## Energy Policy Act Report

In July, the Congressional Energy and Natural Resources Conference Committee released a report on the pending Energy Policy Act. Among the items of interest within the report include Section 630, on medical isotope production, and language within Section 170H, on the treatment of accelerator-produced radioactive material as byproduct material. The Conference Report on the Energy Policy Act was approved in the House on July 28 and in the Senate on July 29.

Most surprising to the nuclear medicine community was Section 170H, Radiation Source Protection, introduced into the Conference Report by Representative Edward J. Markey (D-MA). The language in this section appears to grant the NRC jurisdiction over accelerator-produced radioactive material. SNM issued a statement indicating that the society's leadership is "very concerned that this language could have an unintended but highly detrimental impact on U.S. patients who need unfettered access to life saving diagnostic and therapeutic nuclear medicine procedures." The language of the added section seems to run counter to the Agreement State regulations that have governed certain types of human-made radioactive materials, including most nuclear medicine radioisotopes, since 1959. Since the early 1960s, Agreement States, which now number 33, have had successful comprehensive radiation control programs that include, but are not limited to, regulating the use of diagnostic and therapeutic x-rays, environmental monitoring, and regulating the use of certain radioactive materials, including accelerator-produced radioactive material. In its statement, the SNM indicated concern that "transferring regulation of accelerator-produced radioactive material to the NRC—which does not have experience in this area—from the States would impede patient access to nuclear medicine." SNM and partner associations plan to focus on working cooperatively with the NRC to ensure that upcoming regulations are written in a manner that ensures consumer access to radiopharmaceuticals essential for nuclear medicine procedures.

Section 630, Medical Isotope Production, amends Section 134 of the Atomic Energy Act of 1954 to impose requirements on the export of highly enriched uranium (HEU) for medical purposes and to ensure the safe, timely, and secure use of such material. This will help address flaws within Section 134 that have caused licensing delays as a result of a failure to distinguish the use of HEU to produce medical radioisotopes from other uses. The safe passage of this provision has been a key advocacy initiative of the Council on Radionuclides and Radiopharmaceuticals (CORAR), an association of companies in the United States and Canada who manufacture and distribute radiopharmaceuticals, sealed sources, and radionuclides used in medicine and life science research. Molecular/nuclear medicine societies, including SNM and the American College of Nuclear Physicians, have also assisted CORAR in these efforts.

*Society of Nuclear Medicine*
*U.S. Congress*

## CMS Payment Update and Policy Changes

On August 1, the Centers for Medicare & Medicaid Services (CMS) outlined the contents of the 2006 proposed payment update and policy changes for Medicare physician fee schedules. The proposed rule indicates that payment rates per service for physicians would be reduced by 4.3% for 2006, a reduction required by a statutory formula that takes into account substantial growth in overall Medicare spending in 2004.

"The payment reduction shows the need for more effective ways to pay physicians that help them improve quality and avoid unnecessary costs," said CMS Administrator Mark B. McClellan, MD, PhD. "CMS is working with members of Congress, physician organizations, and other health care stakeholders on ways to improve physician payment without adding to overall Medicare costs, if at all possible."

The physician fee schedule specifies payment rates to physicians and other providers for more than 7,000 health care services and procedures. The fee schedule is updated on an annual basis according to a formula specified by statute. The formula requires CMS to adjust the update up or down depending on how actual expenditures compare to a target rate, the sustainable growth rate (SGR). The SGR is calculated based on medical inflation, the projected growth in the domestic economy, projected growth in the number of beneficiaries in fee-for-service Medicare, and changes in law or regulation. If actual spending exceeds the target, as it did in the past several years, then the law requires CMS to reduce the update factor.

The proposed rule was to be published in the August 8 issue of the *Federal Register*, after Newsline press closing. However, the initial CMS announcement contained 2 items of special interest to the nuclear medicine community. CMS is proposing to reduce payments for "certain diagnostic imaging procedures to reflect their limited additional costs when they are performed on contiguous body parts in the same session with the patient." The CMS state-

ment noted that, "Because these changes are made in a budget neutral manner, these lower payments for multiple diagnostic imaging services will allow higher across-the-board payments for other services under the fee schedule." In addition, the proposed changes will "revise the list of health services for which those physicians are prohibited from self-referring their patients (the physician self-referral rules) to include diagnostic nuclear medicine services and therapeutic nuclear medicine services."

