March 12, 2013

Marilyn B. Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3267-P
P.O. Box 8010
Baltimore, MD 21244–8010

Re: CMS-3627-P Medicare and Medicaid Programs; Part II – Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction

The Society of Nuclear Medicine and Molecular Imaging (SNMMI), with 19,000 members, comprised of physicians, nuclear pharmacists, scientist, technologists, educators and administrators, appreciates the opportunity to provide comments for Part II – Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction. Specifically, we applaud CMS’s recommendation to remove the word direct from the supervision requirement in § 482.53(b)(1).

**Nuclear medicine services (§ 482.53)**

The proposed rule states: “We propose to revise the current requirement at § 482.53(b)(1) by removing the term “direct.” The revised requirement would then require that in-house preparation of radiopharmaceuticals be performed by, or under the supervision of, an appropriately trained registered pharmacist or doctor of medicine or osteopathy. The revision to “supervision” from “direct supervision” would allow for other appropriately trained hospital staff to prepare in-house radiopharmaceuticals under the oversight of a registered pharmacist or doctor of medicine or osteopathy, but it would not require that such oversight be exercised by the physical presence in the hospital at all times of one of these professionals, particularly during off-hours when such a professional would not be routinely present.”

SNMMI applauds CMS’s proposal to revise this current requirement by removing the term “direct.” This change to “supervision” from “direct supervision” would allow for appropriately trained hospital staff to prepare in-house radiopharmaceuticals under the oversight of a registered pharmacist or doctor of medicine or osteopathy, but it would not require their physical presence in the hospital. It is not always practical or necessary for the pharmacist or doctor to be physically present. As a result, these proposed changes to § 482.53(b)(1) would ease unnecessary administrative burden while maintaining quality access to care. Additionally, having appropriately trained, certified or otherwise qualified technologists in rural area hospitals would ensure patients receive critical diagnostic tests when needed. SNMMI met with CMS policy staff on November 21, 2011, where we voiced our concerns and they provided valuable information regarding the current process for reforms. The proposed changes in this rule make it clear that CMS heard our concerns and clearly understood the issues.

The preparation of radiopharmaceuticals is an integral part of a nuclear medicine technologist’s profession and is discussed in SNMMI’s Nuclear Medicine Technologist Scope of Practice. The Scope of Practice document is intended to set forth the standards important in areas of the nuclear medicine
technologist’s responsibilities. Line 29-31 of the Scope of Practice states “Radiopharmaceuticals: Involves the safe handling and storage of radioactive materials during the procurement, identification, calibration, preparation, quality control, dose calculation, dispensing documentation, administration and disposal.” Additionally, the knowledge and skills to prepare radiopharmaceuticals is essential in passing the Nuclear Medicine Technology Certification Board’s Nuclear Medicine Exam. Nuclear medicine technologists are appropriately trained in the preparation of radiopharmaceuticals and the proposed changes to § 482.53(b)(1) support their expertise. Therefore, SNMMI recommends that CMS finalize, without modification, the proposed rule, including the deletion of the word “direct.”

Radiology services in ambulatory surgical centers:
This proposed rule would also reduce the requirements Ambulatory Surgical Centers (ASCs) must meet in order to provide radiological services to match those services they actually perform. ASCs are currently subject to the full hospital requirements for radiology services even though they are only permitted to provide limited radiologic services integral to the performance of certain surgical procedures. Section 416.49(b) of Title 42 of the Code of Federal Regulations outlines the radiologic services requirements that ASCs must meet in order to be Medicare-certified. CMS states that some of the Hospital Conditions of Participation (CoP) requirements are unduly burdensome for ASCs to meet such as the requirement to have a radiologist supervise the provision of radiologic. As a result, SNMMI agrees with CMS’s proposal to remove § 416.49(b)(1) and replace it with the requirement that radiologic services may only be provided when integral to procedures offered by the ASC and must meet the requirements specified in § 482.26(b), (c)(2), and (d)(2). We also agree with removing the existing language at § 416.49(b)(2) and replacing it with the requirement that an MD/DO who is qualified by education and experience in accordance with state law and ASC policy must supervise the provision of radiologic services.

Outpatient Services (§ 482.54)
Finally, CMS proposed to revise the outpatient services CoP to allow for practitioners who are not on the hospital’s medical staff to order hospital outpatient services for their patients when authorized by the medical staff and allowed by state law. The proposed changes are to the requirements at § 482.54, “Outpatient services.” Specifically, CMS is adding a new standard at § 482.54(c), entitled “Orders for outpatient services.” CMS states that it is taking this opportunity to propose these revisions in this rule so that the regulations would codify Interpretive Guideline (IG) changes that CMS recently made regarding the ordering of outpatient services. SNMMI agrees with CMS’s proposed revisions to the requirements to mean that orders for outpatient services may be made by any practitioner who is responsible for the care of the patient; licensed in the State where he or she provides care to the patient; acting within his or her scope of practice under State law; and authorized in accordance with policies adopted by the medical staff, and approved by the governing body, to order the applicable outpatient services.

SNMMI appreciates your consideration of these important changes of significance to SNMMI members regarding the Hospital Conditions of Participation Nuclear Medicine Services 482.53 (b)(1). We appreciate CMSs attention to our member issue. We believe the proposed change, when finalized, will benefit all stakeholders. Should you have any questions, please contact Sue Bunning, Director of Health Policy and Regulatory Affairs at sbunning@snmmi.org or (703) 326-1182.
Sincerely,

Fredric H. Fahey, DSc
President, SNMMI

cc: Virginia Pappas, CAE