**72012-13 Federal Register** / Vol. 75, No. 226 / Wednesday, November 24, 2010 / Rules and Regulations **[CMS–1504–FC and CMS–1498–IFC2]**

Comment:During the past year, we were often questioned about clinical requirements for practitioners supervising extremely specialized services, notably radiation oncology services. One commenter requested that CMS consider the direct supervision requirement to be met for diagnostic or therapeutic radiation oncology services if a non-specialist practitioner who can

handle an emergency provides the direct supervision and also has access by phone or other telemedicine link to a specialist who is able to change the plan of care should the need arise. One

commenter asserted that one does not have to posses the clinical skills to fully provide a service in order to be an effective supervisor.

Response:As we have stated in the Medicare Benefit Policy Manual (Pub. No. 100–02), Chapter 6, Section 20.5.24, ‘‘the supervisory physician or nonphysician practitioner must have, within his or her State scope of practice and hospital-granted privileges, the knowledge, skills, ability, and privileges to perform the service or procedure. Specially trained ancillary staff and technicians are the primary operators of some specialized diagnostic or therapeutic equipment, and while in

such cases CMS does not expect the supervisory practitioner to operate this equipment instead of a technician, CMS does expect the physician or nonphysician practitioner that supervises the provision of the service must be knowledgeable about the test and clinically appropriate to furnish the test. The supervisory responsibility is more than the capacity to respond to an emergency, and includes furnishing assistance and direction throughout the performance of a procedure and, as appropriate to the supervisory physician or nonphysician practitioner and the

patient, to change a procedure or the course of care for a particular patient. CMS would not expect that the supervisory practitioner would make all decisions unilaterally without informing

or consulting the patient’s treating physician or nonphysician practitioner.’’ We do not believe it is sufficient or consistent with our rules for direct supervision for the individual on site to be capable of only emergency management. The supervisory practitioner or nonphysician

practitioner who is physically present should have the training and knowledge to clinically redirect the service or provide additional orders.

Comment:Commenters remain concerned about the potential for liability for services provided prior to CY 2009. They requested that CMS prohibit enforcement of the direct supervision requirements applied to services furnished since January 1, 2001. They also commented that CMS’ statement regarding enforcement in the CY 2010 final rule with comment period (74 FR 60587) forces hospitals to assert and provide supporting evidence that any divergence from CMS’ rules during that time period was a result of error or mistake.

Response*:* In the CY 2010 OPPS/ASC final rule with comment period, we stated that in the case of services furnished in 2000 through 2008, ‘‘we plan to exercise our discretion and decline to enforce in situations involving claims where the hospital’s noncompliance with the direct

physician supervision policy resulted from error or mistake.’’ (74 FR 60587) In summary, after consideration of the public comments we received, we are maintaining our general requirement for direct supervision of all outpatient therapeutic services. However, we are redefining our definition of direct supervision in § 410.27(a)(1)(iv) to remove all references to physical

boundaries and require only ‘‘immediate availability.’’ We are removing § 407.27(g), which defines ‘‘in the hospital’’, because it is no longer necessary. In addition, through CY 2011

we will develop an independent review process for annual consideration of requests for alternative service-specific supervision levels, supported by an independent technical committee,

potentially the APC Panel. We are specifically seeking comment on what the process should look like and the criteria that should be considered for identifying services for which personal,

direct, or general supervision is appropriate. We will establish this process in the coming year through the CY 2012 rulemaking cycle, selecting a specific independent entity to assist in

the process and establishing criteria for determining that a given service should be furnished under general or personal supervision rather than direct supervision…”

Source: <http://edocket.access.gpo.gov/2010/pdf/2010-27926.pdf>

Direct Supervision