

SNM/ACNP GOVERNMENT RELATIONS UPDATE

Nuclear Medicine Exemption

Key staff to the Senate Finance and the House of Representatives Ways and Means Committees have indicated that the nuclear medicine exemption was deliberately structured so that the issue of nuclear medicine involvement in the Radiology Relative Value Scale (RVS) would be reopened. This allows Congress to further consider in 1990 whether nuclear medicine will be treated separately under a resource-based RVS (RBRVS) or will remain under the Radiology RVS. The Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP) will seek to remove nuclear medicine from the radiology fee schedule by removing the Current Procedural Terminology (CPT) codes in the 78,000 and 79,000 series of CPT IV. The removal of the codes would allow all nuclear medicine specialists, irrespective of their practice style or locations, to be treated as other physicians. Under the current setup, nuclear physicians who are part of a larger group may not be able to qualify for the payment modification adopted in 1989. The use of CPT codes to define the specialty would overcome this problem.

SNM/ACNP will also seek to modify the proposed nuclear medicine payment rate for 1991 by asking that reimbursement be based on the 1988 prevailing charges with updates equivalent to those given to other physicians. SNM/ACNP ultimately will seek to be included in the Medicare RBRVS fee schedule effective January 1, 1992. Both the Senate and House are expected to consider Medicare reimbursement issues in July.

Harvard RVS

William C. Hsiao, PhD, head of the Harvard Resource-Based Relative Value Scale Study, sent out surveys to 160 physicians who listed nuclear medicine as their specialty in the American Medical Association Masterfile. Initially, Harvard indicated that the nuclear medicine survey analysis would be completed this spring, but it appears that the study is falling behind. SNM/ACNP's Technical Consultants to the Harvard study — Robert E. Henkin, MD, President of the ACNP, director of nuclear medicine at Loyola University of Chicago, in Maywood, Illinois, Larry L. Heck, MD, nuclear radiologist at Methodist Hospital in Indianapolis, Indiana, Philip O. Alderson, MD, acting chairman of the department of radiology and director of

nuclear medicine at Columbia-Presbyterian Medical Center, in New York City, and Oscar J. Powell, MD — expected to review preliminary survey results at the end of May.

FDA Revitalization

President Bush has asked for \$655 million in spending authority for the Food and Drug Administration (FDA) in fiscal year 1991 — a \$98 million increase over 1990. But the request includes \$157 million that the FDA would be required to raise from user fees paid by drug companies. Despite the Administration's support of user fees, they are not expected to be included in any legislation enacted this year.

NESHAPs/ Clean Air Legislation

SNM/ACNP has issued comments to the Environmental Protection Agency's (EPA) National Emissions Standards for Hazardous Air Pollutants, released last December. The comments stressed that duplicative regulatory reporting requirements created by the EPA would not enhance the public health and safety and that the use of iodine-131 would be jeopardized due to the additional costs imposed. SNM/ACNP recognizes the Nuclear Regulatory Commission (NRC) as the lead agency regulating radionuclide emissions from its medical licensees.

Congress could resolve the issue of dual regulation through the pending Clean Air legislation. SNM/ACNP supported an amendment to the Senate's bill, offered by Senator Alan K. Simpson (R-WY), which would have excluded "source material, special nuclear material, and byproduct material regulated by the [NRC] or by a state that has an agreement with the Commission." That amendment was nullified during later deliberations, but Senator Simpson introduced a second amendment, which passed with the legislation on April 3. The second amendment will require the EPA Administrator to first determine that an NRC or Agreement State licensed facility's regulatory agency was not providing an ample margin of safety to the public before the EPA can implement additional regulations under the Clean Air Act. At press time, the House has yet to approve its version of the Clean Air legislation, but a House/Senate Conference Committee is expected to begin deliberations on a final version of the legislation in June.

PET Reimbursement SNM/ACNP sent comments to the Office of Health Technology Assessment (OHTA) in response to its announcement of a study of positron emission tomography (PET). OHTA also indicated that it would like to complete the assessment by September 30, 1990.

