S
ince April of 2000 the Centers for Medicare & Medicaid Services (CMS) has required direct supervision of therapeutic services in the hospital outpatient setting.

**Setting the Stage**
In calendar years 2009, 2010, and 2011, CMS continued to clarify what direct supervision means and the expectations for meeting the requirements. During that time critical access hospitals (CAHs) and many rural hospitals pushed back, citing difficulty in being able to staff or hire appropriate physicians for all therapeutic services to meet the requirement. Many stakeholders specifically called out specialty services, such as radiation oncology, as difficult to find appropriately trained physicians with expertise for more rural locations.

Based on this feedback, over the years CMS has enforced and then not enforced the need for direct supervision of all therapeutic services in CAHs and, most recently, rural hospitals with 100 or fewer beds. The most recent round of non-enforcement for CAHs and rural hospitals with 100 or fewer beds expired Dec. 31, 2019. Prior to that date, CMS reviewed the requirement for direct supervision across the board to all hospitals—regardless of size or location.

As a refresher, *general supervision* is defined as “procedure is furnished under the physician’s overall direction and control, but that the physician’s presence is not required during the performance of the procedure.”

*Direct supervision* is defined as “the physician or nonphysician practitioner must be present on the same campus where the services are being furnished.” Additionally, for direct supervision, the physician must be able to respond without interval of time and not be providing another service for which he or she cannot step away from.

**Proposing and Finalizing a Change**
During this review, CMS expressed concern that there were two tiers to supervision for the same exact services: general supervision applied for CAHs and rural hospitals with 100 or fewer beds and direct supervision for all other hospitals. Additionally, the agency indicated that it was not aware of any data or information that would lead them to believe that the application of only general supervision in the designated areas has affected the services or care of patients. To alleviate these differences, CMS proposed one supervision standard (general supervision) for all hospital outpatient therapeutic services provided in hospitals, including CAHs, and specifically sought comments on whether services, such as radiation therapy and chemotherapy administration, should be excluded.

After review of comments submitted to the proposed ruling, CMS finalized for calendar year 2020 and subsequent years to change the generally acceptable minimum required level of supervision for all hospital outpatient therapeutic services to general supervision, including radiation therapy and chemotherapy administration. This means that the same minimum level of supervision is required for all hospitals and CAHs.

The agency did stress, however, that changing to general supervision will not prevent any of the hospitals from providing services under direct supervision when the physician administering that service determines that it is appropriate to do so. Many therapeutic services provided in the outpatient setting are highly complex and need direct supervision of the qualified physician. However, hospitals and physicians now have the ability to set the supervision level they believe is appropriate, resulting in direct or personal supervision for some outpatient therapeutic services.

**Other Considerations**
Hospitals and physicians must consider hospital policies, CAH Conditions of Participation, and state scope of work regulations, as well as state and federal laws, which may and do define supervision requirements for certain services and supersede the changes in supervision level as indicated by CMS. For example, brachytherapy and Gamma Knife services are still bound by Nuclear Regulatory Commission and Agreement State Program regulations for the presence of the physician and authorized user.

Additionally, for radiation oncology these changes only pertain to the supervision of the technical services. Physician work and personal presence for the work are not the same as supervision. Many radiation oncology codes have both technical and
professional components. To bill and receive the professional component, physicians must personally provide their services at the time and location where the services are rendered and billed. CMS does not list radiation oncology services as available through telemedicine. There is no indication at this time whether commercial payers have or will adopt this change or expectation in supervision of outpatient therapeutic services provided to their beneficiaries.

Typically, any changes to supervision are addressed by the Hospital Outpatient Payment Panel, and CMS indicated that it will continue to seek the panel’s advice for appropriate supervision levels of hospital outpatient services. CMS also indicated that it will retain the ability to adjust the supervision levels of individual hospital outpatient services to something more intensive than general supervision through the usual notification of changes and comment periods of the rules.

The Medicare Payment Advisory Committee strongly encouraged CMS to monitor outpatient therapeutic services that Medicare beneficiaries receive to ensure that the quality of care is not compromised and error rates do not increase due to lack of physician presence and supervision of services.

CMS also noted that failure of a physician to provide the adequate supervision in accordance with hospital and CAH Conditions of Participation would not cause payment to be denied for that service, but consistent violations of the supervision requirements would result in corrective action plans and finally in termination of the hospital or CAH from Medicare participation. There is no indication whether commercial payers have or will adopt this change or expectation in supervision.

It is important to note that the change to general supervision applies only to the hospital setting; direct supervision is still the regulation in the office and/or freestanding facility setting. The expectation of direct supervision in the office/freestanding facility is outlined in the Medicare Benefit Policy Manual, Chapter 15, which states, “Direct supervision in the office setting does not mean that the physician must be present in the same room with his or her aide. However, the physician must be present in the office suite and immediately available to provide assistance and direction throughout the time the aide is performing services.”

Some specialty organizations have shown support to these CMS changes, whereas others have expressed concern and opposition. In addition, some specialty societies are working together to address the changes in the hope that CMS will make considerations for services like radiation therapy and chemotherapy administration and reverse or change the policy. For example, the American Society for Therapeutic Radiology and Oncology (ASTRO) released a letter regarding its stance on the changes. Within the letter ASTRO indicated that it was opposed to the new policy affecting therapeutic services. The full statement can be found at astro.org/ASTRO/media/ASTRO/Daily%20Practice/PDFs/ASTROGuidanceCMSGeneralSupervisionPolicy.pdf. Additionally, the American Medical Association 2020 Current Procedural Terminology Manual still indicates that chemotherapy and therapeutic services typically require administration under direct supervision. The administration includes “patient assessment, provision of consent, safety oversight, and intra-service supervision of staff.”

Moving forward, radiation and medical oncology departments should review their supervision policies. CMS has left the decision ultimately up to hospitals and physicians to determine the most appropriate supervision level for services in the hospital setting based on practice patterns. Keep in mind, however, that these changes made by CMS do not apply to commercial payers that have not yet adopted a similar policy. For those practicing in the office and/or freestanding setting, direct supervision is still required for therapeutic services—this has not changed. Additionally, it is important to watch for any updates. With the push by some specialty societies to make changes to the minimum supervision level for radiation therapy and chemotherapy administration, it is possible that there could be new or updated guidance during 2020 or beginning for 2021.

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References
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