More details on the proposed changes will appear on the SNM Web site in September. CMS will accept comments on the proposals until September 30, and publish a final rule later this year.

*Centers for Medicare & Medicaid Services*

## Physician "Pay for Performance" Bill Introduced

Less than a week after the Centers for Medicare & Medicaid Services (CMS) announcement on physician fees, U.S. House Ways and Means Health Subcommittee Chair Nancy Johnson (R-CT) introduced a bill that would cancel planned phased-in cuts. Speaking to the media on July 28, she said, "Don't believe for a moment that if Medicare underpays long enough, access won't be affected," Johnson said at a news conference announcing the Medicare Value-Based Purchasing for Physicians Act of 2005. The bill would replace the current sustainable growth rate formula under which physician pay is linked to overall spending with a system that Johnson called "simple, direct, stable, and predictable." The new formula would provide physicians with inflation-based increases each year, with slightly smaller increases for physicians who fail to meet specified quality-based targets. The criteria for measurement would be set jointly by physicians, quality organizations, and Medicare officials.

Several professional organizations, including the American Medical Association (AMA), the American Academy of Family Physicians, and the American College of Physicians, voiced their support for the bill. A survey by the AMA indicated that if CMS implements its current schedule of physician pay cuts, that 38% of physicians would cut back on the number of Medicare patients they treat.

Despite widespread support in the medical community, passage of the bill would prove costly for CMS, and some congressional observers have expressed doubts about its passage at a time when the system is already being challenged to cover the costs of new prescription drug benefits.

*U. S. House of Representatives*

## Rate and Policy Changes for Hospital Outpatient Services

The Centers for Medicare & Medicaid Services (CMS) announced the proposed 2006 Medicare payment rates under the Outpatient Prospective Payment System (OPPS) rule on July 19, with special provisions for higher funding for facilities in rural and isolated areas. "Today's proposed rule will help ensure that beneficiaries have access to quality services in the hospital outpatient setting no matter where they live," said CMS Administrator Mark B. McClellan, MD, PhD.

The proposed rule would continue the gradual decline in coinsurance rates Medicare beneficiaries will pay for many hospital outpatient services. Coinsurance rates for OPPS services are being reduced gradually until the beneficiary's share for any outpatient service will be 20% of the hospital's total payment. Under the proposed rule, the coinsurance rate for 12 additional medical and surgical Ambulatory Payment Classifications (APCs) will decline to the 20% minimum. The proposed rule would also reduce the maximum coinsurance rate for any service to 40% of the total payment to the hospital for the APCs in 2006, down from 45% this year. Over all, average beneficiary copayments for all outpatient services are expected to fall to 30% of total payments under the proposal.

CMS is also proposing to pay for most Part B drugs, biologicals, and radiopharmaceuticals administered in hospital outpatient departments based on competitive market prices. "Paying the same competitive rates for Part B drugs, whether administered in the outpatient department or the physician's office, reflects Medicare's goal to pay appropriately for the drugs regardless of where they are used," said Dr. McClellan. "And we will also pay appropriately for the pharmacy costs of using the drugs."

As part of the "contiguous imaging" changes outlined in broader CMS initiatives, the rule proposed to change OPPS payments for some diagnostic imaging procedures to reflect "their limited additional cost when they are performed with other imaging procedures in the same session with the patient." According to the July 19 statement, when 2 or more of these identified procedures are performed, the first procedure would be paid in full and a discount of 50% would be applied to subsequent procedures.

The proposed rule was published in the July 25th *Federal Register*. Comments will be accepted until September 16, and a final rule is scheduled to be published by November 1, 2005.

*Centers for Medicare & Medicaid Services*

## House Passes Limits on Malpractice Awards

On July 29 the U.S. House of Representatives approved medical malpractice legislation to limit awards in lawsuits for pain and suffering to $250,000. The Help Efficient, Accessible, Low-Cost, Timely Healthcare (HEALTH) bill is sup-

ported by the Bush administration as a measure to repair a "badly broken medical liability system." The bill was introduced and supported by Republican House members who cited a likely cut in insurance premiums of 25%–30% with Senate passage of the measure. The bill was opposed by many Democratic House members. Another provision of the bill provides protection for pharmaceutical companies and medical device makers from paying punitive damages in such suits when their products have been approved for use by the Food and Drug Administration. The bill would also limit lawyers' fees on a sliding scale based on the size of the award and impose a 3-year statute of limitations in most cases. Congressional observers note that this bill, like others that have preceded it, is unlikely to pass the Senate intact.

