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Training and Experience Requirements for Different Categories of Radiopharmaceuticals

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General Comment

See attached file(s)

Attachments

NRHA NRC Comment Letter Dec 2018 FINAL

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Commission

Training and Experience Requirements for Different Categories of Radiopharmaceuticals
Request for Comment

December 26, 2018

The National Rural Healthcare Association (NRHA) is pleased to provide comments to the Nuclear Regulatory Commission regarding Training and Experience Requirements for Different Categories of Radiopharmaceuticals. The NRHA is pleased that the NRC is opening the process to consider additional proactive stakeholder feedback.

NRHA is a non-profit membership organization with more than 21,000 members nationwide that provides leadership on rural health issues. Our membership includes nearly every component of rural America's health care infrastructure, including rural community hospitals, critical access hospitals, doctors, nurses and patients. We work to improve rural America's health needs through government advocacy, communications, education and research.

We encourage the NRC to create a pathway to expand the use of Authorized Users, (AUs), and to do so in a way that promotes the availability of AUs in rural communities.

We believe that one alternative that the NRC should consider is expanding the use of nuclear pharmacists who have the necessary training and experience to protect patient safety and enable them to "team" with oncologists and other doctors to expand the ability of these AUs to treat rural patients.

Patient Access, Section III(C): Critical Shortage of Rural Specialists

We would first like to address the question about "Patient Access" in Section III)(C), and specifically the questions regarding geographic shortages of AUs.

There are currently critical shortages of physicians in rural communities across the country. The patient-to-primary care physician ratio in rural areas is only 39.8 physicians per 100,000 people, compared to 53.3 physicians per 100,000 in urban areas. In an emergency, rural patients must travel twice as far as urban residents to the closest hospital. As a result, 60% of trauma deaths occur in rural America, even though only 20% of Americans live in rural areas.

www.RuralHealthWeb.org

The distribution among specialists is even more acute: while there are 263 specialists for every 100,000 in urban areas, that number drops to 30 specialists per 100,000 residents in rural areas.

While we do not have specific statistics regarding the number of Authorized Users (AU) in rural areas because the NRC does not provide access to that information¹, we assume that the distribution of physician Authorized Users and specialists is at best equal to this overall physician distribution. This means that there is likely a critical shortage of AU in rural areas.

This assumption is supported by the anecdotal evidence that clearly demonstrates that there are several areas of the country that face acute shortages of AUs. For example, testimony provided by Bayer to the ACMUI describes in detail the difficulty it is facing in rural Michigan because of a shortage of AUs.² Another example is the State of Indiana, where the head of NRHA's Rural Oncology task force resides. In Indiana, there are less than 20 oncology centers in the state, most of them located in Indianapolis and the suburbs of Chicago, leaving vast stretches of the state, particularly the southwest, with little access to these types of services.

Based on our experience and the statistics regarding the rural distribution of specialists across the country, we believe that these statistics are not atypical.

Further, we find it very surprising that the NRC would seek to place the burden of identifying areas where shortages may exist *on commentators*, as opposed to engaging in some proactive investigation itself. For instance, as alluded to earlier, the NRC presumably has records that list the location of current AUs. It seems to us that it would be a relatively simple process for the NRC to match that data against population distributions to determine the geographic distribution of AUs.

NRHA is disappointed that the Committee has not expressed a stronger interest in seeking to ascertain the geographic distribution of AUs. If the general distribution of specialists in rural areas is 30 per 100,000, we see no reason to believe that that distribution is any different among AUs. Asking commentators to analyze data *that the NRC possess but has not shared* seems like an inappropriate way to assess whether there is a geographic disparity in the distribution of AUs.

The problems associated with a lack of AUs is further magnified because of the role that treatments and tests administered by AUs play in early detection. Specifically, a significant percentage of the procedures that are performed by AUs are used for testing to determine if medical problems may exist. If rural patients do not have access to those early detection tools,

¹ <https://www.nrc.gov/docs/ML1808/ML18082A687.pdf>

² <https://www.nrc.gov/docs/ML1808/ML18082A687.pdf>

enabling early detection and a better course of treatment, a lack of AUs may result in more severe challenges and disease progression that could have been detected earlier.

In other words, a lack of AUs in rural areas means that problems are not detected as early, and treatment options become more limited. This is a vicious cycle that leads to worse health care outcomes in rural populations.

We have closely followed the debate in the ACMUI subcommittee over the last several months, and share Ms. Laura Weil's concern³ that just because there may be an adequate number of AUs overall, that does not mean that they are adequately distributed across the country to ensure convenient access to care for all populations.

We echo the comments of Ms. Laura Weil, the Consumer Advocate⁴, who stated that:

"If I may add -- this is Laura Weil -- while the Subcommittee's research found no evidence of shortage of Authorized Users, I think it would be a mistake to state that we found that there was demonstrable adequate numbers of Authorized Users in all healthcare settings and in all areas of the United States. We saw no evidence that there is shortage, but we can't say affirmatively that there are enough Authorized Users in all places."

"... MEMBER WEIL: To the comment regarding the raw number of Authorized Users, it does not necessarily ensure patient access. The geographic distribution of those Authorized Users has to be taken into account..."

"MEMBER WEIL: This is Laura Weil again. Just one further clarification. I'm not suggesting that accessibility is in any way a substitute for competence. But I think when we try to make the argument that there's no need to look for an alternate pathway because there are plenty of Authorized Users already available, we have to be careful how we use the word "available" because, then, it's a fallacy to say that every patient in the United States has access to an Authorized User, where there might be another way, if there's an alternate pathway, there might be a way to have people in the community who are perfectly competent and well trained and able to offer those services to people in different geographic locations."

