SNM
Advancing Molecular Imaging and Therapy

Submitted Electronically: http://www.regulations.gov/

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Marilyn B. Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3244–P
P.O. Box 8010
Baltimore, MD 21244–8010

Re: CMS-3244-P Medicare and Medicaid Programs; Reform of Hospital and Critical Access Hospital Conditions of Participation Hospital CoP Nuclear Medicine Services 482.53 (b)(1)

The Society of Nuclear Medicine (SNM), with 17,000 members, comprised of physicians, nuclear pharmacists, scientist, technologists, educators and administrators, appreciates the opportunity to provide comments to this proposed regulation to reform, update and modernize the hospital and critical access hospital Conditions of Participation (CoP) for the Medicare and Medicaid programs, the first comprehensive review and revision in over 25 years. CMS states in this proposed rule, "we welcome suggestions for future rulemaking from affected parties to identify other reforms to the CoPs that would reduce unnecessary burden on hospitals, while allowing maximum flexibility in meeting the Federal requirements necessary to fulfill our quality of care responsibilities." Specifically, our comments will focus on direct supervision as it relates to the CMS Conditions of Participation (CoP) for Nuclear Medicine Services 482.53 (b)(1). We believe that inconsistencies in inspector interpretations from administratively burdensome regulations have led to inappropriate citations which have now led to limited patient access or unnecessary increased costs. Additionally, we will provide general comments regarding a more predictable and transparent process for revising rules as well as the interpretive guidelines.

Background on Nuclear Medicine

In 2010, 17 million nuclear medicine procedures were performed in the United States. Of those, 10.9 million were in hospitals. Over the years, hospitals have been cited by state inspectors with regard to the process of "direct supervision" during the preparation of radiopharmaceuticals rather than ensuring those preparing the radiopharmaceuticals are uniquely qualified and trained to provide those services. These citations have resulted in the discontinuation of afterhours stat procedures which have unnecessarily limited direct access for patients. When an emergency arises, which would warrant the order for an urgent nuclear medicine procedure, it is often not practical or necessary to go to another facility. Waiting for the direct supervision of a registered pharmacist or physician unnecessarily puts the patient at

risk. In 2010, 9% of all nuclear medicine imaging was conducted on an emergency or unscheduled basis, meaning roughly 1,530,000 patients could have been negatively affected by these citations. The estimated number for full-time equivalent (FTE) staff in nuclear medicine departments throughout the country is 36,875 FTEs, including 18,560 technologists or 2.6 per site, all of whom may be influenced by the threat of citation.

Nuclear Medicine 482.53 (b)(1):
We believe CMS, hospitals and most importantly the patient would be better served and protected with modifications to the current CoP removing the word "direct." Additionally, providing enhancements to the interpretive guidelines focusing on the "authorized user (AU),[1]" certification of uniform competencies, radiopharmaceutical preparation qualifications, relevant practice standards, and certification assessments rather than layering staff would be of benefit.

Therefore, the SNM respectfully urges CMS to modify the interpretive guidelines that accompany Section 482.53 (b)(1) which currently states *"In-house preparation of radiopharmaceuticals must be performed by, or directly supervised by, a registered pharmacist, or a doctor of medicine or osteopathy who is qualified through education, experience and training, in the preparation of radiopharmaceuticals, consistent with Federal or State law*." As noted earlier, it is not always practical or necessary for the AU to be physically present or immediately available to provide safe supervision and oversight. We ask CMS to allow the authorized user be given the authority, as noted and consistent with the Nuclear Regulatory Commission (NRC) guidelines, to delegate specific tasks, as they are best suited for determining tasks that supervised individuals can perform and the degree of supervision required. The NRC's Frequently Asked Questions (FAQs) discusses the delegation of supervisory responsibilities and can be found attached. Furthermore, we request that the authorized user put policies in place to clarify the specific tasks delegated and the supervision and certification necessary for each. This clarification would ease unnecessary administrative burden and rightfully place the oversight with the authorized user of radiopharmaceuticals. We believe this revision will allow hospitals to save money while maintaining quality access to care.

[1] Authorized user, as defined by the NRC in § 35.2 Definitions, means a physician, dentist, or podiatrist who—
(1) Meets the requirements in §§ 35.59 and 35.190(a), 35.290(a), 35.390(a), 35.392(a), 35.394(a), 35.490(a), 35.590(a), or 35.690(a); or
(2) Is identified as an authorized user on—
(i) A Commission or Agreement State license that authorizes the medical use of byproduct material;
(ii) A permit issued by a Commission master material licensee that is authorized to permit the medical use of byproduct material;
(iii) A permit issued by a Commission or Agreement State specific licensee of broad scope that is authorized to permit the medical use of byproduct material; or
(iv) A permit issued by a Commission master material license broad scope permittee that is authorized to permit the medical use of byproduct material.

