American College of Radiology

Good Afternoon Practicing Physician Advisory Council Members and Centers for Medicare and Medicaid Services Representatives:

Thank you for this opportunity to speak today on behalf of over 33,000 radiologists, interventional radiologist, radiation oncologists and medical physicists. My name is (insert name of speaker) and I am a practicing diagnostic radiologist in (insert location of speaker's practice). I work at (insert name of speaker's practice). I am also the (insert ACR position of speaker). It is in this capacity, as a representative of the American College of Radiology, that I speak to you today.

During the five minutes allotted for oral testimony, I will summarize my comments to the supervision of diagnostic imaging services and will discuss the consequences of allowing non-physician personnel such as clinical nurse specialists (CNS), nurse practitioners (NPs), and physician assistants (PA) to supervise diagnostic imaging services. The consequences I will highlight in this testimony include effects on:

I. Quality of Care;
II. Radiation Safety;
III. Malpractice Implications.

In addition, I will also comment briefly on:

IV. Other
- Sustainable Growth Rate (SGR);
- Coverage of Contrast Media.

Should time not allow for verbal comment on these areas, the information is in the written testimony distributed to you prior to this meeting.

While CMS has not specifically published a proposal to allow non-physician personnel to supervise diagnostic imaging services, the testimony I provide today is in response to Mr. Terry Kay's (Director of the Division of Practitioner and Ambulatory Care Center for Health Plans and Providers, CMS) request for input on this possibility. As I understand it, Mr. Kay spoke to the PPAC briefly in December and mentioned that there were some operational issues regarding the supervision of "diagnostic tests" by non-physician personnel. As per Mr. Kay's example, these issues specifically regarded a NP, CNS or PA's ability (in accordance with appropriate state law) to perform diagnostic tests and receive payment for them as compared to their inability to supervise these same diagnostic tests.

The ACR is extremely concerned by CMS's verbal indication that consideration is being given to allowing non-physician personnel the ability to supervise physician services.

While it not clear what Mr. Kay's definition of the term "diagnostic tests" includes, the ACR strongly believes that independent supervision of any imaging study is well beyond the scope of education, training or certification received by any of the non-physician practitioner groups.

The ACR remains extremely concerned that CMS in 2000 (effective date) expanded the scope of practice for CNS, NPs and PA* to order, perform and interpret diagnostic imaging services **without physician supervision** when they are authorized by the State. The ACR maintains its position that the ability of CNS, NP and PA's to **independently** (as per State law) perform, interpret and bill for diagnostic imaging examinations of Medicare patients presents a significant threat to quality of care. The ACR opposes any expansion of the independent practice of these groups to include supervision of diagnostic imaging studies.

- PA's require general supervision

I. Quality of Care:

The ACR maintains that expanding the scope of care to allow supervision of physician services by these non-physician personnel will jeopardize the quality of care Medicare beneficiaries receive and there is no evidence to the contrary.

Imaging Examination Quality

Extensive training, experience and expertise of a radiologist who has had specific training and experience in supervising diagnostic imaging studies is critical to the assurance of quality imaging and appropriate patient care. CMS has recognized this fact in its regulation for supervision of portable x-ray services by stating, "Portable X-ray services are provided under the supervision of a licensed doctor of medicine or licensed doctor of osteopathy **who is qualified by advanced training and experience in the use of x-rays for diagnostic purposes**. (emphasis added)"

Film and image quality is a critical factor in obtaining an accurate diagnosis. If examinations are of poor quality then abnormalities, which may have been obvious on a high quality exam, will be missed. This will lead to delay in diagnosis, increased cost for repeat studies and overall suboptimal care for Medicare beneficiaries.

