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The National Professional Society of Pharmacists

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406

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PETITION RULE PRM 35-9
(54FR 38239)

Secretary of the Commission
U.S. Nuclear Regulatory Commission
Docketing and Service Branch, Docket # PRM-35-9
Washington, DC 20555

Dear Mr. Secretary:

The American Pharmaceutical Association (APhA) is the national professional society of pharmacists, the third largest health care profession in the United States. Nuclear pharmacists constitute an active portion of APhA's membership.

In response to the September 15, 1989 Federal Register notice of a Petition for Rulemaking Change for 10 CFR parts 30, 33 and 35, APhA hereby expresses strong support for the petition filed by the American College of Nuclear Physicians and the Society of Nuclear Medicine. The revisions requested will assist in putting an end to unnecessary barriers which unduly prevent the practice of pharmacy and medicine and the exercise of those rights conferred on individuals authorized by state and federal licensure agencies. Adoption of the proposed revisions will enhance the capabilities of pharmacists and physicians to use their professional skills to mitigate disease and suffering.

Pharmacists are highly educated and trained individuals who have had five to six years of advanced education before they are allowed to "sit" for state licensure examinations. Pharmacy education consists of lectures, laboratories and practical experience in the art of compounding and formulating drugs; drug synthesis, chemistry and action; and the federal and state laws that regulate drug use. Nuclear pharmacists and in particular board certified nuclear pharmacists, have further specialized training in the safe and proper use of radiopharmaceuticals. Pharmacists possess the knowledge to safely prepare and modify radiopharmaceutical kits and compound radiopharmaceutical prescriptions as written by physicians, consistent with federal drug laws and state pharmacy laws.

The practice of pharmacy and medicine is conferred upon those professionals who have long been recognized to be the "experts" of their respective disciplines and Nuclear Regulatory Commission (NRC) regulation of those disciplines is unnecessary. APhA perceives NRC's current regulation to be contrary to longstanding, established Food and Drug Administration (FDA) policy with respect to the practice of pharmacy and medicine, as well as in conflict with state's rights governing professional practice under its jurisdiction.

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The proposed revision will correct inconsistencies between current NRC regulations and existing regulation by FDA and the states. The current incompatibility is causing serious problems in the optimal delivery of quality nuclear medicine care and the implementation of nuclear medicine research. FDA is responsible for assuring consumers that drugs and devices are safe and effective. The FDA regulates all radiopharmaceuticals whether they are made by manufacturers, nuclear pharmacists or their designees in medical institutions or in centralized radiopharmacies. FDA has the federal authority to regulate all research and clinical use of radioactive drugs directly or indirectly, as the petitioners noted.

Development of new radiopharmaceutical therapy is unduly hampered by current NRC regulations. Nuclear pharmacy activities authorized by the FDA and the states are not allowed under current NRC regulations. Although a nuclear pharmacist is authorized by state license to prepare radiopharmaceuticals for patient administration with a prescription, current NRC regulations severely restrict such preparation to rigid reconstitution of standard kits and to dispensing doses of radiopharmaceuticals distributed by manufacturers. We agree with the petitioners' request that the NRC revise its regulations to allow free-standing radiopharmacies licensed under 10 CFR 32.72 and 10 CFR 32.73 to also compound radiopharmaceuticals. Restrictive licenses should be amended by NRC, without charge to the licensee, to remove the requirement to reconstitute radiopharmaceuticals in accordance with the manufacturer's instruction.

We agree with the petitioners that 10 CFR part 35 should be revised to recognize all the mechanisms that FDA uses to authorize the use of radiopharmaceuticals. APhA also agrees with petitioners that granting of the petition would allow nuclear physicians and nuclear pharmacists to reconstitute non-radioactive kits differently from the method recommended by the manufacturer. Granting of the petition would also allow nuclear pharmacists and nuclear physicians to prepare radiopharmaceuticals whose manufacture and distribution are purposefully not regulated by FDA. Revision of the current NRC regulations will recognize the appropriate scope of the practice of pharmacy and medicine.

For example, there are many instances when reconstitution of a standard kit would not be appropriate for use with a child or an individual patient with a particular physical deficiency. The pharmacist must be able to make a preparation that is safe and effective for use with each individual patient. This often requires the pharmacist to vary from strict reconstitution of the standard kit. Not all patients are the same; therefore, reconstitution of standard kits for all patients can have an adverse effect on some patients. The current NRC regulation actually serves to jeopardize the health and welfare of Americans by prohibiting a necessary and fundamental aspect of the practice of pharmacy and medicine.

In conclusion, APhA strongly supports the proposed rulemaking change and urges NRC to adopt the revisions as petitioned. We commend the Secretary for publishing this petition for rulemaking. Adoption of these proposed revisions will lead to greater advances in the development of diagnostic and therapeutic radiopharmaceuticals. Revised regulations will free nuclear pharmacists and nuclear physicians of unnecessary barriers to their life-saving work. Please contact APhA if we can provide any further information.

Sincerely,

John A. Gans, Pharm.D.
Executive Vice President

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