AHLA PG Briefing

CMS Lowers Physician Supervision Requirement for Outpatient Therapeutic Services in 2020 OPPS Final Rule

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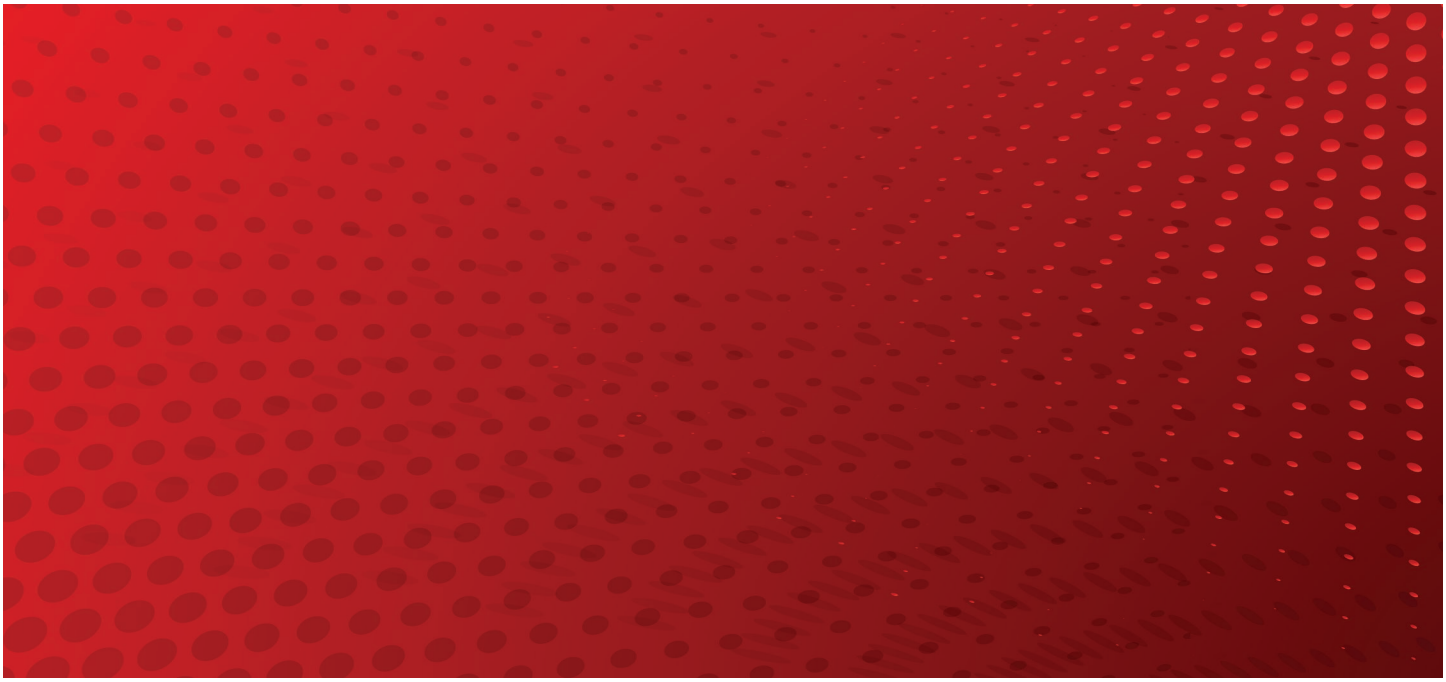

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Beginning calendar year 2020, the Centers for Medicare & Medicaid Services (CMS) will change the minimum required level of supervision from direct supervision to general supervision for all outpatient therapeutic services in all hospitals and Critical Access Hospitals (CAHs).[1] This change ensures a standard minimum level of supervision for each outpatient therapeutic service furnished incident to a physician's service.[2]

Background on Medicare-Covered Outpatient Therapeutic Services and Physician-Ordered Services

Under 42 C.F.R. § 410.27, Medicare Part B pays for hospital therapeutic or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service, including services furnished under the "direct supervision" of a physician or nonphysician practitioner.[3] "Direct" supervision means the physician or nonphysician practitioner must be immediately available, but not physically present, to furnish assistance and direction throughout the performance of the procedure.[4] "Nonphysician practitioners" means clinical psychologists, licensed clinical social workers, physician assistants, nurse practitioners, clinical nurse specialists, or certified nurse-midwives.[5]

Hospital therapeutic or CAH services and supplies means "all services and supplies furnished to hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs

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[1] *CY 2020 Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System Final Rule (CMS-1717-FC),* CTRS. FOR MEDICARE & MEDICAID SERVS. (Nov. 1, 2019), https://www.cms.gov/newsroom/fact-sheets/cy-2020-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-0.
[2] 84 Fed. Reg. 39398, 39402 (proposed Aug. 9, 2019) (finalized Nov. 1, 2019); 84 Fed. Reg. 61142, 61146 (Nov. 12, 2019).
[3] 42 C.F.R. § 410.27(a)(1)(iv). The *Medicare Benefit Policy Manual* states that these services must be furnished as an "integral" part of the physician or nonphysician practitioner's professional service in the course of treatment of an illness or injury, and distinguishes between services incident to physicians' services and services incident to services furnished in office and physician-directed clinic settings (*Medicare Benefit Policy Manual*, Ch. 6, § 20.5.2, CTRS. FOR MEDICARE & MEDICAID SERVS. (rev. 169) (Mar. 1. 2013)).
[4] 84 Fed. Reg. 39398, 39638 (proposed Aug. 9, 2019); 42 C.F.R. § 410.32(b)(3)(ii). A physician's physical presence in the room is denoted as "personal supervision" (42 C.F.R. § 410.32(b)(3)(iii)).
[5] 42 C.F.R. § 410.27(g).

and biologicals which are not usually self-administered."[6] Services furnished "in the hospital or CAH" means services provided in the "areas in the main building(s) of the hospital or CAH that are under the ownership, financial, and administrative control of the hospital or CAH; that are operated as part of the hospital or CAH; and for which the hospital or CAH bills the services furnished under the hospital's or CAH's CMS Certification Number."[7]

For outpatient therapeutic services not furnished directly by a physician or nonphysician practitioner, CMS expects that "hospital bylaws and policies would ensure that the therapeutic services are being supervised in a manner commensurate with their complexity, including personal supervision where appropriate."[8] For hospital outpatient therapeutic services and supplies furnished under the order of a physician or other nonphysician practitioner "during any course of treatment rendered by auxiliary personnel, the physician must personally see the patient periodically and sufficiently often to assess the course of treatment and the patient's progress and, when necessary, to change the treatment regimen."[9] CMS previously changed the supervision levels from direct supervision to general supervision in the following illustrative service examples: nail trimming, blood transfusion services, arterial blood withdrawal, bladder irrigation, group psychotherapy, and flu shot administration.[10]

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[6] 42 C.F.R. § 410.27(a).
[7] *Medicare Benefit Policy Manual*, Ch. 6, § 20.5.2, CTRS. FOR MEDICARE & MEDICAID SERVS. (rev. 169) (Mar. 1. 2013).
[8] *Medicare Benefit Policy Manual*, Ch. 6, § 20.5.2, CTRS. FOR MEDICARE & MEDICAID SERVS. (rev. 169) (Mar. 1. 2013).
[9] *Medicare Benefit Policy Manual*, Ch. 6, § 20.5.2, CTRS. FOR MEDICARE & MEDICAID SERVS., (rev. 169) (Mar. 1. 2013). In particular, a hospital service or supply would not be considered incident to a physician's service if the attending physician merely wrote an order for the services or supplies and referred the patient to the hospital without being involved in the management of that course of treatment. *Id.*
[10] *Hospital Outpatient Therapeutic Services That Have Been Evaluated for a Change in Supervision Level,* CTRS. FOR MEDICARE & MEDICAID SERVS. (Mar. 10, 2015), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.

2020 OPPS Final Rule Changes Direct Physician Supervision Requirement to General Supervision for All Hospital Outpatient Therapeutic Services

CMS proposed in the 2020 Outpatient Prospective Payment System (OPPS) Proposed Rule (2020 OPPS Proposed Rule) to change the minimum required level of physician supervision from direct to general supervision for all outpatient therapeutic services furnished by all hospitals and CAHs.[11] CMS finalized the 2020 OPPS Proposed Rule without modification in the 2020 Outpatient Prospective Payment System Final Rule (2020 OPPS Final Rule) on November 1, 2019 and published it on November 12, 2019, to take effect January 1, 2020.[12] As previously mentioned, "direct" supervision means the physician or nonphysician practitioner must be immediately available, but not physically present, to furnish assistance and direction throughout the performance of the procedure.[13] "General" supervision means that the procedure is furnished under the physician's direction and control, but not in the physician's presence.[14] CMS describes "supervisory practitioner" and "direct supervision" in the Medicare Benefit Policy Manual:

> A supervisory practitioner may furnish direct supervision from a physician office or other nonhospital space that is not officially part of the hospital or CAH campus where the services are being furnished as long as he or she remains immediately available. . . . 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 therapeutic equipment, and while in such cases CMS does not expect the supervisory physician or nonphysician practitioner to operate this equipment instead of [a] technician, CMS does expect the physician or nonphysician practitioner to be knowledgeable about the therapeutic

[11] 84 Fed. Reg. 39398, 39526 (proposed Aug. 9, 2019).
[12] 84 Fed. Reg. 61142, 61363 (Nov. 12, 2019), https://www.federalregister.gov/documents/2019/11/12/2019-24138/medicare-program-changes-to-hospital-outpatient-prospective-payment-and-ambulatory-surgical-center.
[13] 84 Fed. Reg. 39398, 39638 (proposed Aug. 9, 2019); 42 C.F.R. § 410.32(b)(3)(ii).
[14] 84 Fed. Reg. 39398, 39526 (proposed Aug. 9, 2019); 42 C.F.R. § 410.32(b)(3)(i).

> service and clinically able to furnish the service. The supervisory responsibility is more than the capacity to respond to an emergency, and includes the ability to take over performance of a procedure or provide additional orders.[15]

CMS also describes the term "immediate availability" in the Medicare Benefit Policy Manual:

> Immediate availability requires the immediate physical presence of the supervisory physician or nonphysician practitioner. CMS has not specifically defined the word "immediate" in terms of time or distance; however, an example of a lack of immediate availability would be situations where the supervisory physician or nonphysician practitioner is performing another procedure or service that he or she could not interrupt. Also, for services furnished on-campus, the supervisory physician or nonphysician practitioner may not be so physically distant on-campus from the location where hospital/CAH outpatient services are being furnished that he or she could not intervene right away. The hospital or supervisory practitioner must judge the supervisory practitioner's relative location to ensure that he or she is immediately available.[16]

Rationale of General Physician Supervision Requirement

In the 2009 OPPS Proposed Rule, CMS required direct supervision for hospital outpatient therapeutic services paid for by Medicare.[17] In the 2010 OPPS Final Rule, CMS clarified that the direct supervision requirement also applied to CAHs.[18] Subsequently, CAH and small hospital stakeholders claimed difficulty in recruiting

[15] *Medicare Benefit Policy Manual*, Ch. 6, § 20.5.2, CTRS. FOR MEDICARE & MEDICAID SERVS. (rev. 169) (Mar. 1. 2013).
[16] *Medicare Benefit Policy Manual*, Ch. 6, § 20.5.2, CTRS. FOR MEDICARE & MEDICAID SERVS. (rev. 169) (Mar. 1. 2013).
[17] 84 Fed. Reg. 39398, 39525 (proposed Aug. 9, 2019).
[18] 84 Fed. Reg. 39398, 39525 (proposed Aug. 9, 2019).

physicians and nonphysician practitioners to practice in rural areas. CAHs and small hospitals historically experienced supervisory staff shortages, especially in specialty and high-volume services such as radiation oncology services.[19] Therefore, in March 2010, CMS instructed all Medicare Administrative Contractors (MACs) to not enforce the direct supervision requirements for CAHs and extended this nonenforcement in subsequent years.[20] In 2011, CMS extended the nonenforcement of the requirement to small rural hospitals with fewer than 100 beds[21] through calendar year 2019.[22] CMS confirmed in the 2020 OPPS Final Rule that notwithstanding its nonenforcement of the direct supervision requirement for CAHs and small hospitals, such facilities may still provide direct supervision for outpatient therapeutic services when the administering physicians "decide that it is appropriate to do so."[23]

Since 2010, CMS continued to monitor these supervisory staff issues and has not "learned of any data or information from CAHs and small rural hospitals indicating that the quality of outpatient therapeutic services has been affected by requiring only general supervision for these services."[24] The direct supervision option for outpatient therapeutic services, combined with existing state law regarding scope of medical practice and the Medicare Conditions of Participation governing supervisory physician and staff requirements,[25] may explain the lack of data and information indicating compromised quality of outpatient therapeutic services in small hospitals and CAHs exempt from the direct supervision requirement. Nonetheless, CMS in the 2020 OPPS Proposed Rule (and as reflected in the 2020 OPPS Final Rule) has "come to believe that the direct

