SNM/ACNP Government Relations Update

To inform Newsline *readers of the latest regulatory and legislative developments affecting nuclear medicine, the directors of the joint government relations office of The Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP) present the following report from Washington.*

Department of Health and Human Services

■ Medicare Reimbursement

After passage of the Technical Corrections Act (TCA) of 1991, introduced by both houses in March, all nuclear medicine procedures will be reimbursed according to the historical values that were previously applied only to physicians billing 80% or more for nuclear medicine services. The provision means that the entire nuclear medicine community will be reimbursed following a blend of one-third by the radiology relative value scale (RVS) and two-thirds by 101% of the prevailing charges in 1988.

■ CLIA '88

HCFA has not made final any of the regulations under the clinical laboratory improvement amendments of 1988 (CLIA '88). HCFA was deluged by over 60,000 comments after proposing the first set of regulations in 1990. The final rules are expected to differ greatly from the originals. A high-level task force with representatives of HCFA, the Centers for Disease Control, and the Food and Drug Administration is reconsidering the testing levels included in the initial proposal. The American Medical Association (AMA) along with the Health Industry Manufacturers Association, the Health Industry Distributors

Association, and the American Hospital Association launched an impact study of the CLIA'88 regulations scheduled for completion next month. Several states have enacted or are trying to mount state-level CLIA provisions to be recognized under federal law.

■ Medicaid

As part of a congressionally mandated study on Medicaid physician payment, the Physician Payment Review Commission (PPRC) contracted the National Governors' Association to survey state Medicaid programs in 1990. The survey sought information on payment methods, frequency of payment updates, and problems with physician participation. The survey compared fee levels for 23 services commonly used by Medicaid beneficiaries and found wide variation across states. The data also substantiate earlier analyses indicating that Medicaid programs pay physicians less than Medicare and private payers—Medicaid pays about 69% of what Medicare does on a national average although the ratio varies widely from state to state.

■ Medicare Fee Schedule and RBRVS

The Health Care Financing Administration (HCFA) published a proposed Medicare fee schedule in June that could drastically reduce Medicare payments to physicians. Reimbursements for nuclear medicine procedures stand to drop 52% from 1988. SNM and ACNP maintain that HCFA's proposal could do away with nuclear medicine services in all but urban areas and in multispecialty imaging practices. In July, the ACNP and SNM prepared comments for HCFA and sent statements to House and Senate subcommittees urging changes in the proposed fee schedule. HCFA plans to issue a final version of the schedule in October to commence in January 1992.

■ DPA/SPA Assessment

The Office of Health Technology Assessment (OHTA) indicates that its long-awaited reassessment of dual-photon absorptiometry (DPA) and single-photon absorptiometry for bone density measurement may soon be completed. Meanwhile, Sen. John Glenn (D-Ohio) and Rep. Olympia Snowe (R-Maine) have reintroduced bills to provide reimbursement for bone densitometry. The measures died last year in Congress and it is unclear whether they will fare better this time around.

■ SPECT Reimbursement

HCFA's Office of Payment Policy sent a memo to regional administrators in March acknowledging inconsistent Medicare reimbursement for single-photon emission computed tomography (SPECT). "We have heard allegations that some carriers recognize SPECT procedures as covered services," the memo states, "but pay for them at the fee schedule level of other nuclear medicine services...If carriers determine SPECT procedures to be covered services, they should pay for them using the relative value units established for the SPECT procedure in the Radiology National Relative Value Scale." The agency has stopped short of a national policy.

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■ PET Assessment

OHTA assessment of positron emission tomography (PET) is stalled— officials say the agency will wait to render recommendations on PET until the FDA gets around to approving the new drug applications for PET radiopharmaceuticals.

Food and Drug Administration

■ Blue Ribbon Commission

The FDA needs more authority, funding, and status in the federal government to do its job, an advisory panel on the FDA concluded in its final report in April. Established by Health and Human Services Secretary Louis Sullivan, MD, the fifteen-member "blue ribbon commission" spent a year studying the FDA's problems. Secretary Sullivan said he agreed with much of the commission's report, but opposed elevating the FDA's status within the bureaucratic hierarchy.

