so there is no onerous "gatekeeper."

In Spring 1994, the SNM Commission on Health Care Policy released a set of "Talking Points" expressing the Society's concerns for reform. The document noted that freedom of choice must be protected under reform legislation—both the patient's choice of physician, and the physician's ability to participate as provider under any health plan. The document also calls for nuclear medicine's specific inclusion under the basic benefits package, as it is often mistakenly assumed to be included under the heading of "radiology procedures."

At least two other pieces of health care legislation related to reform, have been the concern of both general and specialty medical societies, including SNM. The Harkin/Hatfield Amendment proposes to raise additional funds for medical research by taxing up to 1% on premiums to a health research fund and adding a check-off item on federal income tax forms. The Hatch-Thurmond/Archer Health Care Antitrust Improvement Act would increase physician involvement in health care delivery decisions by amending anti-trust laws and creating safe harbors for physicians comparable to those developed by the Department of Justice. Health care delivery decisions are increasingly made at the corporate level, and physician management of the health care delivery system may help keep mere financial goals from jeopardizing health. SNM has supported both Harkin/Hatfield and Hatch-Thurmond/Archer.

Although the Society has yet to endorse any of the general health care reform bills, its role has been more to watch Congress and ensure that whatever shape reform takes will be conducive to nuclear medicine practice. "The fact is that fee-for-service is very viable and HMO's do not have as much influence as we thought," Dr. Wagner said.

"Our accomplishments in health care reform are essentially two-fold," Dr. Conway said. "We have created the Health Care Reform Committee of the Commission on Health Care Policy, particularly the program on state monitoring. And through the Joint Office we have accomplished legislative actions, like the compromise on the Metzenbaum amendment" (see *Newsbriefs*, this issue p. 26N). The Society's accomplishments in health care reform, Dr. Conway contends, are still ongoing, and have arisen through a continuous effort to make sure legislation keeps nuclear medicine practice as viable as possible.

—Lantz Miller

NRC Proposes Ruling on Patient Release, Agreement States

IN JUST OVER ONE MONTH THIS SUMmer, the Nuclear Regulatory Commission published two proposed rules in the Federal Register that would significantly affect nuclear medicine practice. On June 15, the agency published "Criteria for the Release of Patients Administered Radioactive Material," (10 CFP Parts 20 and 35), which would set new restrictions on how soon certain patients exposed to radiopharmaceuticals could be released from supervision. On July 21, the NRC published "Adequacy and Compatibility for NRC and Agreement State Radiation Control Programs Necessary to Protect Public Health and Safety," which could strongly affect the control that each Agreement State has over its own policies as endowed by federal law.

"This is the NRC's last-ditch effort to keep its materials program intact," said SNM Vice-President Carol S. Marcus, PhD, MD, of the Agreement States rule. Dr. Marcus, who is also director of the Nuclear Medicine Outpatient Clinic, Harbor-UCLA Medical Clinic, has been closely monitoring the development of this rule over the past two years, and of the patients'-release rule for even longer. She said that Agreement States rule essentially would make the States "be a carbon-copy of the NRC. This is war on the Agreement States."

The Agreement States program started with the Atomic Energy Act (AEA) of 1954, allowing states if they choose, to set their own standards for handling materials licensees, which include nuclear medicine departments. Proponents of the Agreement States system contend that it allows greater flexibility and efficiency.

Determining Expected Dose

The new standard for releasing patients administered radiopharmaceuticals would change the doses at which an institution must take prescribed actions concerning the patient. The NRC, contending that its "primary concern is public health and safety," (*Federal Register*, Vol. 59, No. 114, Wednesday, June 15, 1994) states that the patient may expose other individuals to radiation, thus there should be a dose limit as a patient release criterion. Previously, the dose equivalent was set at 5

mrem per hour at 1 meter, or 30 mCi radiopharmaceutical content, while the proposed standard sets the levels at 500 mrem maximum per year for an individual exposed to the patient. The institution thus would have to determine the expected dose rate to individuals who come in contact with the patient, accounting for decay rates. Further, if the annual dose to anyone exposed to the patient will likely exceed 100 mrem, the institution must maintain records on the released patient, and on the calculated total dose to an individual likely to be exposed to the patient, for three years.

