

## PUBLIC AFFAIRS UPDATE



### ACNP/SNM Submit Letter of Disapproval on Part 35

In a letter to the Nuclear Regulatory Commission, the Society and College stated that the Final Draft Rule for Part 35 is unnecessary, unduly prescriptive, and falls short of the directives given at the start of the process. Furthermore, in the absence of a risk-based study, ACNP/SNM find the NRC's regulation to be "wholly unsupported and dangerous."

The NRC has been working on the revisions to 10 CFR Part 35 for almost two years. The final rule was released to the commission on August 1999. When the process first began, it was with the understanding that the revisions would take into consideration the risk incurred from the modality, but the NRC has never completed a risk assessment. Earlier this year, Chairman Shirley Ann Jackson told Congress that the rule, while not being "risk-based," was risk-informed. ACNP/SNM feel that this judgment ignores the fact that whether one chooses a risk-based or risk-informed methodology, the process begins with a competent risk assessment. The Society and College believe that without a sound, scientific risk assessment, the regulation is based on guesswork. In the commission-released document, the NRC states that the need for a risk analysis is not necessary because it would be expensive and delay enactment of the rule. The commission claimed that the benefit of such a study was outweighed by the benefits of moving forward with the current document.

The SNM Public Affairs Department has completed an initial review of how the final document compares to the ACNP/SNM's previous comments to the NRC. Except for a few small victories, the NRC apparently ignored most of those comments as well as most of the comments made by other stakeholder groups.

### Physician Fees

Now that Congress is back in session, it is rumored that revisions to the Balanced Budget Amendment and Medicare reforms will be considered. The Society of Nuclear Medicine, American Medical Association, and other organizations wrote to the members of the House Ways and Means and Commerce committees, and to the Senate Finance Committee, urging these bodies to include improvements to Medicare's Sustainable Growth Rate (SGR) system.

In the Balanced Budget Amendment, SGR was set up as a way to determine a target growth rate for Medicare spending on physician services. Payments are adjusted up or down annually depending on whether actual spending is below or above the target range. No other group is subject to this system, and spending on physician services has been growing more slowly than other Medicare benefits. In its March report to Congress, the Medicare Payment Advisory Commission recommended SGR improvements. SNM also strongly recommended that these improvements be enacted this year before the range between Medicare's rate and physicians' practice costs becomes much wider.

### HHS to Create Regulations on Individual Privacy

In August the deadline passed for Congress to enact laws protecting the privacy of individually identifiable health information. The task now falls to the Health and Human Services Department. Secretary Donna Shalala has indicated that a proposed privacy regulation will be published in the Federal Register this fall. The statutory deadline for the final rule is February 2000.

### DOE Appropriations a "Wait-and-See" Game

The Energy and Water Appropriations Bill for Fiscal Year 2000 is in a state of limbo until the House and Senate hold a joint conference to work out the difference between the two bills. The Senate named its conference participants (Senators Domenici, Cochran, Gorton, McConnell, Bennett, Burns, Craig, Stevens, Reid, Byrd, Hollings, Murray, Kohl, Dorgan, and Inouye) before leaving for the summer break. Conferees have not yet been named for the House, but one step has been taken. The House voted on September 13 to work on the energy and water funding bill.

SNM has been watching this process closely. The appropriations bill not only funds the Department of Energy's isotope program, ensuring an adequate supply of much-needed medical isotopes to the medical community, but it also contains the Advanced Nuclear Medicine Initiative (ANMI). The ANMI funding will allow the DOE to sponsor nuclear medicine science using a peer review selection process, as well as encouraging the training of individuals in nuclear medicine by establishing scholarships, and initiating a focused program to apply alpha-emitting isotopes to fight a gamut of malignant diseases.

—William Uffelman and Amanda Sullivan