■ Radiopharmaceutical Review

Efforts continue to streamline the review process for radiopharmaceuticals. The ACNP and SNM presidents met in May with members of FDA's Office of Drug Evaluation including Wiley Chambers, acting director of the Medical Imaging, Surgical and Dental Drug Products Division. Industry has traditionally claimed that the FDA's complicated instructions and lack of guidance impede the approval process for radiolabeled drugs. The Medical Imaging Division agreed to meet with industry representatives to outline a review process to improve communication. Also in May, FDA's Associate Commissioner James S. Benson and Ombudsman Amanda Peterson, JD, asked the ACNP and SNM to work with Ms. Peterson to develop a new process for radiopharmaceutical review in CDRH. The stepped-up dialogue with the FDA and Commissioner Kessler's marshaling of resources could result in some improvements in the regulation of radiopharmaceuticals. During congressional oversight hearings on the FDA in March, the Washington Office testified in writing to the House Subcommittee on Health and the Environment. The testimony cited problems with the approval process for radiopharmaceuticals and suggested solutions such as the creation of a division of diagnostic drugs.

■ Safe Medical Devices Act of 1990

The reporting requirements of the Safe Medical Devices Act impinge minimally on nuclear medicine facilities, according to Barbara Croft, MD, vice-chair of SNM's nomenclature and relative value scale committee, who attended a meeting convened by CDRH in April to discuss the amendment to the Food, Drug and Cosmetic Act.

Assistant Director of Government Relations Valerie Fedio, left, and Director Kristen Morris, right, with Capt. William H. Briner (USPHS, ret.), past chairman of the SNM government relations committee who stepped down from the post in July after serving 16 years. His successor is Stanley J. Goldsmith, MD.

■ Commissioner Kessler

Commissioner David Kessler, JD, MD, faces increased pressure to streamline approvals without jeopardizing the public's health and safety. Achieving this goal will be tough at a time when budgets are shrinking and the FDA is already straining to meet demands. SNM and ACNP representatives meeting with the commissioner discussed a proposal to reorganize the Medical Imaging, Surgical, and Dental Drug Products Division by transferring radiopharmaceutical approval to the Center for Devices and Radiological Health (CDRH). Dr. Kessler expressed familiarity with the concept, but said he would not "micro-manage" at that level. The commissioner will rather delegate such decisions to Carl Peck, PhD, director of the Center for Drug Evaluation and Research. An FDA hearing is scheduled for September 6 to address the scope and definition of a "combination drugs division" within the CDRH. Some radiopharmaceuticals could be considered candidates for FDA approval through this new division.

Department of Energy

■ National Biomedical Tracer Facility

A task force comprising government, industry, and SNM and ACNP representatives presented a feasibility study on a national biomedical tracer facility (NBTF) to the DOE in April. Richard Holmes, MD, chairman of the NBTF task force testified to the House Appropriations subcommittee on Energy and Water Development and presented the DOE-funded study to Congress. The ACNP and SNM asked for $2 million from the 1992 federal budget for design and siting of the tracer facility. DOE's Office of Health and Environment Research expressed support for the tracer facility in a letter signed by Division Director David Galas and a letter from Admiral James Watkins, secretary of the department. DOE's Office of Isotope Production plans to submit a request for funding to begin construction in fiscal 1993. The NBTF has fans in Congress but given the strapped federal budget, funding will have to come through a DOE presidential budget request.

■ Medical Applications Program

The ACNP and SNM recommended a cost-of-living increase of 6% per year from 1988 for DOE's medical application program. The increase would yield

$42,135,000 for fiscal 1992. Richard Reba, MD, testifying before a House Science, Space and Technology subcommittee, stressed the need for increased funding for the medical applications program. He also called for invigorated peer review of DOE grants. Contributing to the decline of funds for nuclear medicine research, he said, is the practice of automatic funding without peer review for ongoing projects. For example, funding of boron neutron capture therapy was continued in last year's federal budget despite negative peer review by the DOE's Health and Environmental Research Advisory Committee.