SPECT Reimbursement Recent successes for SPECT reimbursement under Medicare have been achieved in Maryland and Florida and under Medi-Cal in California, due to the persistent efforts of nuclear medicine physicians. In addition, the American College of Radiology (ACR) made a presentation on SPECT during a closed meeting of the medical directors of the various Medicare carriers, which was held in Baltimore on December 13. The SNM/ACNP position paper was submitted for consideration by the meeting participants.

DPA and SPA In the April 10 *Federal Register*, OHTA announced that it is coordinating a reassessment of dual photon absorptiometry and single photon absorptiometry. At this time, coverage continues for single-photon absorptiometry only. Groups such as the National Osteoporosis Foundation have launched a major effort aimed at getting reimbursement for both technologies. SNM/ACNP will continue to work with these groups on this issue.

NRC Petition The SNM/ACNP successfully generated an extensive letter writing campaign to demonstrate support of the petition to change 10 CFR Part 35, Medical Uses of Byproduct Material (see *Newsline*, August 1989, p. 1296). Several organizations, including the American Medical Association, the Small Business Administration, and the American Pharmaceutical Association, filed comments. The fate of the Petition is pending, though SNM/ACNP continues to pursue prompt implementation with the NRC. In the meantime, the NRC staff is working on an interim exemption, possibly to be implemented transitionally.

NRC QA Regulations The NRC published its Proposed Rule on Basic Quality Assurance Program, Records and Reports of Misadministrations or Events Relating to the Medical Use of Byproduct Material in the January 16, 1990 *Federal Register* (see *Newsline*, April 1990, p.22A). In comments submitted to the NRC, SNM/ACNP asserts that the NRC's proposed restrictive regulation is not warranted in light of the extremely low incidence of both diagnostic and therapeutic misadministration of radiopharmaceuticals, particularly when it is compared with the incidence of non-radiopharmaceutical misadministration.

SNM President Richard A. Holmes, MD, ACNP President Robert E. Henkin, MD, Carol S. Marcus, PhD, MD, director of the outpatient nuclear medicine clinic, Harbor-University of California, Los Angeles Medical Center, and J. David Bernardy, director of federal regulatory affairs, Du Pont Medical Products, met with the NRC Commissioners over a two-day period in February to discuss the proposed QA rule and the Part 35 Petition.

NRC Training and Experience SNM/ACNP submitted a response to an NRC consultant's draft study on training and experience criteria for personnel involved in the medical use of byproduct material. SNM/ACNP considered the report "flawed methodologically" and was unable to support the recommendation to reduce the training period for cardiologists, the assertion that lack of training contributes to misadministration, or the recommendation that the NRC should become involved in staffing requirements and continuing medical education. The NRC staff is working on changes in response to the comments, but, because of other initiatives, the staff has not set a definite timetable for the revised study.

New NRC Member On November 20, 1989, the Senate confirmed the nomination of Forrest J. Remick to be a member of the NRC for a term of five years expiring June 30, 1994. Mr. Remick, who was sworn in as a Commissioner on December 1, assumes the seat vacated by Lando W. Zech, Jr. Mr. Remick has been a member of the NRC's Advisory Committee on Reactor Safeguards since August 1982 and was appointed Chairman of that Committee in January 1989.

FY 1991 Budget On May 1, the House approved a \$1.3 trillion budget for 1991. The budget includes fiscal year 1991 Medicare cuts of \$1.7 billion. President Bush had proposed reductions of \$5.5 billion to the Medicare Budget. The Senate Budget Committee continues deliberations on its fiscal plan for 1991.

Allied Health Appropriations Sharon Surrell, CNMT, and Marcia Boyd, CNMT, testified before the House and Senate Appropriations Committees, Subcommittees on Labor, Health and Human Services, Education, and Related Agencies regarding the nuclear medicine technologist manpower shortage and the need for increased appropriations to support Allied Health Project Grants and Contracts under the Health Professions Reauthorization Act.

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