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Health Care Advisory

Hospital Outpatient Physician "Supervision": CMS's Latest Rule Offers Greater Operational Flexibility But Still Exemplifies the Issue's Complexity

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KEY POINTS

- A new CMS Medicare Rule for Calendar Year 2020 reduces the default level of supervision required for hospital outpatient therapeutic services in all hospitals, from "direct" to "general" supervision.
- The Rule offers greater operational flexibility to providers. "General supervision" requires that the hospital services be furnished under the supervisory practitioner's overall direction and control, including by telephone or other electronic device.
- CMS retains the ability to increase the supervision level of an individual hospital outpatient service to a higher level.
- Violations of physician supervision requirements can lead to reimbursement denials and whistleblower lawsuits.
- CMS will monitor for any decline in the quality of outpatient therapeutic services provided to Medicare beneficiaries as a result of the new payment policy.
- CMS expects hospitals, in bylaws and policies, to set the levels of supervision for outpatient services commensurate with the complexity of the services.

Medicare providers often ask themselves — or ask legal counsel — the simple question, "What level of supervision applies here?" The answer is hardly ever simple, and, frustratingly, often leads to more questions. What is the service? Who is providing it? In what setting? Will Medicaid be billed? What federal and state laws may regulate the service or the practitioner? Has a regulator defined supervision, or referenced a level of supervision without a definition?

For **clinic** and **emergency room** services — also known as "hospital outpatient therapeutic services"[1] — CMS recently finalized its proposal to reduce the required level of supervision from *direct to general* supervision.

[1] *Medicare Benefit Policy Manual* (MBPM), Ch. 6, § 20.5.2.

This one rule, limited to one payer and one service, illustrates how complex the supervision rules can be.

This is a brief review of the basic principles.

The most recent development: The 2020 Outpatient Prospective Payment System (OPPS) Final Rule

Starting this January 1, Medicare will require merely *general* supervision as the default level of supervision for *all hospital outpatient therapeutic services* in *all* hospitals, including critical access hospitals (CAHs) and small rural hospitals having 100 or fewer beds.

CMS finalized this significant change in its Calendar Year 2020 OPPS rulemaking, 84 Fed. Reg. at 61142 (Nov. 12, 2019), published in the *Federal Register* today.[2]

Medicare currently requires the higher level of *direct* supervision by physician and certain non-physician practitioners (including clinical psychologists, licensed clinical social workers, physician assistants, nurse practitioners, clinical nurse specialists, or certified nurse-midwives) as the minimum default standard for hospital outpatient therapeutic services — with the exception of services at CAHs and small rural hospitals with fewer than 100 beds. At the latter, the controlling standard has been general rather than direct supervision, due to enforcement instructions and legislative actions in place since 2010. 84 Fed. Reg. at 61360.

The new rule will end this "two-tiered system." Requiring that the "default minimum level of supervision for each hospital outpatient therapeutic service is 'general'" sets a "uniformly enforceable supervision standard for all hospital outpatient therapeutic services." *Ibid*.

General vs. direct supervision; hospitals gain significant operational flexibility

General supervision requires that the hospital services be furnished under the supervisory practitioner's "overall direction and control", 42 C.F.R. §§ 410.27(a)(1)(iv)(B), 410.32(b)(3)(i).[3]

Direct supervision requires that a supervising practitioner be "immediately available to furnish assistance and direction throughout the performance of the procedure." 42 C.F.R. § 410.27(a)(1)(iv)(A).

Neither requires that the supervisory practitioner be in the room during the service. Yet CMS has in the past distinguished general from direct supervision by requiring an element of physical presence for the latter. (*See*, e.g., 75 Fed. Reg. at 71800, 72008 (Nov. 24, 2010).) The direct supervision standard requires immediate availability to furnish assistance and direction throughout the performance of the procedure, and would not be met if a supervisory practitioner was performing another procedure or service that he or she could not interrupt. (*See* MBPM, Ch. 6, § 20.5.2.) CMS's 2020 Final Rule recognizes that requiring direct supervision "places an additional burden on providers." 84 Fed. Reg. at 61360.

