GOVERNMENT RELATIONS UPDATE

The following report is derived from a presentation by the Joint Government Relations Office of The Society of Nuclear Medicine and the American College of Nuclear Physicians.

REIMBURSEMENT FOR HEALTH CARE

▲ CPT. After receiving an outside recommendation for changes in reimbursement for a whole-body scan followed by a SPECT scan, the Health Care Financing Administration (HCFA) agreed to the change and stated it would notify the regional offices and carriers. Currently a claim for such a reimbursement results in rejection of payment for one of the two procedures. The recommendation called for use of the -51 modifier for multiple procedures performed on one patient on the same day. This modifier was originally for multiple surgical procedures, with a reimbursement rate of 100% for the first procedure, 50% for the second, and 25% for the third. The HCFA said actual reimbursements may not be affected for some time, though the second procedure should be reimbursed at 50%.

▲ SPECT Project. The 1992-93 SPECT Project cycle concluded in June, and contracts for two data collection and two clinical analysis studies were signed and funded during this cycle. One data collection project for SPECT practice cost evaluation remains authorized but unfunded. The first effort for the 1993-94 cycle was to develop a business plan that will assist the SPECT Project in identifying projects to fund this year and will broaden the participation of the nuclear medicine industry. Data from the first cycle studies are nearing completion and should become available within two months.

▲ PET. Reimbursement for PET imaging remains limited, though some third-party carriers continue to cover PET for specific indications. The Food and Drug Administration (FDA) has not yet approved FDG for brain imaging; until FDA issues its decision, the Office of Health Technology Assessment refuses to release its evaluation of PET for Medicare Reimbursement.

Some existing PET centers may have to comply with good manufacturing practice once the FDA approves FDG. Some facilities are concerned that they may not be able to comply with these regulations and still provide cost-effective PET.

HEALTH CARE POLICY

▲ Health Care Reform. White House watchers expect that President Clinton's health care reform plan, slated for September release, will be an outline of principles without answers to questions such as how to finance it or what will constitute a basic benefit package. No one expects Congress to introduce new legislation this season. Ira Magaziner, Clinton's chief health policy aide, told medical society specialty presidents that the proposal will establish health care criteria and a national benefits package; identify outcome and quality goals; standardize paperwork; and organize the system to provide universal coverage.

The plan, to be phased in through the end of the decade, will completely re-form the insurance system into health alliances and prohibit risk-pooling. Though managed care will be the prevailing form of insurance, the proposal will not exclude fee-for-service plans—though such plans might have difficulty providing acceptable compensation for the practitioner and still compete with the growing managed care plans. In the proposal's only nod to funding, employers will pay 80% of the weighted average premium. The consumer may purchase more expensive benefits out of pocket.

Magaziner promised that the proposal will address liability tort reform, though he gave no specifics.

▲ State-Level Reform. Meanwhile, the states have been actively reforming health care: Forty-eight have introduced some form of health-care legislation, and many legislatures are adjourning this summer with the promise that health reform will be at the top of their agenda when they reconvene. But among the variety of bills passed, few proposals were comprehensive.

▲ Bans on Self-Referral. As of June 21, states had pending or passed legislation to prohibit physician self-referral. This year, governors of Georgia, Maryland, Maine, South Carolina, Tennessee, and Virginia signed into law legislation that restricts or prohibits self-referral. If federal legislation prohibiting self-referral is passed with the budget reconciliation legislation, it may allow states to enact more stringent limitations.

▲ Medicare Budget. The House and Senate scheduled final votes in early August on a plan to reduce federal spending over five years; the budget plan represents a compromise of versions passed by both houses—in which both proposed large Medicare spending cuts. The House version, which passed May 27, indicated $50 billion in cuts from Medicare

and $8 billion from Medicaid. The Senate version, approved June 25, recommended $65 billion in cuts from Medicare and $8 billion from Medicaid. Clinton proposed $46 billion in Medicare cuts over five years. The House-Senate conference version has Medicare spending cuts of $56 billion over the next five years, with the expected rise in Medicaid limited by $7 billion.