Additionally, having appropriately trained, certified or otherwise qualified technologists[2] in rural area hospitals would ensure patients receive critical diagnostic tests when needed. **We respectfully request that CMS remove the word "direct" in Section 482.53 (b)(1) to reflect the delegation authority of the authorized user.**

Rulemaking to Future Reforms:
The SNM thanks the CMS policy staff, with whom we met on November 21, 2011, for providing valuable information regarding the current CoP process for reforms. We encourage CMS to develop and implement predictable timetables as well as ensure transparent processes for timely modifications. We are concerned with the lack of ongoing open opportunities to modify and update the CoP as well as the lack of a clearly defined process for modifying the interpretive guidelines. We believe 25 years is far too long for formal review and urge CMS to implement, at minimum, a yearly opportunity to allow for meaningful transparent stakeholder input.

The Society of Nuclear Medicine (SNM), headquartered in Reston, VA, is a nonprofit scientific and professional organization that promotes the science, technology and practical application of nuclear medicine and molecular imaging. SNM strives to be a leader in unifying, advancing and optimizing molecular imaging, with the ultimate goal of improving human health.

The SNM appreciates your consideration of this important change to the Hospital CoP Nuclear Medicine Services 482.53 (b)(1). We would like to restate our offer to continue to work with CMS on the Hospital CoP as well as its interpretive guidelines. As stated during our November 21, 2011 meeting, we believe our members are uniquely qualified to provide valuable input to CMS on the topic of nuclear medicine technology. Should you have any questions, please

[2] A certified nuclear medicine technologist is an allied health professional certified in nuclear medicine technology and educated in patient care, whom, under the direction of an authorized physician user (AU), is committed to applying the art and skill of diagnostic and therapeutic nuclear medicine procedures through the safe and effective use of radionuclides. Current professional standards adopted by the Society Of Nuclear Medicine (SNM), the Society Of Nuclear Medicine Technologist Section (SNMTS); the American College Of Radiology (ACR) and the American Society of Radiologic Technologists (ASRT) state that a "nuclear medicine technologist prepares and verifies quality of radiopharmaceuticals under the direction of an authorized user." Additionally, "a nuclear medicine technologist performs imaging procedures by administering radiopharmaceuticals and/or pharmaceuticals using standard precaution techniques."

contact Sue Bunning, Director of Health Policy and Regulatory Affairs at sbunning@snm.org or (703) 326-1182.

Respectfully Submitted,

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SNM President

RE: NRC view of "supervision" and "direct supervision"

(Yellow highlights added)

Reference: NRC--Frequently Asked Questions About Licensing Medical Uses of Byproduct Material Under Revised 10 CFR Part 35
http://www.nrc.gov/materials/miau/med-use-toolkit/faqs-part35.html

Delegation of Supervisory Responsibilities

Can the authorized user (AU) delegate supervisory responsibilities to a chief technician who supervises others in specific tasks associated with using or preparing byproduct material? [10 CFR 35.27] (Q&A ID 0103043)

Only AUs and authorized nuclear pharmacists (ANPs) are authorized to use or prepare, respectively, byproduct material in the practice of medicine. However, it is frequently necessary for an AU or ANP to delegate specific tasks associated with the use or preparation of byproduct material in the practice of medicine to other individuals. Section 35.27 allows for this delegation of tasks as long as the individuals are properly supervised and instructed. The AUs and ANPs are best suited for determining tasks that supervised individuals can perform and the degree of supervision that each individual needs.

Refer to "Supplementary Information," Section III, "Summary of Public Comments and Responses to Comments" for §35.27, as published in the *Federal Register* on April 24, 2002.

The NRC Web site has the information published in the Federal Register on April 24, 2002 at the following web page:
http://www.nrc.gov/reading-rm/doc-collections/cfr/fr/2002/20020424.html

By searching this page for "degree of supervision" you can find the following text that supports the answer to the FAQ shown above. [Which also may be found on page 20285 (third column, first full paragraph) of the Federal Register for April 24, 2002]:

The topic under review is: *Section 35.27, Supervision*
Issue 1: Why Does This Section Include Requirements for Supervising Individuals?

Comment. Commenters had a number of concerns about the requirements for supervising individuals in this section. One concern was that there is no requirement for a licensee to notify the NRC that it operates in the manner permitted by this section, i.e., a licensee does not have to inform NRC when it allows supervised individuals to use byproduct material. Therefore, this section is not consistent with other sections in the regulations that only allow licensees to

conduct activities that are permitted by their licenses. This section should be deleted or changed to require licensees to apply for a supervised user program within their license applications. In addition, commenters noted that if NRC is not made aware of this type of activity, it is not conducive to inspection activities.

