



OMB Approves Limited Clearance for QM Rule

The Office of Management and Budget (OMB) has approved a limited clearance request for paperwork collection associated with the Nuclear Regulatory Commissions (NRC) Quality Management (QM) Rule. The NRC had requested a three-year clearance to continue collecting paperwork associated with the inspection and enforcement of the QM rule. The OMB, in part due to comments submitted by the Society of Nuclear Medicine (SNM) and the American College of Nuclear Physicians (ACNP), denied a three-year clearance opting instead for only 18 months.

In the clearance notice, the OMB indicated that they continue to have concerns with the burden and possible lack of practical utility of the information collection requirements. As part of the clearance, NRC has agreed to initiate reform of the QM rule with recognition of the different risks involved in different nuclear specialties, such as the differences between diagnostic and therapeutic nuclear medicine, and reduce reporting frequency, such as by going from annual QM plan reviews to a review every two to three years.

The OMB expects a written progress report on the status of NRC reforms for this paperwork collection requirement at the time of its next renewal (18 months from now).

At that time, the next renewal will focus on the progress the NRC has made towards burden reduction, consistent with the requirements of the Paperwork Reduction Act that information collections have practical utility and minimize the burden on respondents.

ACNP and SNM Make Presentation at CRCPD Meeting

The Conference of Radiation Control Program Directors (CRCPD) held their annual meeting in Tacoma, WA from April 27- May 1, 1997. The CRCPD represents the Directors of Radiation Protection programs in all 50 states. One of the topics discussed at the meeting was the issue of NRC reform of the medical program. Representing the ACNP and SNM, Robert Carretta, MD, chairman of the ACNP/SNM Government Relations office, presented the views of both groups on this issue: (a) that diagnostic nuclear medicine is essentially a low-risk activity when handled by appropriately trained individuals; (b) he also pointed out that the ACNP and SNM had encouraged the NRC to further investigate the level of regulation necessary for therapeutic nuclear medicine. Following further discussion with the NRC, the ACNP and SNM believe the NRC will conclude that therapeutic nuclear medicine is also a low risk activity. Finally, Carretta extended an invitation to CRCPD members to work with the ACNP and SNM as the regulatory reform process moves forward.

Also, presenting at the meeting was Donald Cool, Director of the Division of Industrial and Medical Nuclear Safety at the NRC. Cool outlined the Commissions Staff Requirements Memorandum (see last month's *Newsline* p. 40N) and discussed how the NRC staff planned on gathering information and developing a rulemaking that would reform 10 CFR 35.

Legislative Update

H.R. 1060 PHARMACY COMPOUNDING BILL

This legislation, introduced by Representative Burr (R-NC) and has 53 co-sponsors, would clarify the role of the pharmacist, under a physician's approval, in compounding certain medications under state law. The bill would also nullify the rulemaking for PET requiring compliance with CGMP regulations.

H.R. 1411 FDA REFORM BILL

Also introduced by Representative Burr (R-NC), this legislation contains language regarding compounding and the FDA process for approving radiopharmaceuticals.

LEGISLATIVE NETWORK

The following ACNP and SNM members, in response to an action alert sent out by the ACNP/SNM Government Relations Office have sent letters to their member of Congress asking for support of H.R. 1060: Mickey Clarke,

CNMT, Barry Siegel, MD, Edward Silberstein, MD, Jim Ponto, Roy McCulloch, CNMT, Lynne Roy, CNMT and Lynnette Fulk, CNMT.

If your name is not on this list and you have contacted your member of Congress on this issue, please forward a copy of your letter to the attention of David Nichols at the SNM office. If you are interested in participating in our grassroots efforts, or would like a copy of the action alert for H.R. 1060, please contact David Nichols at (703) 708-9773 or dnichols@snm.org. A copy of the alert is also available on the SNM home page at www.snm.org.

PET LEGISLATION

The ACNP and SNM expect the Senate to introduce legislation that would reform the regulation of PET, through reform of the Food, Drug and Cosmetic Act, as well as insuring reimbursement for non-FDA approved uses of PET.

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