▲ **CLIA.** In June, the Centers for Disease Control and Prevention (CDCP) recommended modifying the Clinical Laboratory Improvement Amendments (CLIA) to expand the criteria for waiver for instruments; recognize physician specialties for physician-performed microscopy laboratory testing; and consider establishing a new category of testing to limit CLIA regulations for certain tests.

▲ **AHCPR.** On June 30, the House approved fiscal 1994 appropriation legislation for the Department of Health and Human Services, including funds for the Agency for Health Care Policy and Research (AHCPR). The bill offers a $20 million increase over fiscal 1993's $128 million for AHCPR. The Clinton Administration proposed $158 for AHCPR.

Nuclear Regulatory Commission

▲ **Congressional Hearings: Agreement States.** On June 30, Chairman Mike Synar (D-OK) of the House Government Operations Committee's Energy, Environment, and Natural Resources Subcommittee heard testimony on the role of the Agreement State Programs in protecting public health. The hearing was concomitant with a report from the General Accounting Office (GAO), "Nuclear Regulation: Better Criteria and Data Would Help Ensure Safety of Nuclear Materials," which made no distinction between "nuclear medicine" and any medicine using radiation. Four NRC commissioners, the GAO, and the Organization of Agreement States testified. Concerned that the NRC was lax in evaluating Agreement State Programs, Synar focused on the agency's ability to determine the adequacy and compatibility of the agreement states.

Concurring that NRC had made some errors, NRC Chairman Selin offered initiatives to curtail future errors: to develop a compatibility policy with the agreement states through workshops; to assure, in accordance with the Atomic Energy Act, early and substantive state input into the rulemaking process; to re-examine the current regulatory program and identify possible improvements in oversight of medical licensees; to consider a compatible core-performance evaluation measure for agreement states and NRC licensees as a basis for graded performance instead of pass/fail; and to give the Commission annual briefings on the entire Agreement State Program to identify problems and possible problem states. Synar's committee continues investigating NRC policies and procedures.

▲ **Congressional Hearings: Nuclear Medicine Regulation.** Senator John Glenn's (D-OH) Government Affairs Committee hearings on May 6 on nuclear medicine regulation resulted in a request that the NRC, FDA, and the Council of Radiation Control Program Directors submit recommendations by August 6 on how to regulate nuclear medicine. The NRC assembled a task force to develop recommendations for Senator Glenn's committee and solicited responses from the regulated community. It is unclear whether this process will result in legislation.

▲ **Budget Appropriations.** The House Appropriations Committee, Energy and Water Subcommittee, approved a fiscal 1994 NRC budget of $550 million for salaries, expenses, and the Inspector General's Office. Of this sum, $22 million will come from the Nuclear Waste Fund, leaving $528 million to come from licensing fees, inspection services, and other services and collections. Of the final figure, 15%, or $83.9 million, goes to the materials section; 54%, or $294.5 million, to the reactor portion; and 31%, or $169 million, to maintenance and support. The bill is expected to pass the Senate and be signed by the President this fall.

▲ **User Fees.** On July 30, the NRC published a final rule resulting from comments on the proposed rule to set licensing, inspection, and annual fees. Major points of the rule were that the NRC will not examine pass-through criteria for a group of licensees owing to lack of resources and knowledgeable staff members for evaluating the relevant market criteria to make such a decision; that the NRC revoked the exemption for Non-Profit Educational Institutions (see "News Briefs"); and that the NRC decided that support for developing low-level radioactive waste (LLRW) facilities benefits all licensees, and thus all should bear a portion of the cost—large generators producing over 1,000 cubic ft of LLRW per year will pay $61,000, and small generators will pay $1,100.

▲ **Radiopharmacy Regulations.** On June 17, the NRC published a proposed rule on the preparation, transfer for commercial distribution, and use of byproduct material for medical use. The rule will provide greater flexibility by allowing properly qualified nuclear pharmacists and authorized users who are physicians greater discretion to prepare radioactive drugs containing byproduct material for medical use. The proposed rule would also accommodate medical use of radiolabeled biologics and research using byproduct-containing material on human subjects. Comments on this proposed rule are due October 15.

