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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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General Comment

To Whom It May Concern,

I am a private, board certified Nuclear Medicine Physician who current practices as a one person group. I deliver Nuclear Medicine Therapy to 4 different Medical Urology clinics in 3 states. I travel to each site in order to give these patients their therapies. I am the exact person that you will affect if you change your policy on who can deliver radionuclide therapies.

Although I am definitely concerned with my career, I want to open your eyes to where you may be led. This is a battle of where the money is going. I assure you, if you lower the restrictions of what you define as an AU, these upcoming high cost theragnostics will exploit the already skyrocketing costs of medicine.

You have an example -The NRC lowered the restrictions for Cardiologists to be the AU's sometime in the late 1990's. Once Cardiologists could order a scan and also receive re-imbursement as the "owner" of the patients and the modality, the number of Nuclear Cardiac Diagnostic scans rose exponentially! But, the Nuclear community did not benefit. Basically, the practice of medicine changed in that arena.

Do not think that if you change these restrictions, that you will not change the direction of medicine, and also the costs of medicine. I would venture to guess that, for example (in my current field), if the Urologists could order and administer therapies themselves that have costs in the tens of thousands of dollars, that there would

be more therapies given (annual average) if they could self refer without restrictions. Currently, the drug companies are 'working to find' trained physicians such as myself to administer the drugs. If the patients are already at their Urologist, why aren't they receiving the therapy? I believe that they are not motivated financially to refer!

I assure you, the practice of medicine will change if there is money behind both the drug companies and the doctors delivering. Currently, there are laws within medicine that state that physicians cannot self refer and gain money on both sides of the equation. This is to prevent exploitation of the patient. For example, I cannot give non-radioactive chemotherapy drugs. Why not? Because I am not trained and board certified to give chemotherapy drugs!

If you change the pathway for physicians who are less trained in matters of radiation safety and administration to be able to order and administer a costly drug, you are essentially motivating self referral, and giving a legal pathway for non-board certified radiation trained physician to make this unhindered decision. The ultimate costs for the patients and Medicine will undoubtedly escalate.

I was trained on your regulations and am required to uphold them and incorporate them within my medical training. If this proposal is allowed, what is your purpose? Then, do these "lower radioactive drugs" that are coming available only get regulated by the FDA? I do not know all of the answers, but I would strongly suggest that you do not take lightly the decision that you will be making to consider alternative pathways for non-radiation trained physicians to be AU's.

Thank you for your time.

Sincerely,
Barbara J. Cook, MD