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[19] 84 Fed. Reg. 39398, 39525-26 (proposed Aug. 9, 2019).
[20] 84 Fed. Reg. 39398, 39525 (proposed Aug. 9, 2019).
[21] CMS separately includes hospitals with a rural wage index as part of the small hospital category. *Release: Enforcement Instruction on Supervision Requirements for Outpatient Therapeutic Services in Critical Access Hospitals and Small Rural Hospitals*, CTRS. FOR MEDICARE & MEDICAID SERVS. (Feb. 22, 2017), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.
[22] 84 Fed. Reg. 39398, 39525 (proposed Aug. 9, 2019); *see also Release: Enforcement Instruction on Supervision Requirements for Outpatient Therapeutic Services in Critical Access Hospitals and Small Rural Hospitals,* CTRS. FOR MEDICARE & MEDICAID SERVS. (Feb. 22, 2017), https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index.html.
[23] 84 Fed. Reg. 39398, 39526 (proposed Aug. 9, 2019) (finalized Nov. 1, 2019); 84 Fed. Reg. 61142, 61360 (Nov. 12, 2019).
[24] 84 Fed. Reg. 39398, 39526 (proposed Aug. 9, 2019); 84 Fed. Reg. 61142, 61360 (Nov. 12, 2019).
[25] *See generally* 42 C.F.R. pt. 482.

supervision requirement for outpatient therapeutic services places an additional burden on providers that reduces their flexibility to provide medical care," while acknowledging that "[l]arger hospitals and hospitals in urban or suburban areas are less affected by the burden and reduced flexibility of the direct supervision requirement."[26]

The result of CMS' nonenforcement of the direct supervision requirement for CAHs and small hospitals is a "two-tiered system . . . with direct supervision required for most hospital outpatient therapeutic services in most hospital providers, but only general supervision required for most hospital outpatient therapeutic services in CAHs and small rural hospitals with fewer than 100 beds."[27] To implement a "uniformly enforceable supervision standard for all hospital outpatient therapeutic services," CMS proposed in the 2020 OPPS Proposed Rule and finalized in the 2020 OPPS Final Rule to "change the generally applicable minimum required level of supervision for hospital outpatient therapeutic services from direct supervision to general supervision for services furnished by all hospitals and CAHs."[28]

Caveats to General Supervision Requirement for All Outpatient Therapeutic Services

Pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services continue to require direct supervision in the 2020 OPPS Final Rule.[29] Nonsurgical extended duration therapeutic services that have a substantial monitoring component typically performed by auxiliary personnel, have a low risk of requiring the physician's or nonphysician practitioner's immediate availability after the initiation of the service, and are not primarily surgical in nature, will continue to require direct supervision pursuant to the 2020 OPPS Final Rule during the initiation of the service

[26] 84 Fed. Reg. 39398, 39526 (proposed Aug. 9, 2019); 84 Fed. Reg. 61142, 61360 (Nov. 12, 2019).
[27] 84 Fed. Reg. 39398, 39526 (proposed Aug. 9, 2019); 84 Fed. Reg. 61142, 61360 (Nov. 12, 2019).
[28] 84 Fed. Reg. 39398, 39526 (proposed Aug. 9, 2019) (finalized Nov. 1, 2019); 84 Fed. Reg. 61142, 61363 (Nov. 12, 2019) (to be codified at 42 C.F.R. § 410.27).
[29] 42 C.F.R. § 410.27(a)(1)(iv)(D); 84 Fed. Reg. 39398, 39638 (proposed Aug. 9, 2019) (finalized Nov. 1, 2019) (to be codified at 42 C.F.R. § 410.27).

and may be followed by general supervision at the discretion of the supervising physician or nonphysician practitioner.[30]

In the future, CMS will continue to consider advice from the Hospital Outpatient Payment (HOP) Panel, which is composed of "appropriate representatives of providers" who advise the Secretary of Health and Human Services, "on the appropriate level of supervision" for hospital outpatient therapeutic services.[31] Finally, CMS retains "the ability to consider a change to the supervision level of an individual hospital outpatient therapeutic service to a level of supervision that is more intensive than general supervision through notice and comment rulemaking."[32]

An "alternative OPPS policy" CMS considered in the 2020 OPPS Proposed Rule, but did not propose nor finalize, was to preserve direct supervision instead of general supervision as "the minimum required default level for most hospital outpatient therapeutic services with the exception of those services that have been evaluated by the HOP Panel and received a change in supervision level based on those recommendations."[33] CMS also considered changing the required supervision level for cardiac rehabilitation services from direct to general supervision, but did not ultimately propose this change in the 2020 OPPS Proposed Rule.[34]

Physician Supervision Rule Before Codification of 2020 OPPS Final Rule

Below is in part the physician supervision rule at 42 C.F.R. § 410.27 prior to codification of the 2020 OPPS Final Rule.