■ Molybdenum-99 Supply

The DOE asked Congress for authority to borrow $8 million in fiscal 1992 to convert one of its reactors into a molybdenum-99 (^{99}Mo) production facility (see *Newsline*, June 1991, p. 32N). In a formal statement to Congress, the SNM and ACNP supported the DOE request. Meanwhile, officials at DOE's Fast-Flux Test Facility (FFTF) near Richland, Washington are promoting FFTF's capacity to produce ^{99}Mo. Higher-ups at DOE favor closing the reactor, which each year costs about $100 million to run. Congress and the governor of Washington seem intent on saving FFTF. Two bills that have been introduced in Congress mandate a DOE partnership with isotope user organizations to create a center for isotope and energy research and development.

Nuclear Regulatory Commission

■ User Fees

The NRC assessed severely increased user fees last month, despite protests from nuclear physicians, institutions, and industry about the potential impact on health care. (see *Newsline*, July 1991, p. 23N) By law, the agency must fund itself entirely from fees assessed to licensees during fiscal years 1991 to 1995. The final fee schedule, published July 10, established a maximum annual fee of $1800 for "small entities"—that means $1 million or less in annual gross receipts for physicians in private practice.

■ Interim Rule on Medical Radionuclides

In April, the ACNP and SNM formally recommended that NRC withdraw the final interim rule on the medical use of radionuclides and remand the rule to the Advisory Committee on the Medical Uses of Isotopes (ACMUI) for reconsideration. From discussions at an ACMUI meeting in May it appears that the NRC will be conferring with the FDA on the issue. The NRC has yet to address several sections of the petition for rulemaking changes submitted by the SNM and ACNP in 1989, although the commission held a workshop in August to discuss establishing an "authorized radiopharmacist" in NRC regulations. Several states view the NRC's stance as an intrusion into state authority and have vowed to oppose the federal agency. In addition, Syncor International filed suit against the NRC challenging the effect of the rule on the practice of radiopharmacy. A settlement reached in July is expected to affect central labs nationwide.

■ Enforcement Legislation

The NRC has called on Congress to pass laws giving the regulators more power to impose penalties on licensees. The proposed "Omnibus Nuclear Power Safety and Security Enhancement Act of 1991" would do away with current measures that require NRC inspectors to give prior notice to licensees before showing up at the door. The bill's primary purpose, however, is to give NRC the authority to prosecute individuals who tamper with nuclear reactors.

■ Quality Assurance

The NRC issued a final rule on "quality management" in July with new requirements for medical licensees to implement quality assurance programs. The Advisory Committee on the Medical Uses of Isotopes (ACMUI) has deemed that no quality assurance rule is needed from the NRC. NRC deemed its rule "quality management" to distinguish it from the quality assurance program of the Joint Commission on Accreditation of Healthcare Organizations (JCAHO). The NRC recently received the approval of the Office of Management and Budget to go ahead with a mail survey on quality assurance among 2400 medical licensees —even though the final rule has already been published.

■ New Chairman

Ivan Selin, formerly State Department undersecretary for management, became chairman of the NRC on July 2, succeeding Kenneth M. Carr. Confirmation hearings have begun for Gail DuPlanque —the nominee to fill the fifth spot on the commission.

■ Radiation Safety Standards

The NRC published in May its revised standards for protection against ionizing radiation. The revisions conform to the recommendations of the NCRP and the International Commission for Radiological Protection (ICRP). The new standards became effective in June, but licensees may wait until 1993 to put the rules in effect. Carol S. Marcus, MD, PhD, submitted a petition for rulemaking to the NRC requesting revisions of 10 CFR parts 20 and 35. Among other requests, the petition asks the NRC to restore to five mSv (500 mrem) the allowable radiation dose to others from patients receiving radiopharmaceuticals. The ACNP and SNM filed comments with the NRC in support of Dr. Marcus's petition.