Environmental Protection Agency

▲ **Emission Standards.** High-level representatives from the EPA and NRC met on June 16 to discuss the EPA's

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proposed recision of National Emission Standards for Hazardous Air Pollutants (NESHAPs) for Sub Part I. The recision would protect the NRC's sole jurisdiction over the regulation of radionuclide air emissions for material licensees, including nuclear medicine facilities. In 1990, Congress directed EPA to hold the NESHAPs for NRC medical licensees in abeyance pending evaluation of whether licensees were within an ample margin of safety under sole NRC jurisdiction. EPA based its recision proposal on a survey of licensees; the data indicated that NRC licensees operated within EPA standards when complying with NRC regulations. A proposed rule rescinding these NESHAPS was expected in August.

Low-Level Radioactive Waste

▲ California. The California Department of Health Services continues to delay issuing a license for the Ward Valley LLRW disposal facility, though the California State Court of Appeals ruled favorably for the site on May 7. The U.S. Department of Interior's (DOI) Bureau of Land Management also has not set a date to transfer the land, though the DOI was continuing to review the site. The review included an unfavorable report by the DOI's U.S. Geological Survey, which questioned the validity of some environmental impact studies on the area and called for additional studies before land transfer. The site also may be named a critical habitat for the endangered desert tortoise; a suit on behalf of the tortoise is on hold in a California court, pending DOI's identifying the animal's critical habitats.

▲ New York. The New York State Assembly failed to act on a bill that would have designated West Valley as suitable for an LLRW facility. This failure threatens the state's access to South Carolina's Barnwell facility. The Southeast Compact Commission is reviewing New York's status.

▲ Central Interstate Compact. On April 14, the Southeast Compact Commission voted unanimously to terminate its contract with the Central Interstate Radioactive Commission, effective July 1 and affecting Arkansas, Louisiana, Oklahoma, and Kansas. There is currently no plan to reconsider the Central Compact's access to Barnwell.

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Nuclear Regulation

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izing radiation used in medical diagnosis and therapy; 4) develop federal regulations for all sources of ionizing radiation used in medical therapy, with the states responsible for implementation; or 5) develop federal regulations for all sources of ionizing radiation used in medical therapy and diagnosis, with the states responsible for implementation.

The Underlying Issues

Efficient, and cost-effective oversight in the use of medical nuclear materials, seemingly a straightforward goal, is hardly a simple concept when one faces a proliferation of agencies and overlap in agency responsibilities; lack of clearly defined overall authority for regulation; lack of standardization in regulations and their implementation from state to state; lack of an integrated information system for collecting and analyzing required data; lack of accountability and quality control of regulatory activities at both federal and state levels; and excessive budgets that call into question the cost benefit of existing agency services. The press's sensationalization of horrifying but isolated incidents of radiation injuries, accidents, and deaths is only the tip of the iceberg.

The reporting has, ironically, paved the way for much-needed examination of the state of affairs of federal and state nuclear regulatory activities and, according to Morris, "has stimulated useful debate that is educating Congress and the staffs of regulatory agencies as well as professional associations and organizations." However, as Nagle points out, "It is essential to proceed cautiously toward the goal of more effective oversight, to prevent insidious escalation of already excessive hidden costs to the health care industry of radiation regulation, to avoid duplication of efforts among agencies, and to forestall the potential to crossover into medical practice purview. To assume the source of underlying problems without careful examination is to potentially identify solutions that may only aggravate the problem." ACNP and SNM have therefore urged that the NRC first obtain an objective study from a separate, scientific organization such as the National Academy of Sciences-Institutes of Medicine before a strategic plan to address perceived problems and before selecting one of the five options NRC outlined in its report to Congress.

"Quality control of uses of ionizing radiation and radiation medical devices through regulation is essential to the safety both of patients and professional staff in medical facilities," Nagle continues. "It must, however, be accomplished in a fashion that balances reasonable cost with reasonable benefit while protecting public safety without jeopardizing the capacity of medical facilities to provide essential services, either because intrinsic costs escalate or because frightened patients decline the services."

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