This new Rule, by reducing the default supervision standard to general, gives hospitals significantly more operational flexibility. *Ibid*. General supervision has been "historically interpreted" to allow for modes of supervision other than in-person, including availability by telephone or other electronic device. 74 Fed. Reg. at 60316, 60583 (Nov. 20, 2009); 75 Fed. Reg. at 72008. CMS in this Final Rule noted that general supervision means that "the medical personnel performing the procedure are being monitored and receiving guidance from a qualified physician even if the physician is not physically present." 84 Fed. Reg. at 61362.

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[2] Department of Health and Human Services, Centers for Medicare & Medicaid Services, "Medicare Program: Changes to Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Revisions of Organ Procurement Organizations Conditions of Coverage; Prior Authorization Process and Requirements for Certain Covered Outpatient Department Services; Potential Changes to the Laboratory Date of Service Policy; Changes to Grandfathered Children's Hospitals-Within-Hospitals; Notice of Closure of Two Teaching Hospitals and Opportunity to Apply for Available Slots." Available here.

[3] Note that all citations to 42 C.F.R. § 410.27 are to the current version of the regulation (pre-2020).

Some details: A specific service may still have specific supervision requirements

Although the new Calendar Year 2020 Rule will require general supervision as the default level of supervision, CMS may choose to require direct or even *personal* supervision for particular services. *Id*. at 61490. (The current, pre-2020, rule takes a similar approach by allowing CMS to assign general or personal supervision to particular services even though the default is direct supervision. 42 C.F.R. § 410.27(a)(1)(iv)(B).)

Personal supervision requires the supervising practitioner to be in "attendance in the room during the performance of the procedure." 42 C.F.R. §§ 410.27(a)(1)(iv)(B), 410.32(b)(3)(iii).

CMS has not yet designated any procedures as requiring this highest level of supervision but has assigned general supervision to some services.[4] And even under the new Rule, CMS will continue to require direct supervision for some services. *See* 84 Fed. Reg. at 61490. E.g.,

- Certain nonsurgical extended duration therapeutic services (NSETDS) require a minimum of direct supervision during the initiation of the services followed by general supervision at the discretion of the supervising practitioner. 42 C.F.R. § 410.27(a)(1)(iv)(E); MBPM, Ch. 6, § 20.7. (NSETDS are not primarily surgical in nature, can last a significant period of time, have a substantial monitoring component usually performed by auxiliary personnel, and have a low risk of requiring the supervisory practitioner's immediate availability after the initiation of the service. *Ibid*.)
- Pulmonary and cardiac rehabilitation services must still be directly supervised, and only by physicians. (Supervision for these services must be by a doctor of medicine or osteopathy, 42 C.F.R. § 410.27(a)(1)(iv)(D), while Medicare outpatient hospital therapeutic services generally may be supervised by a physician or certain non-physician practitioners.)

CMS reasoned in the 2020 OPPS Rulemaking that providers can always decide to set a higher level themselves, and other laws and regulations indeed already subject some services to other levels of supervision. Hospitals, under this Final Rule, can still choose to provide direct or personal supervision for outpatient services "when the physicians administering the medical procedures decide that it is appropriate to do so." 84 Fed. Reg. at 61360, 61362. And personal supervision may be required by a hospital's bylaws, credentialing procedures, and policies if "the complexity of the service" warrants it. 74 Fed. Reg. at 60584.

For example, some public comments cited in the rulemaking were concerned that a higher level of supervision might be warranted for radiation therapy, hyperbaric oxygen treatments, and wound care services — all highly skilled services that might have rare but serious complications. 84 Fed. Reg. at 61362. CMS replied that, as for any hospital service, "Providers have the flexibility to establish what they believe is the appropriate level of physician supervision for these procedures, which may well be higher than the requirements for general supervision." *Ibid*.

CMS also noted that providers must adhere to conditions of participation, federal and state regulations for the services, and state standards for scope of practice for medical personnel who provide these services, and that the "combination of providers' desire to ensure the safety of their patients and the regulations governing these procedures . . . should ensure that these procedures will be appropriately supervised . . . whether the default level of physician supervision is direct supervision or general supervision." *Ibid*. CMS accordingly declined to require a higher supervision level in this rulemaking while acknowledging the variety of other laws that can always be at play.

