Diagnostic test supervision: CMS relaxes rules but also creates ambiguity

Takeaways

- The long-time Medicare requirements that only physicians can supervise diagnostic tests are changing
- CMS relaxed the supervision requirements permitting non-physician practitioners to supervise certain types of tests, but left ambiguity in the new rules

Until recently, strict Medicare rules allowed only fully licensed physicians to take responsibility for the supervision of diagnostic tests. The Centers for Medicare and Medicaid Services (CMS) this year revised these long-standing rules, handing an expansion of purview to non-physician practitioners. But unfortunately, ambiguities in the drafting of the rule might have created compliance confusion on which levels of diagnostic tests allow supervision under the more flexible requirements.

As early as January 2019, CMS began to offer more flexibility in how diagnostic tests could be performed and who could take responsibility for their supervision. The first step toward flexibility that month was recognition that radiologist assistants (RAs) and radiology practitioner assistants (RPAs), who have higher levels of training, should be allowed to perform Level 3 tests even when the physician is not in the room, so long as the RAs and RPAs act within their scope of practice under state licensing laws. Not all states have defined such licensure for these practitioners, but the vast majority of states have such rules, facilitating increased flexibility in the performance of certain image-guided tests.

Pandemic brought change

In addition to expanding the role of RAs and RPAs, the COVID-19 public health emergency created a need for CMS to liberalize long-standing requirements that only fully licensed physicians could supervise many tests. CMS did this first on an interim basis and then, later, permanently. But, as we discuss below, the actual language of the new rules adopted this year raises questions as to how they should be applied.

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Expanded purview for non-physician practitioners

The interim rule released in 2020 allowed for the first time, during the public health emergency, nurse practitioners (NPs), clinical nurse specialists (CNSs), physician assistants (PAs), and certified nurse-midwives (CNMs) – collectively referred to by CMS as non-physician practitioners (NPPs) – to supervise diagnostic tests.

The interim rule change applied to tests performed in physician offices, hospital outpatient departments, and provider-based facilities. Only in the independent diagnostic testing facility setting were these NPPs still barred from supervising diagnostic tests.

As a result, during the public health emergency, no physician presence was required, even for Level 2 and Level 3 tests, if an NPP provided the necessary supervision of the technologist performing that test.

These reforms created considerable anticipation in the diagnostic imaging industry that CMS would extend the relaxed requirements when it created new permanent rules. As anticipated, CMS made such changes in its 2021 rules, but whether they fully accomplished these reforms is an open question.


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Supervision rule: Is change overdue?

The supervision rules have not kept pace with the skills and training of ancillary personnel such as radiologic technologists and radiologist assistants.

The experience and capabilities of advanced practice providers that CMS refers to as non-physician practitioners have evolved as well.

When the supervision rules were created in the late 1990s, many advanced diagnostic imaging services (MRI, CT, and PET) were in their relative infancy, and the mandate that only physicians could supervise these tests was accepted as appropriate.

Changes in clinical practice, safety protocols, and equipment have caused stakeholders, including CMS, to reconsider the supervision rules.

Failing on supervision can be costly

Diagnostic imaging facilities have had to be cognizant of these rules and how to manage the performance of the tests they furnish. Failure to provide the appropriate level of supervision for a diagnostic test can render the service not "reasonable and necessary" and, therefore, not reimbursable under Medicare rules. More concerning, failure to provide for diagnostic test supervision consistent with Medicare's requirements has resulted in fraud and abuse allegations by the government that claims submitted by various providers for such testing services were false claims. Those investigations often have led to substantial monetary settlements and corporate integrity agreements with the government that often accompany such settlements.

Medicare rules prescribed that physicians alone could provide general supervision of plain film X-ray, ultrasound studies, nuclear medicine scans, and non-contrast MRI and CT services. And when contrast media was administered to enhance the image quality of an MRI or CT scan, Medicare demanded the on-site presence and direct supervision by a physician for these "Level 2" diagnostic tests. When those contrast MRI and CT studies were performed in independent diagnostic testing facilities, Medicare program integrity rules required the supervising physician to be "proficient" in the performance and interpretation of that these tests, effectively mandating the on-site presence of radiologists for those procedures furnished in independent diagnostic testing facilities (IDTFs).

Additionally, studies that make use of real-time fluoroscopic imaging guidance, such as barium swallow studies, arthrography, or myelography, required even greater physician presence. These fluoroscopic-guided services are referred to as "Level 3" tests that require the supervising physician to be present in the room throughout the performance of the test.

Confusion in the 2021 Medicare physician fee schedule

In its 2021 Medicare physician fee schedule rule, CMS stated that **all** diagnostic tests are supervised by physicians or, to the extent permitted by state law, one of the agency's designated NPPs.

Despite that apparently clear statement of regulatory policy, language promulgated in the final rules stated that physicians provide general supervision, with no mention of NPPs. Also, seemingly contradicting the rule change to permit all tests to be supervised by NPPs, CMS stated that Level 3 tests requiring personal supervision means a physician must be in attendance in the room throughout the performance of the test. Yet again, no reference was made as to whether the various categories of NPPs were permitted to supervise Level 3 tests. However, CMS has left language in place in the rules that physicians may provide direct rather than personal supervision when Level 3 tests are performed by RAs and RPAs acting within their scope of practice under state licensing laws.

CMS did clearly state that physicians **and** NPPs are permitted to provide direct supervision for Level 2 tests that require the proximity of being in the office suite and immediately available, but not in the room where the test is administered.

Conclusion

The bottom line is that the most recent rulemaking from CMS remains unclear on the authority of NPPs to supervise any diagnostic tests. It's possible that CMS made drafting errors in crafting the language in the Code of Federal Regulations. Or, despite the ambiguity in the drafting of the rule, the limited role of NPPs may have been intentional on the part of CMS.

Nevertheless, it is clear that changing circumstances in the delivery of testing services have sparked regulatory reform. Stakeholders in the imaging space will need to stay tuned to learn what CMS actually intended regarding how these services are to be performed. Given the potential for fraud and abuse scrutiny when tests are not supervised in total accord with Medicare rules, imaging providers and suppliers need to remain scrupulous in assuring adherence to a conservative interpretation of these rules until CMS provides further clarifications.

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