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CMS's Outpatient Supervision Rules – A Moving Target

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The Centers for Medicare and Medicaid Services (CMS) has long taken the position that, in order for outpatient hospital services to be covered by Medicare, the services must be supervised by a physician or, in some instances, by a non-physician practitioner. The extent to which that supervision must be demonstrated, however, has been a moving target. In the 2000 Outpatient PPS Rule — that is, the original provider-based rule — CMS said that supervision was presumed to be present if the outpatient service was furnished in the hospital or in a provider-based department located on the hospital's main campus. Thus, most people fairly assumed that the supervision requirement did not pose a significant issue, at least for outpatient services furnished in a hospital or in an on-campus, provider-based location of the hospital. That changed, however, in 2008 when CMS did an about face and began requiring, as a condition of coverage, that hospitals be able to demonstrate physician supervision of outpatient services. No longer was it presumed that hospital outpatient services were supervised even when those services were furnished on the campus of the hospital. CMS's 2008 position created considerable consternation, and since that time CMS has adjusted its position regarding supervision with each OPPS update. These changes are most recently reflected in FFY 2011 Final Outpatient PPS Rule, which went on display November 2, 2010, and will be published in the Federal Register on November 24, 2010.

CMS's Current Rules (in effect through December 31, 2010)

Currently, all hospital outpatient therapeutic services, whether furnished in a hospital or in an on-campus or off-campus provider-based department, must be furnished under direct supervision. The therapeutic services may be supervised by either a physician or a qualified non-physician practitioner except when those services involve cardiac rehabilitation services, intensive cardiac rehabilitation services and pulmonary rehabilitation services, all of which require physician (not NPP) supervision.

For outpatient hospital diagnostic services, the level of supervision depends on the level specified in the physician fee schedule for that particular service or procedure. If general supervision is required under the physician fee schedule, that designation controls. Conversely, if direct or personal supervision is required, the hospital must be able to demonstrate that those levels of supervision were present in order for the diagnostic service to be covered as a hospital outpatient service. Unlike the standard for therapeutic services, however, the supervision of hospital outpatient diagnostic services must be furnished by a physician. NPPs may not provide the required supervision.

Under the direct supervision standard, the supervisory personnel must be immediately available to furnish assistance and direction throughout the performance of the procedure. This means that the individual must not be performing another service or procedure that he or she could not interrupt and must not be so physically far away that he or she could not intervene in the supervised service "right away" or "without interval of time."

Additionally, whether it be for therapeutic or diagnostic services, the supervisory personnel must have, within his or her scope of practice, the knowledge, ability and hospital-granted privileges to perform the service being supervised. The individual must have the ability to change the procedure or the course of treatment and must be someone who is clinically appropriate to supervise the service or the procedure. In other words, the person must be able to do more than simply respond to an emergency and, instead, must be able to step in and perform the service.

Currently, CMS's rules for therapeutic services require that, during the performance of the procedure or service, the supervisory practitioner be physically on the same hospital campus as the service being supervised. The supervisory practitioner need not be physically located in the hospital, at least for services provided on the main campus of the hospital, but must be immediately available. For services furnished in off-campus locations, however, the supervisory practitioner must be present in the specific provider-based department during the performance of the procedure and must be immediately available to furnish direction and assistance.

Similarly, for outpatient diagnostic services, CMS's proximity requirement currently requires that the supervisory physician be on the campus and immediately available. If the service is furnished in an off-campus location, the physician must be present in the provider-based department and immediately available. Additionally, and quite significantly, CMS requires that outpatient diagnostic services furnished under arrangement in non-hospital locations be subject to the hospital supervision requirements. Stated another way, outpatient diagnostic services provided under arrangement in free-standing imaging centers or physician offices or clinics must be furnished under the same level of supervision as similar services furnished at the hospital. Thus, for those services requiring direct supervision, the supervisory physician must be present in the performing physician group's office suite or other non-hospital location where the service is being performed and must be immediately available during the performance of the procedure.

CMS's New Rules (Effective January 1, 2011)

For 2011, CMS has changed the rules again. In the OPPS rule that CMS put on display in early November, CMS reiterated its position that supervisory personnel must be immediately available — that is, available to furnish assistance and direction throughout the performance of the procedure. CMS repeated its position that "immediately available" means capable of being able to intervene right away or, as CMS has said, "without interval of time." Thus, according to CMS, the requirement that one be physically present and immediately available, no matter where the supervisory practitioner might be situated, ultimately determines how far away that practitioner may be located.