■ Below Regulatory Concern

The NRC placed a moratorium on enactment of the "below regulatory concern" (BRC) policy in July and began a "consensus-building" effort to guide the commissioners in making a final policy (see *Newsline*, August 1991, p. 26N). NRC regulation will continue status quo at least until the commission's consensus-building group of medical and industry representatives—including the ACNP

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and SNM—returns with recommendations on the policy next year. Legislation introduced by Rep. George Miller (D-California) and Sen. George Mitchell (D-Maine) opposes the BRC policy, but as a result of the consensus-building initiative, Rep. Miller delayed hearings on his bill until this month.

Environmental Protection Agency

■ Resource Conservation Recovery Act

Congress is considering the reauthorization of the Resource Conservation Recovery Act (RCRA). If accepted, RCRA would duplicate NRC authority over radioactive waste. The measure would apply also to transportation of radioactive waste and limit on-site storage to no more than 90 days.

■ Clean Water Act

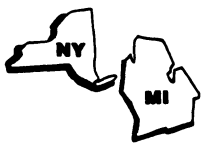
Lawmakers are exploring the reauthorization of the Clean Water Act. When the act was revamped in 1987, Congress proposed stricter regulations for the release of medical isotopes into waterways. The proposed language was dropped from the final bill in 1987, but has the potential of resurfacing during this consideration.

■ White House Involvement

In the debate on the Clean Air Act, the Committee on Interagency Radiation Research and Policy Coordination (CIRRPC) supported the ACNP and SNM claim that regulation by both the NRC and the EPA was unnecessary. CIRRPC has agreed to continue to monitor dual regulation issues, including the EPA data collection process during the stay on NESHAPS for medical licensees. The Competitive Counsel, a presidential panel that evaluates federal regulation, will be approached for assistance as well.

■ NESHAPS

EPA suspended in April its national emission standards for airborne radionuclides until November 15, 1992 (see *Newsline*, June 1991, p. 29N). The agency has already deemed that nuclear power reactors operate at an acceptable safety level under existing regulations. Medical licensees hope for a similar ruling, but lack the thorough-going data kept by the power reactors. EPA plans to survey medical licensees by mail to determine if they operate within a margin of safety acceptable to the agency. The agency expects to have survey letters sent to 350 material licensees by this month.



Low-Level Radioactive Waste Lawsuits

■ New York

The state of New York has appealed a court decision to dismiss the state's challenge of the constitutionality of the Low-Level Radioactive Waste Policy Amendments Act (LLRWPAA). New York opposed the provision that requires states to accept title and possession of privately-generated waste—or pay damages to the generators—if the state has not established a suitable dump by 1996. The SNM and ACNP have supported the Federal Government in this case by signing a friend-of-the-court brief.

■ Michigan

The Midwest Interstate Low-Level Radioactive Waste Commission, a seven-state compact, ousted the state of Michigan in July. The decision follows four years of legal wrangling since the commission picked Michigan as the home for a low-level waste dump for the compact states. While Michigan authorities regroup to comply with LLRWPAA, the state's private generators are suing to get access to dumps in the three sited states —South Carolina, Nevada, and Washington—that refused to accept any more waste from Michigan in November 1990.

Veteran's Administration

■ Special Pay

In April, the President signed into law special pay rate legislation aimed at filling posts for medical specialists at VA hospitals. The law should allow VA medical directors to boost salaries and provide retention pay and special pay for "scarce" specialists. The law limits special pay to $40,000 for a total salary of no more than $134,000 for 1991.

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and interested membership-at-large share with one another their views of the future to determine the best course for the society to take. The process is a lengthy one and will not be concluded during my term. We anticipate that the outgrowth of the process will strengthen SNM immeasurably and position it well for the future.

Before I close, I would like to thank you once again for your confidence in me as we enter this effort together. I welcome any comments and feedback that you would be kind enough to give me. This is an exciting time for our profession, our specialty, and thanks to you, an exciting time for me.

Leon S. Malmud, MD
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