While not all physicians receive the same training in the use of x-rays and other modalities of medical imaging for diagnostic purposes, it is important to iterate the training received by radiologists as we believe this is the standard against which other pathways of advanced training must be judged. The supervising individual must have the necessary training to assure high quality examinations. Radiologists, for example, receive at least five years of training after medical school in academic departments with dedicated faculty to equip them with these skills. This includes knowledge of

radiographic exposure parameters and knowledge of the effects of changing kV, mA and exposure time on the images. An understanding of even more complex imaging physics is necessary in order to appropriately supervise computed tomography, ultrasound, nuclear medicine or magnetic resonance imaging studies. A supervising individual's training must also include an environment where they have seen and evaluated an extremely large number (tens of thousands in the case of a typical radiology resident) of imaging studies for technical quality under the supervision of a qualified physician. The bottom line is that if examinations are not recognized as poor quality, then there is an inherent likelihood of misinterpretation.

Supervision

Supervision of imaging examinations requires a level of medical knowledge that is well beyond the typical training of the non-physician practitioners.

The elements necessary for a physician to supervise all imaging studies include but are not limited to:

1. Setting up protocols for examinations;
2. Determining the number of films and views;
3. Proper radiographic technique;
4. Proper patient positing;
5. Proper radiation exposure techniques and completeness;
6. Proper equipment specifications;
7. Radiation Safety.

In addition to the issues of protocol, quality assurance and radiation safety described above, the following is necessary:

1. Adequate knowledge of anatomy and pathology: Protocols are often changed during the course of the examination dependent on clinical symptoms and signs or as a result of the initial images. For example, a physician needs to determine when IV contrast is appropriate or what additional images will be needed to best delineate, for example, a small mass in the pancreas or navicular fracture of the wrist.

2. Specific training and experience in the use of IV contrast and the treatment of contrast reactions. A physician must be readily available to respond if a patient experiences a complication.

Imaging services such as angiograms and barium enemas are even more complex and require a physician’s attendance in the room during the performance of the procedure.

The ACR has developed Standards to ensure proper qualifications for physicians who supervise or perform these examinations in order to ensure quality and appropriate patient care.

Independent Diagnostic Testing Facilities (IDTFs) / Portable x-ray Services:

In addition, allowing non-physician personnel to supervise diagnostic imaging services will also have drastic implications on IDTFs (entity independent of a physician office or hospital) and portable x-ray services. A supervising physician is responsible for the direct and ongoing oversight of the quality of the testing performed, equipment used and personnel employed, in these settings.

II. Radiation Safety:

CNS and NP's lack sufficient education and training in radiation physics, radiation protection, radiation biology (particularly the impact of radiation on the developing embryo or fetus) to balance the clinical needs of the patients with the risk of radiation exposure. They have not received sufficient training to understand changes in positioning or changes in examination protocols that may limit radiation exposure without severely compromising the diagnostic information obtained. Expansion of the scope of practice of these individuals into diagnostic imaging without this knowledge base creates great potential for unnecessary and excessive exposure in both the office and IDTF settings.

III. Malpractice Implications:

Another problem that could arise if CMS eliminates the requirement that physicians supervise diagnostic tests is malpractice liability. If a nurse practitioner or physician assistant lacks proper training and experience, he or she could be responsible for an adverse event that could result in a malpractice lawsuit. That litigation likely would be far reaching – naming the non-physician and the physician, hospital, health plan or clinic that employs the provider. Each defendant in a lawsuit attributable to negligent supervision by an NP or PA would have to take valuable time away from patients and could face significant costs.

Increased malpractice risks incurred by non-physicians would further contribute to the already volatile professional liability insurance market. Physicians throughout the United States struggle to obtain and keep adequate, affordable liability coverage. The prospect of additional claims for direct or vicarious liability based on a non-physician's inadequate supervision of diagnostic tests could shrink the market even further.

Summary / Telehealth:

In summary, there is no comparison between the training and expertise of a nurse practitioner and a physician specialist. It is difficult for us to consider a NP and CNS as having the education, training and experience necessary to serve in these supervisory roles. We agree with CMS's prior regulations that supervision of diagnostic tests must remain the responsibility of a physician who **is qualified by advanced training and experience in the use of x-rays (or other imaging modalities) for diagnostic purposes**. Such physicians can participate in the clinical decision making process as a part of the medical team caring for the patient.