*U.S. House of Representatives*

## NRC to Issue New Visitor Radiation Dose Limits

The NRC announced on July 13 the approval of new procedures for permitting visitors to patients undergoing nuclear medicine treatment or brachytherapy to receive radiation doses above current regulatory limits if warranted by the patient's needs. Under NRC regulations, the permissible annual radiation dose to any member of the public, including hospital visitors, is 0.1 rem. Visitors to patients who cannot be discharged under NRC regulations are permitted to receive a dose of up to 0.5 rem under certain circumstances.

According to the press release from the NRC, 2 recent cases involving exposures of visitors have shown that those limits are not sufficient to take certain patient needs into account. When a family member or friend becomes a caregiver and is actively involved in the patient's care, a hospital licensee trying to enforce the regulatory dose limits may have to choose between risking potential NRC enforcement action by violating the regulatory limits or compromising the patient's care to minimize the caregiver's dose. Licensees currently may request emergency, case-specific exemptions from NRC regulations for these situations, asking NRC staff to determine an allowable dose above the regulatory limit. This approach lacks standard procedures for granting exemptions and may not always ensure appropriate control of the caregiver's exposures.

The newly approved procedures would allow the licensee to determine a dose limit based on the conditions of a specific case and establish standard procedures for requesting and granting an expedited license exemption. Caregivers would be given instruction on ways to limit their exposure. NRC regional offices will have authority to grant expedited exemptions for limits up to 5 rem, provided the licensee submits sufficient justification. Requests for limits above 5 rem will require special justification by the licensee and additional review by the agency's Office of Nuclear Materials Safety and Safeguards.

The NRC staff expects to issue a Regulatory Issues Summary on the new procedures, including guidance on their implementation, by mid-2006. Until then, the current procedures for requesting an exemption from the regulatory requirement remain in effect.

*Nuclear Regulatory Commission*

## National Tracking System for Radioactive Materials

On July 20, the NRC issued a release indicating that the commission is "considering amending its regulations to implement a national tracking system for certain radioactive materials used for academic, medical, and industrial purposes." According to the release, NRC is working with other federal agencies and states to develop the National Source Tracking System to monitor certain radioactive materials in specific quantities. During 2002 and 2003, NRC worked with other agencies and the international community to reach agreement on which radioactive materials and sources should be tracked. Those sources are detailed in the International Atomic Energy Agency (IAEA) *Code of Conduct on the Safety and Security of Radioactive Sources.* In a related story, the IAEA also announced in July the launch of a satellite tracking system for sensitive nuclear materials in Europe.

The proposed amendment to NRC regulations would require licensees to report information on the manufacture, transfer, receipt, or disposal of those sources of interest to an automated National Source Tracking System, to be administered by the NRC. The radioactive materials include specified amounts of $^{227}$Ac, $^{241}$Am, $^{252}$CI, $^{60}$Co, $^{244}$Cm, $^{137}$Cs, $^{244}$Gd, $^{197}$Ir, all plutonium isotopes, $^{210}$Po, $^{147}$Pm, $^{75}$Sc, $^{90}$Sr, $^{228}$Th, $^{229}$Th, $^{170}$Tm, and $^{169}$Yb. The press release and formal announcement also indicated that other isotopes might be added to this list as the system is developed. Although routine nuclear medicine practice would not be affected immediately by the new system, medical researchers should be aware of changing requirements.

Each licensee would also have to provide its initial inventory of nationally tracked sources to the National Source Tracking System and annually verify and reconcile the information in the system with the licensee's actual inventory. In addition, the amendment would require manufacturers to assign a unique serial number to each nationally tracked source.

Written comments should be submitted by October 11, and complete details of the proposed amendments and instructions for comments are contained in a July 28 *Federal Register* notice (available at http://www.regulations.gov/freddocs/05-14919.htm).

*Nuclear Regulatory Commission*