed in an ASC is determined by local carriers.

The interim rule is a major departure from the proposed rule, which was originally issued on November 26, 2004. In that rule, CMS proposed to add 25 procedures and delete 100 procedures from the list. Comments submitted to CMS convinced the agency to abandon many of the proposed deletions—The final rule provides for the addition of 65 procedures and the deletion of only five.

CMS RELEASES PROPOSED COVERAGE DETERMINATION ON CERTAIN PART B DRUGS FOR NON-HODGKIN'S LYMPHOMA

CMS recently released a proposed determination on the off-label use of drugs used to treat non-Hodgkin's lymphoma (NHL). The preliminary coverage decision is that there is insufficient evidence to change current CMS policy on the off-label use of Zevalin® or BEXXAR® for the treatment of NHL. The decision, however, would not modify the existing requirement for coverage of these and other anticancer diagnostic or therapeutic agents for FDA-approved indications nor coverage for any off-label uses of these agents in clinical trials.

CMS's decision is based on the criteria CMS uses to determine that a drug improves outcomes. In reviewing its coverage policy, CMS determines, among other things,

whether or not the drug improves net health outcomes in the Medicare population that are at least equivalent to established alternatives. In this assessment, CMS places greater emphasis on health outcomes actually experienced by patients, such as quality of life, functional status, duration of disability, morbidity and mortality, and less emphasis on outcomes that patients do not directly experience, such as intermediate outcomes, surrogate outcomes and laboratory or radiographic responses.

CMS ultimately determined that the existing literature did not show sufficient outcomes data to warrant a change. However, CMS states that:

"[t]he proposal does not obviate the need for contractors to continue to review the medical literature and determine the conditions under which radioimmunotherapy used in anti-cancer diagnostic or treatment regimens for medically accepted indications is reasonable and necessary. Contractors will not infer from this NCD that any off-label uses of these agents should not be approved.

This policy also does not withdraw Medicare coverage for items and services that may be covered according to the existing national coverage policy for Routine Costs in a Clinical Trial (National Coverage Determination Manual, section 310.1)."

RESTRUCTURING OF MEDICARE CLAIMS APPEALS

CMS is preparing to implement a long-anticipated provision of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act, (or BIPA) that radically revamps the Medicare appeals process for denied claims. CMS officials discussed the upcoming changes at an Open Door Forum in Baltimore on April 15, 2005.

Under the revised policy, all redeterminations, including all first level appeals, and will be conducted by fiscal intermediaries (FIs) and carriers.

New Qualified Independent Contractors (QICs) will handle second level reconsiderations, while the Administrative Law Judges that will be involved will be specifically designated to handle Medicare cases, rather than handling other Social Security Act appeals.

Under the new procedures—which will become fully effective for physicians and other Part B suppliers next year—it will be necessary to submit virtually all of the relevant medical and other information at the initial "reconsideration" level of appeal.

While the new process provides additional opportunities for providers to participate in appeals—rather than relying solely on beneficiary appeals of certain issues—the process likewise facilitates carrier and intermediary participation in ALJ hearings. At the fourth level, which is a

Medicare Appeals Council (MAC) review, appellants need to identify the particular parts of the ALJ decision that they believe are wrong and explain why. Following exhaustion of all administrative appeals, the case may be filed in federal district court.

For more information on the new Medicare claims appeals process, check the CMS Web site at www.cms.hhs.gov and the Federal Register at www.access.gpo.gov/su--docs/fedreg/frcont05.html.

CONCLUSION

AFROC will continue to monitor legislative activity in Congress, particularly as it relates to proposals to increase physician payments in light of the scheduled decrease. Clearly this is a top priority among members and within the broader physician community. Stay tuned to future newsletters for developments occurring in Washington, DC and other timely news impacting freestanding centers.

June 9, 2005

Mrs. Sheila Gell
Executive Director
Association of Freestanding Radiation Oncology Centers
1875 Eye Street NW, 12th. Floor
Washington D.C. 20006

Dear Mrs. Sheila Gell,

Recently, members of the New York City Police Department met with you to explain the NYPD's counter-terrorism initiative *Operation Nexus* and request your association's assistance in disseminating the *Operation Nexus* message to your membership. I wish to thank you for your assistance in communicating law enforcement's concerns about unusual customer requests, suspicious inquiries or out-of-the-ordinary business transactions and the potential for a link to terrorist activity.

Attached is the NYPD *Operation Nexus* material specific to your membership. An electronic version of this document will also be e-mailed to you by Lieutenant Christopher Higgins of the Terrorist Incident Prevention Unit so that you may format it accordingly.

Thank you again for your help in protecting our citizens against another terrorist attack. The willingness of your membership to work as partners with the NYPD and law enforcement is extremely vital and greatly appreciated.

Sincerely,
Raymond W. Kelly
Police Commissioner

attachment

ASSOCIATION OF FREESTANDING RADIATION ONCOLOGY CENTERS JOINS NYPD "OPERATION NEXUS"

The New York City Police Department's Operation Nexus is a broad network of business and enterprises joined in an effort to prevent another terrorist attack against our citizens. This network already includes over 25,000 firms and is being joined by nationwide business, professional and trade associations that have agreed to transmit this Operation Nexus "Best Practices" message to their members.

Operation Nexus is driven by the NYPD's belief that individuals seeking to commit acts of terrorism may portray themselves as legitimate customers in order to purchase or lease certain materials or equipment, or to undergo certain formalized training to acquire important skills or licenses. There is also a concern that these individuals may simply steal certain types of vehicles, equipment or materials in the inventory of legitimate businesses. Whatever the method, once appropriated these items could then be used to facilitate a terrorist plot.

Through Operation Nexus, the NYPD actively encourages business owners, operators and their employees to apply their particular business and industry knowledge and experience against each customer transaction or encounter to discern anything unusual or suspicious that might indicate a link to terrorism. You are urged to report such instances to local or federal authorities in addition to informing the NYPD through its counter terrorism hotline at 1-888-NYC-SAFE.

With these goals in mind, the NYPD requests the following list of suspicious activities, though not all inclusive, be considered as part of "Best Practices" counter-terrorism guidelines for notifying law enforcement authorities:

- Theft or loss (regardless of amount, e.g. pilfering) of radioactive materials or equipment that contains radioactive elements.
- Suspicious individuals observed in the vicinity of storage rooms containing radioactive materials or in sensitive locations.
- Theft or loss of entry keys or identification passes/badges that furnish access to areas containing radioactive materials.
- Theft of hazardous material storage containers.
- Unknown persons videotaping or photographing your facility.
- Persons loitering inside/outside of your facility for no apparent reason.

Recent departure overseas of employees with access to chemical, biological, radiological, nuclear material or termination of employment.

As a participant in Operation Nexus, the NYPD will continue to share information it obtains that might be useful to association members. In pursuing this cooperative counter-terrorism mission, if you have any questions or would like more information about *Operation Nexus*, please visit the NYPD website at www.nyc.gov/nypd and locate the Counter Terrorism link. Notably, the above information is in part a result of feedback from individuals in your industry and is continuously updated. If you wish to contribute additional examples of "Best Practices" guidelines for your industry, please visit the NYPD website.



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