[4] CMS "Hospital Outpatient Therapeutic Services That Have Been Evaluated for a Change in Supervision Level" (March 10, 2015), available here. The agency retains its ability to consider increasing the supervision level of an individual hospital outpatient service to a level more intensive than general supervision through notice and comment rulemaking, and continues to have the Hospital Outpatient Payment Panel provide advice on the appropriate supervision levels for hospital outpatient therapeutic services. 84 Fed. Reg. at 61360-61.

CMS has revised a decades-old payment standard; hospitals should diligently strive to understand and comply with the New Rule

The transition from direct to general supervision is likely a welcome one for hospitals, but it is a significant departure for CMS, which had rejected general supervision as the minimum standard for hospital outpatient services when commenters suggested it in the past. *See*, e.g., 74 Fed. Reg. at 60583-84 (2009) *and* 75 Fed. Reg. at 72008 (2010).

Hospitals must, accordingly, be careful to understand and comply with CMS's new expectations.

Violations of these physician supervision requirements can lead to reimbursement denials and whistleblower lawsuits (whether meritorious or not).

The supervision standards, however, have not always been consistently construed or applied. Medicare adopted the direct supervision requirement in 2000, and CMS initially observed, "We assume the physician supervision requirement is met on hospital premises because staff physicians would always be nearby within the hospital." 65 Fed. Reg. at 18434, 18525 (Apr. 7, 2000).

But CMS issued a "clarification" and "restated the existing policy" eight years later, because

> "some stakeholders may have misunderstood our use of the term 'assume' . . . believing that our statement meant that we do not require any supervision . . . or that we only require general supervision for those services. This is not the case. It has been our expectation that hospital outpatient therapeutic services are provided under the direct supervision of physicians in the hospital and in all provider-based departments . . . both on-campus and off-campus departments of the hospital." 73 Fed. Reg. at 68502, 68702-03 (Nov. 18, 2008).

CMS thus has administratively moved from seemingly "assuming" physician supervision, to specifically requiring direct supervision, to now only requiring general supervision — all as deemed consistent with the statutory requirement that hospital outpatient services be provided "incident to physicians' services." Social Security Act § 1861(s)(2)(B) (codified at 42 U.S.C. 1395x(s)(2)(B)).

The government regulator charged with implementing and enforcing payment requirements has the leeway to learn from experience and further interpret the meaning of statutes and regulations.

Providers are often not that lucky.

The meaning of direct supervision in particular has not always been crystal clear, and CMS, lacking an easy way to monitor the standard, has essentially left it up to whistleblowers to raise "any concerns about patient safety due to inappropriate supervision."[5] This was rarely the best context for resolving disputes about the standard's meaning. Plaintiffs in False Claims Act cases easily misinterpreted direct supervision to require a level of physician presence that is more akin to *personal* rather than *direct* supervision. It seems reasonable to hope that CMS's Final rule implementing a lower level of general supervision will reduce the opportunity for litigation on this issue.

This does not diminish the continuing importance of 42 C.F.R. § 410.27 for hospitals seeking payment under Medicare Part B for outpatient services. This Rule contains *conditions of payment* (i.e., "Medicare Part B pays . . . if"). Failure to comply may lead to a Medicare payment denial. Fortunately, hospitals should find it easier to meet the payment standard established under the new Rule.

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[5] Medicare Payment Advisory Commission Report, p. 6, Physician Supervision Requirements in Critical Access Hospitals and Small Rural Hospitals (Dec. 2017), available here.

Some other supervision requirements are merely *conditions of participation*, which may *not* "cause payment to be denied for that individual service" (84 Fed. Reg. at 61360) (e.g., Medicare hospital patients must be under the care of a physician (42 C.F.R. § 482.12(c)(4)), *see ibid.*). They too are of paramount importance in complementing the supervision requirement set under this payment rule. CMS reminds hospitals that consistent violations of *conditions-of-participation* supervision requirements can lead to provider corrective action plans and, ultimately, termination from Medicare participation if deficiencies are not cured. *Ibid.*

CMS also commits to monitor for any decline in the quality of outpatient therapeutic services provided to Medicare beneficiaries as a result of the new payment policy (84 Fed. Reg. at 61361). Hospitals should keep this in mind as well, when reviewing or setting the appropriate supervision standards for particular outpatient hospital services in provider credentials and hospital bylaws and policies.

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