The ACR is sensitive to the need to assure Medicare beneficiaries access to care in rural and underserved settings and understands access to care is in part, a reason for CMS' decision to allow NP, CNS and PA the ability to perform diagnostic imaging examinations. However, the use of teleradiology is a solution to this potential access to care concern as it improves access to radiological interpretations and still allows for Medicare patients to receive the performance and interpretation of diagnostic imaging examinations as supervised and interpreted by a physician. The ACR is happy to further discuss with CMS or PPAC ways in which the population of rural and underserved areas of the country can safely receive the same quality diagnostic imaging examinations with supervision and interpretation by radiologists through the use of telehealth. If the scope of telehealth services is expanded, the ACR would like to discuss our Standards on Teleradiology and Digital Image Data, as certain standards of telehealth should be met to ensure the quality of radiologic images transmitted electronically.

The ACR promotes quality care and accordingly requests that CMS make important physician supervision decisions based on that fundamental objective. I thank CMS for seeking public input on this topic prior to officially proposing such a change in regulation and urge CMS to eliminate any possibility of allowing non-physician personnel the ability to supervise physician services.

IV. Other (time permitting):

Medicare Update and the Sustainable Growth Rate (SGR):

The ACR continues to be extremely concerned about Medicare's formula for annually updating payments for physicians' services and its impact on access and quality of care. It is well documented that the expense for performing services is increasing, not decreasing. With respect to the SGR, the ACR encourages CMS to include national Medicare coverage decisions issued by CMS in the SGR formula. For example, in radiology alone, over the past two years CMS has expanded coverage for 1) digitization of film, radiographic images for screening mammography and computer-aided detection, 2) percutaneous image-guided breast biopsy for palpable lesion(s), 3) percutaneous transluminal angioplasty of the carotid artery concurrent with stenting in an approved FDA clinical trial, 4) fluoro-2-deoxy-D-glucose (FDG) Positron Emission Tomography (PET)) for lung, esophageal, colorectal, lymphoma, melanoma, head and neck cancers as

well as myocardial viability and refractory seizures, 5) FDG PET as an adjunct service to standard imaging modalities for breast cancer, and 6) FDG PET for myocardial viability. No allowance has been made in the SGR for these additional covered services. As regulatory rulings, these should result in expansion of total Medicare reimbursement as Congress had intended.

Outpatient Drugs in the SGR:

The ACR urges CMS to remove outpatient drugs from the SGR formula. The outpatient drugs that Medicare covers, which include many new cancer drugs, are included within the SGR pool but no allowance is made in the target for the significant increases in the costs of these drugs. The elements of the SGR formula need to be very predictable; in order to estimate costs for the target, and the cost of these drugs is too hard to project. Considerable funding is allocated to the National Cancer Institute to develop these drugs, however, adequate funds need to be allocated in the MFS to cover the cost of administering the drugs to patients.

Coverage of Low Osmolar Contrast Media (LOCM):

The ACR encourages the PPAC and CMS to consider the Medicare beneficiary when evaluating the coverage of Low Osmolar Contrast Media and assure access to this contrast agent by maintaining LOCM as a separately codeable and reimbursed as a separate payment by CMS. CMS must not follow, for Part B, the recent precedence set by HOPPS/APCs, which bundled the payment of LOCM into the APCs. LOCM is compromised of nonionic agents, which have been shown to be associated with less discomfort and have a lower incidence of adverse effects, a benefit of most importance to the elderly and fragile population of Medicare beneficiaries. For these reasons, CMS should also expand the coverage of LOCM under the current five criteria to further include patients with renal insufficiency (particularly those with diabetes), patients with generalized debilitation as determined by a physician, patients at high risk for contrast extravasation, and patients receiving contrast by power injector. This is what ACR requested two years ago and continues to stress as an appropriate update to LOCM coverage for quality patient care.

I thank you for the opportunity to present the position of the ACR on these very important issues. I welcome any questions the Panel may have at this time and at any time following today's meeting.

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