> (a) Medicare Part B pays for therapeutic hospital or CAH services and supplies furnished incident to a physician's or nonphysician practitioner's service, which are defined as all services and supplies furnished to

[30] 42 C.F.R. § 410.27(a)(1)(iv)(E); 84 Fed. Reg. 39398, 39638 (proposed Aug. 9, 2019) (finalized Nov. 1, 2019) (to be codified at 42 C.F.R. § 410.27).
[31] 84 Fed. Reg. 39398, 39405 (proposed Aug. 9, 2019); 84 Fed. Reg. 61142, 61360-61 (Nov. 12, 2019).
[32] 84 Fed. Reg. 39398, 39526 (proposed Aug. 9, 2019); 84 Fed. Reg. 61142, 61361 (Nov. 12, 2019).
[33] 84 Fed. Reg. 39398, 39624 (proposed Aug. 9, 2019); 84 Fed. Reg. 61142, 61479 (Nov. 12, 2019).
[34] 84 Fed. Reg. 39398, 39624 (proposed Aug. 9, 2019); 84 Fed. Reg. 61142, 61479 (Nov. 12, 2019).

hospital or CAH outpatients that are not diagnostic services and that aid the physician or nonphysician practitioner in the treatment of the patient, including drugs and biologicals which are not usually self-administered, if—

(1) They are furnished—

[. . .]

(iv) Under the direct supervision (or other level of supervision as specified by CMS for the particular service) of a physician or a nonphysician practitioner as specified in paragraph (g) of this section, subject to the following requirements:

> (A) For services furnished in the hospital or CAH, or in an outpatient department of the hospital or CAH, both on and off-campus, as defined in § 413.65 of this subchapter, “direct supervision” means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed;
>
> (B) Certain therapeutic services and supplies may be assigned either general supervision or personal supervision. When such assignment is made, general supervision means the definition specified at § 410.32(b)(3)(i), and personal supervision means the definition specified at § 410.32(b)(3)(iii);
>
> (C) Nonphysician practitioners may provide the required supervision of services that they may personally furnish in accordance with State law and all additional requirements, including those specified in §§ 410.71, 410.73, 410.74, 410.75, 410.76, and 410.77;

(D) For pulmonary rehabilitation, cardiac rehabilitation, and intensive cardiac rehabilitation services, direct supervision must be furnished by a doctor of medicine or a doctor of osteopathy, as specified in §§ 410.47 and 410.49, respectively; and

(E) For nonsurgical extended duration therapeutic services (extended duration services), which are hospital or CAH outpatient therapeutic services that can last a significant period of time, have a substantial monitoring component that is typically performed by auxiliary personnel, have a low risk of requiring the physician's or appropriate nonphysician practitioner's immediate availability after the initiation of the service, and are not primarily surgical in nature, Medicare requires a minimum of direct supervision during the initiation of the service which may be followed by general supervision at the discretion of the supervising physician or the appropriate nonphysician practitioner. Initiation means the beginning portion of the nonsurgical extended duration therapeutic service which ends when the patient is stable and the supervising physician or the appropriate nonphysician practitioner determines that the remainder of the service can be delivered safely under general supervision; and

(v) In accordance with applicable State law.

Finalized Amendments to Physician Supervision Rule as Per 2020 OPPS Final Rule

Below are the amendments to the physician supervision rule to be codified at 42 C.F.R. § 410.27, effective January 1, 2020.[35]

[35] 84 Fed. Reg. 61142, 61490 (Nov. 12, 2019).

§410.27 Therapeutic outpatient hospital or CAH services and supplies incident to a physician's or nonphysician practitioner's service: Conditions.

* * * * *

(a) * * *

(1) * * *

(iv) Under the general supervision (or other level of supervision as specified by CMS for the particular service) of a physician or a nonphysician practitioner as specified in paragraph (g) of this section, subject to the following requirements:

(A) For services furnished in the hospital or CAH, or in an outpatient department of the hospital or CAH, both on and off-campus, as defined in § 413.65 of this chapter, general supervision means the definition specified at § 410.32(b)(3)(i).

(B) Certain therapeutic services and supplies may be assigned either direct supervision or personal supervision. For purposes of this section, direct supervision means that the physician or nonphysician practitioner must be immediately available to furnish assistance and direction throughout the performance of the procedure. It does not mean that the physician or nonphysician practitioner must be present in the room when the procedure is performed. Personal supervision means the definition specified at § 410.32(b)(3)(iii)[.]

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