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Yttrium-90 Microsphere Brachytherapy Sources and Devices Therasphere and SIR-Spheres

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General Comment

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November 22, 2017

I am writing to you as an MD in the middle of my fellowship in Interventional Radiology, and as a member of The Society of Interventional Radiology (SIR), a physician association comprised of over 6,100 members representing the majority of practicing interventional radiologists in the United States. I am corresponding to voice my strong opposition to the proposed changes to the "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance" that would eliminate vendor involvement from the Interventional Radiology pathway to Authorized User (AU) status.

The current process, known as Pathway 2, has been in place since the concept evolved that Interventional Radiologists are the logical choice for AU of these devices. For these procedure, Interventional Radiologists:
perform required dosimetry to deliver appropriate activity to the patient,
oversee and ensure appropriate Yttrium-90 (Y90) device handling and preparation,
directly administer the therapy to the patient, and

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coordinate the longitudinal care of patients following these procedures.

Interventional Radiologists are the only Authorized Users capable of performing all four steps above. The existing collaboration between physicians and industry helps ensure safe and comprehensive training in the use of Y90 devices. The existing guidelines have been tremendously successful while maintaining impeccable safety. Manufacturer And User facility Device Experience (MAUDE) reports have remained 10/year for both devices since 2013. The majority of the
MAUDE reports focus on procedural complication and treatment toxicities seen with all types of hepatic embolization, not
specific to the Y90 devices. It seems statistically implausible that reduced vendor involvement will result in a measurable
improvement in safety.

Proposed changes to the current arrangement, in which physicians and industry work closely together to ensure the appropriatetraining of interventional radiologists in the safe use of these devices will make it exceedingly difficult for Interventional Radiologists developing a clinical practice in radioembolization. Without the current direct training provided offsite by the device vendors, physician training will have to be solely performed by direct proctoring. Securing physician proctors is a challenge and can result in the delay in care, impacting cancer outcomes; physicians have limited time and availability away from their own clinical practices. Placing additional responsibilities on physician proctors may also have the untoward effect of limiting access to care, particularly for programs in underserved areas. The unanticipated consequence of the proposed changes is that training Interventional Radiologists in the safe and effective use of these devices will suffer greatly and patient access to care will diminish.

In summary, Interventional Radiologists deliver high quality minimally invasive care via imaging guidance, employing a
variety of technologies. Training with other devices, such as aortic stent grafts, spinal augmentation devices, and atherectomy tools frequently involves a combination of vendor and physician collaboration. These relationships are a supplement to core training in hepatic embolization that is accomplished in fellowship. However, fine details regarding all devices may not be included in all programs. The existing NRC guidelines have facilitated training Interventional Radiologists in the safe and effective use of the Y90 devices, benefiting patients, physicians, and the government. There is no evidence of a need for change to the current NRC guidelines.

Sincerely,

Mircea Cristescu