Relaxation of Proximity Test For Services Provided at the Hospital or in Provider-Based Locations

In the 2011 rule, CMS apparently has recognized that the "immediately available" requirement is an adequate limitation. Thus, for 2011, the Agency has revised its definition of direct supervision to remove the requirement that the supervisory practitioner be on the same campus or in an off-campus department of the hospital. Instead, beginning January 1, 2011, direct supervision will require simply that the individual be immediately available, meaning physically present, interruptible, and able to furnish assistance and direction throughout the performance of the procedure, but without reference to any physical boundary such as a campus or a department.

CMS's rule change means that physicians or other practitioners may be in locations close to the hospital campus, but not actually on the campus itself. For services currently provided at the main hospital and in on-campus locations, this may provide little relief. Practitioners will still need to be able to intervene "right away," and thus will not be able to go far away from the service site. For supervision furnished in provider-based, off-campus locations, however, CMS's rules might be quite beneficial. Currently, CMS requires that the supervisory practitioner be physically located in the provider-based department in which the service is being furnished. The individual, according to CMS's current standard, cannot be in another location, such as another department or in a physician's office, that might be located adjacent to the provider-based department. Under the 2011 modification to its rule, however, CMS will allow the supervising physician to be in any location within the building that is off-campus and that houses multiple provider-based departments of the hospital, as long as that practitioner is immediately available.

Continuation of Proximity Requirement for Services Provided Under Arrangements

CMS's position that supervision can be provided without reference to any specific physical boundary applies to all outpatient therapeutic services and to most hospital outpatient diagnostic services where direct supervision is required. The one exception to this standard is for under arrangement services. As noted above, in the 2010 OPPS rule, CMS specified that hospital outpatient diagnostic services provided under arrangement must follow the physician supervision requirements for individual tests listed in the Medicare physician fee schedule. CMS specified that when direct supervision is required for the diagnostic service and the service is furnished in an under arrangement off-campus location, the supervising physician must be present in that location and immediately available to render assistance. CMS continued this requirement in its 2011 rule, stating that diagnostic services furnished under arrangement in an off-campus location and subject to direct supervision must be furnished by a physician who is in the office suite and immediately available to furnish direction and assistance throughout the performance of the procedure.

Non-Surgical Extended Duration Therapeutic Services.
As part of the 2011 rule, CMS has created a new category of services — non-surgical extended duration therapeutic services — that will be subject to different supervision rules. These services require direct supervision during the initiation period followed by a minimum standard of general supervision for the duration of the services By "initiation of the service," CMS means that direct supervision commences with the beginning portion of the service and ends when the patient is stable and the supervising physician or other appropriate NPP believes that the remainder of the service can be delivered safely under his or her general supervision and control without needing his or her immediate availability.

CMS has defined non-surgical extended therapeutic services as those that (1) can last a significant period of time; (2) have a substantial monitoring component that is typically provided by auxiliary personnel; (3) have little risk of requiring the physician's or appropriate NPP's immediate availability after the initiation of the service; and (4) are not primarily surgical in nature. CMS has listed a number of codes that fall within this guideline, including a number of infusion therapies and certain hospital observation services. CMS expressly did not include, however, chemotherapy administration and blood transfusions within this category.

CAHs and Small Rural Hospitals.
CMS also has provided temporary relief for critical access hospitals and small rural hospitals having 100 or fewer beds. Those hospitals, during 2011, will be exempt from CMS's supervision requirements applicable to outpatient therapeutic services.

Ober|Kaler's Comments
Hospitals, and particularly smaller community hospitals, have been wrestling for some time with practical issues associated with CMS's supervision requirements. If, for example, a hospital does not have a radiologist who is immediately available in each instance that a "direct supervision" test is required, what does the hospital

do? In the 2011 rule, CMS provided little relief for hospitals in this situation. The Agency repeated its position that although the supervisory physician does not have to be of the same specialty of the service being performed, the individual must be State licensed and possess hospital privileges to perform the service. CMS stated that it has "been clear that we require the supervisory practitioner to be knowledgeable enough about the service to be able to furnish assistance and direction, and not merely manage an emergency." CMS opined, however, that while "not all practitioners are qualified to supervise services of any specialty, . . . for many common OPPS services, . . . hospitals can adjust their by-laws and privileging standards sufficiently to cover practitioners who may wish to act in a supervisory capacity." Many hospitals may question this statement and ask whether, as a practical matter, they can adjust their by-laws and privileging standards sufficiently to meet CMS's standards. If they cannot, they will either have to obtain additional supervisory capacity or persuade CMS or Congress to change the rules.