Another concern was that this section permits individuals, including physicians, to use byproduct material without completing the training and experience requirements for AU status. This also allows a physician who does not meet the training and experience requirements for an AU to perform the duties of the AU without the AU being present. If the training and experience required to become an AU is necessary, the supervising AU should be required to be present (e.g., during the administration and reading of films), and the supervised physician should be required to attain licensure in a specified period of time.

Another commenter also said that this section should be deleted, but said that if the section is retained it should be revised to meet minimal ACGME teaching requirements for physicians. Recommended changes relate to whether: the supervising physician and the supervised physician must be within the same city (and preferably in the same building); the number of physicians supervised at one time should be limited; the duration of a physician working under the supervision of an AU should be limited; the NRC should verify the ability of the supervising individual to teach; the supervised program should have a curriculum, goals, objectives, handouts, and testing; and the NRC should be notified that a supervised physician program is in effect.

Some commenters said that there was no need for this section because its provisions are covered in other sections of Part 35. For example, proposed § 35.11 (b) and (c) state that a specific license is not needed for individuals receiving, possessing, using, transferring, and preparing byproduct material under the supervision of an AU or ANP, respectively. In addition, commenters said that paragraphs (a) and (b) of this section, that contain requirements for supervised individuals to follow the instructions of the supervising AU or ANP, should be deleted. If there is a failure to properly supervise, the licensee, not the supervisor, will ultimately be responsible because paragraph (d) of this section holds the licensee responsible for the acts and omissions of supervised individuals.

In addition, one commenter said that the ANP should be added to paragraph (a) because, in order to prepare material, the material must first be received, possessed, and used.

Response. Under part 35, only AUs and ANPs identified on a medical use license are allowed to use or prepare, respectively, byproduct material in the practice of medicine. It is frequently necessary for an AU or an ANP to delegate specific tasks associated with using or preparing byproduct material to other individuals who do not have the same training in the use or preparation of the byproduct material for medical use. This section allows for that delegation, if the individuals are properly supervised and instructed. The supervised individuals must also be required to follow the instructions of the supervisor for medical uses of radioactive material or for preparation of byproduct material for medical uses, the licensee's written radiation protection program procedures and written directive procedures, the license conditions, and the regulations of this chapter. These provisions do not require prior notification of the NRC that a licensee has

delegated tasks associated with the medical use of byproduct material, e.g., tasks such as package receipt, administration, and disposal of the radioactive waste. Such a requirement would be an unnecessary burden and negate the flexibility afforded to licensees in conducting their medical use programs.

The AUs and ANPs are best suited to determine what tasks supervised individuals are capable of performing and the degree of supervision that each needs. Consequently, this section does not include prescriptive requirements for training or list delegatable tasks. The NRC believes that the requirements in this section provide the best balance between NRC's responsibility to assure the public health and safety and the licensee's responsibility for the safe use of byproduct material.

We have not added ANP to paragraph (a) of this section because this requirement is tied to § 35.11(b)(1), which only allows individuals to receive, possess, use, or transfer material under the supervision of an AU. Section 35.11(b)(2) permits the preparation of byproduct material for medical use under the supervision of an AU or ANP, unless prohibited by license condition.

[Note: AU="Authorized User" and ANP="authorized nuclear pharmacist"]

SNMTS
Advancing Molecular Imaging and Therapy

An SNM *Technologist Section* (SNMTS) Presidential Task Force established in the summer of 2010 developed the following revised *SNMTS Scope of Practice* for nuclear medicine technologists. Members of the task force were Richard Noto, MD, Danny Basso, AS, CNMT, NCT, FSNMTS; Jeanne Dial, MEd, CNMT; David Gilmore, MS, CNMT, NCT, RT(N,R). FSNMTS; Marcia Hess- Smith, BS, CNMT; Sara Johnson, MBA, CNMT,NCT; Brenda King, CNMT, FSNMTS; Cindi Luckett-Gilbert, MHA, CNMT, PET,RT (N), FSNMTS; Lyn Mehlberg, BS, CNMT, FSNMTS; Frances Neagley, BA, CNMT, RT (R,N), FSNMTS; Kathy Thomas, MHA, CNMT, PET, RT (R)(N)(CT), FSNMTS. The task force was chaired by Lynne T. Roy, MS, MBA, CNMT, RT (N), FSNMTS

This document is not intended to modify or alter existing tort law; rather it should serve as a concise outline of nuclear medicine technology skills and responsibilities.