The proposed rule in the Federal Register extensively discusses Dr. Marcus' work with the NRC on the issue and how the agency attempted to incorporate her petitions and the ACNP's in the new rule. In a July 11, 1994 letter to NRC Secretary Samuel Chilk, however, Dr. Marcus wrote that in making the changes, "NRC adds a bizarre calculation expectation, an astonishing and inappropriate paperwork burden, and an extra requirement for estimated anticipated exposures in the 100-500 mrem range that is inconsistent with... even the intent of the 'new' 10 CFR Part 20 itself." Furthermore, the added costs from doing extra work as the rule ordains are a source of contention: "The arbitrary designation of $33 per patient as the cost of this rule underestimates this cost by a factor of at least 1700%," Dr. Marcus wrote, "not even counting the costs of record-searching and record-obtaining for patients who receive more than one therapy dose in one year, [etc.]."

Background radiation in the U.S. averages 300 mrem annually (500 mrem in Denver), and an airline passenger receives another 100 mrem annually for each 100,000 miles flown. But in the *Federal Register*, the NRC, with its mission to protect public health and safety, implied that potential exposure from radiopharmaceutical-treated patients, who "can expose others around them to radiation until the radioactive material has been excreted or decayed away," warrants the rule changes.

Controlling the Agreement States

The July 21 rule also intends to protect public health and safety—through defining the terms "adequate" and "compatible," which are used in the AEA's mandate to those states that decide to discontinue the NRC's regulatory authority. A state's program must be "adequate to protect public health and safety" and compatible with the NRC's regulations. However, the NRC has found that without further definition of these terms, a lack of uniformity has grown in the way the Agreement States handle regulated materials. "The regulated community desires strict adherence to uniform national radiation standards so that licensees meet the same standards in all states and will not be subject to different regulations in different states," the proposed rule asserts.

But critics see this move of the NRC's as differently motivated. "The concern is that the NRC is becoming too prescriptive in what the Agreement States can do," said David Nichols, regulatory affairs coordinator at the SNM/ACNP Joint Government Relations Office. "This rule brings the NRC back into control of the Agreement States." The proposed rule does in fact include a plan for assuring that the Agreement States conform to the new definitions, including a Management Review Board "to make the decision on the adequacy of existing Agreement State programs."

"This has developed over two years, and our [SNM] leadership has not taken [preventative] steps," Dr. Marcus said. "The membership needs to know what is going on... We will need the membership writing to governors, congressmen, attorneys general, to express what we need." According to Mr. Nichols, the Joint Office has hired a lawyer to draft a comment letter to the NRC on "why the NRC should not implement this rule change."

Critics are concerned that the NRC is becoming too prescriptive in saying what the Agreement States can do.

In the past, other involved SNM members, including Stanley J. Goldsmith, MD, clinical director of Nuclear Medicine, Memorial Sloan-Kettering Cancer Center (New York, NY), have supported the NRC's tighter control of Agreement State function (see *Newsline*, March 1992, p. 27N). Dr. Goldsmith's and Dr. Marcus' views are compatible insofar as both are concerned about unnecessary over-regulation. As Dr. Goldsmith observed, "I am concerned that state legislative and regulatory processes may be overly responsive to political pressure from local anti-nuclear activists who continue to bring pressure for controls which are costly and unnecessary in terms of public health and safety. Moreover, a patchwork of controls, varying from state to state, would further complicate nuclear medicine and practice." He added, "At the same time, the NRC has clearly been excessive in their 'crackdown' on medical practice procedures. It is reminiscent of a police department enforcing traffic and nuisance issues to show their presence when in fact more significant issues which are less visible to the public are not addressed."

Public comments on the Agreement States rule are welcome up to October 21, 1994, sent to the Secretary if the Commission, U.S. Nuclear Regulatory Commission, Washington DC 2055-0001. Copies of the rules are available from the Joint Government Relations Office, 1101 Connecticut Avenue, NW, Ste. 700, Washington DC 20036, Attn: David Nichols; tel. (202) 429-5120.

—Lantz Miller