This rural health care crisis demonstrates why the ACMUI and the Nuclear Regulatory Commission should approach this issue with some urgency, which appears to be lacking based on the transcripts of the ACMUI hearings.

In other words, we would hope that the NRC would use this opportunity to revisit this issue as a clarion call to find alternate pathways for rural patients to obtain treatment, especially with alpha and beta radiopharmaceuticals such as Bayer's Radium 223 Dichloride (Xofigo™), rather than a leisurely investigation with too few resources allocated to it.

³ CITE

⁴ <https://www.nrc.gov/docs/ML1808/ML18082A687.pdf> (Emphasis added)

Impact of the Shortage of AUs on Rural Patients

Additionally, we'd like to provide some perspective on patient convenience and how a lack of rural availability of specialty services impacts consumers and health care.

In the rural health care setting, patient convenience is a major determining factor in terms of when and how a patient seeks treatment.

Rural communities tend to be less wealthy and more remote, meaning that travel time can be a significant factor and impediment to adequate healthcare coverage. For example, going to an appointment several hours away would mean that the patient would likely have to take at least one day off of work for each appointment, and a caregiver or driver may also have to do so. If the treatment takes multiple days, costs of lodging and the cost of time away from work must also be considered. Because the typical rural patient has less income, that in and of itself could have severe economic consequences for the rural family. If multiple treatments are necessary, that magnifies the adverse impact.

Because of these challenges, rural patients may choose to take less effective tests and treatments that may be available locally, such as external beam radiation therapy instead of a systemic radiotherapy injection involving alpha or beta emitters. Because these treatment options are less effective, that could harm patients and/or miss the effective evaluation of a possible problem.

In other words, the adverse impact of a lack of AUs in the rural setting is magnified.

Patient safety

The NHRA agrees that patient safety and ensuring that trained personnel are available to protect patients and the environment when radioactive materials are used is important. However, these challenges must be weighed against convenience, which could force a rural family to choose between cost, convenience and their health.

As discussed above, using highly-trained, non-physician AUs could be part of the alternative pathway that helps the NRC break-through this challenge.

Section III) (D) Other Suggested Changes to T&E Regulations

A Possible Solution: Nuclear Pharmacists

We agree with Dr. Palestro of the ACMUI: You “can’t legislate geographic distribution.”⁵ And with Mr. Pat Zanzonico. “I think we all certainly understand and empathize with patients who really are put out to undergo a specific procedure, a specific procedure of any kind. And there

⁵ <https://www.nrc.gov/docs/ML1808/ML18082A687.pdf>

are all kinds of medical procedures from open heart surgery to whatever that are only done in specialized centers, likewise, some forms of cancer chemotherapy. And as unfair and as onerous as it may be, those procedures are performed only at centers where the practitioners are competent to perform them. And while accessibility should be a consideration in using radiopharmaceuticals clinically, certainly in therapy, in particular, it just strikes me it can't be a decisive consideration.”

However, this should NOT mean that the ACMUI and the NRC simply throw up its hands up and ignores the problem or does not even engage in a high priority attempt to resolve the problem.⁶ Instead, we urge the Committee to assume that there is an asymmetrical geographic distribution that adversely impacts rural communities, and works to attempt to find a solution for that challenge.

NRHA is not an expert of the type and extent of training that is required to become an AU. However, the proposed RFI and accompanying investigation talks EXCLUSIVELY about the requirements and changes that should be made **for physicians**. While Section D mentions “authorized nuclear pharmacists” in passing, we believe that the NRC should expand its inquiry to determine **IF NON-PHYSICIANS** can be utilized to help alleviate the geographic disparity.

For example, nuclear pharmacists that are trained in nuclear safety and are AUs could serve as part of a team that administers alpha and beta emitters to patients. Many of these are located in or closer to rural communities, and could enable a patient to obtain their test or treatment locally with their own doctor instead of having to travel to obtain treatment from a doctor that they don't know. This would satisfy the Nuclear Regulatory Commission's legitimate concerns about radiation safety, but would also address the rural shortcomings. It is therefore possible to address a reduced specific limited hours of training for the oncologist in radiotherapy with alpha and beta radiopharmaceuticals, such as Xofigo.

Therefore, we urge the ACMUI and NRC to “think outside the box,” and look at other types of AUs that could fill the vast hole in rural communities face as a way to help bridge the gap.

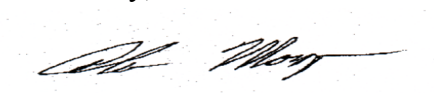
We would be happy to work with the ACMUI to investigate other alternatives, but again urge the ACMUI to make closing this gap a priority, rather than allowing this rural crisis to become even more acute.

National Rural Health Snapshot	Rural	Urban
Percentage of population	19.3%	80.7%
Number of physicians per 10,000 people	13.1	31.2

⁶ In completing his thought about geographic distribution of AUs cited in Footnote 6, Dr. Palestro went on to say that “I don't know how [the geographic distribution] is overcome.” To the NRHA, that makes it appear as though he is resigned to the problem, and does not even make an attempt to think about ways to resolve it.

Number of specialists per 100,000 people	30	263
Population aged 65 and older	18%	12%
Average per capita income	\$45,482	\$53,657
Non-Hispanic white population	69-82%	45%
Adults who describe health status as fair/poor	19.5%	15.6%
Adolescents who smoke	11%	5%
Male life expectancy in years	76.2	74.1
Female life expectancy	81.3	79.7
Percentage of dual-eligible Medicare beneficiaries	30%	70%
Medicare beneficiaries without drug coverage	43%	27%
Percentage covered by Medicaid	16%	13%
<i>All information in this table is from the Health Resources and Services Administration and Rural Health Information Hub.</i>		

Sincerely,



Alan Morgan
Chief Executive Officer
National Rural Health Association