NUCLEAR MEDICINE TECHNOLOGY

Nuclear medicine which includes molecular imaging, is the medical specialty that utilizes sealed and unsealed radioactive materials in the diagnosis and therapy of various diseases. This practice also includes the utilization of pharmaceuticals (used as adjunctive medications) and other imaging modalities with or without contrast to enhance the evaluation of physiologic processes at a molecular level. The nuclear medicine technologist is an allied health professional who, under the direction of an authorized user, is committed to applying the art and skill of their profession to optimize diagnostic evaluation and therapy through the safe and effective use of radiopharmaceuticals and adjunctive medications.

The practice of nuclear medicine technology requires multidisciplinary skills that are needed to use rapidly evolving instrumentation, radiopharmaceuticals, adjunctive medications and techniques. The responsibilities of the nuclear medicine technologist include, but are not limited to, patient care, quality control, diagnostic procedures, radiopharmaceutical and adjunctive medication, preparation and administration, in vitro diagnostic testing, radionuclide therapy, and radiation safety. The nuclear medicine technologist can also participate in research.

In order to perform these tasks, the nuclear medicine technologist must successfully complete didactic and clinical education. Education includes, but is not limited to, methods of patient care, immunology, cross sectional anatomy, pharmacology, nuclear medicine and radiation physics, radiation biology, radiation safety and protection, nuclear medicine instrumentation, quality control and quality assurance, computer applications for nuclear medicine, general

diagnostic nuclear medicine procedures, radionuclide therapy, positron emission tomography (PET), computed tomography (CT), radionuclide chemistry, radiopharmacy, medical ethics and law, healthcare administration, health sciences and research methods, and medical informatics.

Graduates of accredited programs are eligible to sit for certification examinations offered by the *Nuclear Medicine Technology Certification Board* and the *American Registry of Radiologic Technologists*.

The spectrum of the nuclear medicine technologist's responsibilities varies widely across the country and may exceed basic skills outlined in the technologist's initial education and certification. Practice components presented in this document provide a basis for establishing the areas of knowledge and performance for the nuclear medicine technologist. It is assumed that for all activities included in this scope of practice, the nuclear medicine technologist has received the proper education and is in compliance with all federal, state and institutional guidelines including proper documentation of initial and continued competency in those practices and activities. Continuing education is a necessary component in maintaining the skills required to perform all duties and tasks of the nuclear medicine technologist in this ever-evolving field.

THE SCOPE OF PRACTICE

The scope of practice in nuclear medicine technology includes, *but is not limited to*, the following areas and responsibilities:

- **Patient Care:** Requires the exercise of judgment to assess and respond to the patient's needs before, during and after diagnostic imaging and therapeutic procedures and in patient medication reconciliation. This includes record keeping in accordance with the Health Insurance Portability and Accountability Act (HIPAA).
- **Quality Control:** Requires the evaluation and maintenance of a quality control program for all instrumentation to ensure optimal performance and stability.
- **Diagnostic Procedures:** Requires the utilization of appropriate techniques, radiopharmaceuticals and adjunctive medications as part of a standard protocol to ensure quality diagnostic images and/or laboratory results.
- **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.
- **Adjunctive Medications:** Involves the identification, preparation, calculation, documentation, administration and monitoring of adjunctive medication(s) used during an in-vitro, diagnostic imaging, or therapeutic procedure. Adjunctive medications are defined as those medications used to evoke a specific physiological or biochemical response. Also included

are the preparation and administration of oral and IV contrast used in the performance of imaging studies.

- **In Vitro Diagnostic Testing:** Involves the acquisition of biological specimens with or without oral, intramuscular, intravenous, inhaled or other administration of radiopharmaceuticals and adjunctive medications for the assessment of physiologic function.
- **Operation of Instrumentation:** Involves the operation of:
  - Imaging instrumentation:
    - Gamma camera systems with or without sealed sources of radioactive materials or x-ray tubes for attenuation correction, transmission imaging or diagnostic CT (when appropriately educated, trained and/or credentialed).
    - PET imaging systems with or without sealed sources of radioactive materials or x-ray tubes for attenuation correction, transmission imaging or diagnostic CT (when appropriately trained and/or credentialed)
    - Bone density imaging systems with x-ray tubes
  - Non-imaging instrumentation:
    - Dose calibrators
    - Survey instrumentation for exposure and contamination
    - Probe and well instrumentation
    - Ancillary patient care equipment as authorized by institutional policies.
- **Radionuclide Therapy:** Involves patient management, preparation and administration of therapeutic radiopharmaceuticals, under the personal supervision of the Authorized User
- **Radiation Safety:** Involves practicing techniques that will minimize raditation exposure to the patient, health care personnel and general public, through consistent use of protective devices, shields, and monitors consistent with ALARA (as low as reasonably achievable) and establishing protocols for managing spills and unplanned releases of radiation.

REFERENCES

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